

MINISTRY OF HEALTH OF THE REPUBLIC OF UZBEKISTAN



TASHKENT PHARMACEUTICAL INSTITUTE

**Organization of pharmaceutical production and Quality Management's
department**

**"ORGANIZATION OF PHARMACEUTICAL PRODUCTION"
EDUCATIONAL AND METHODOLOGICAL COMPLEX OF THE SUBJECT**

Fields of knowledge: 900 000 - Health and Social Security

Fields of education: 910000 - Health

Direction of ucation: 60910800 - Industrial Pharmacy(by type)



Toshkent – 2023

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1- lecture. The main goals of the development of the pharmaceutical industry. The main concepts and terms of the science” organization of pharmaceutical production”. International requirements in pharmaceutical production. GMP requirements.

Plan:

1. The main goals of the development of the pharmaceutical industry.
2. The main concepts and terms of the science "organization of pharmaceutical production".
3. International requirements in pharmaceutical production.
4. GMP requirements

Base words and phrases: pharmaceutical activities, pharmacological agents, medical equipment, medical supplies, poor-quality medicine and medical item, prescription, medicinal plant raw materials.

The allotted time is 2 hours.

The importance of the discipline” organization of pharmaceutical production " as an educational discipline consists in the excellent formation of specialist skills in students, the formation of general skills in organizing the production of ready-made medicines produced on an industrial scale in them, and ensuring the assessment of the quality of finished products in pharmaceutical production in GMP in terms of modern technology.

The tasks of the discipline” organization of pharmaceutical production " include the organizational structure of the pharmaceutical industry; systems with production authority; international standards for the organization of pharmaceutical production (GLP, GMP) ; international standards for the correct distribution of drugs (GDP), fundamentals and content of the state Pharmacopoeia, regulatory documents necessary for the organization of pharmaceutical production, work with equipment and apparatus used in the organization of pharmaceutical production, vending machines and semi-machines, study of factors affecting the biological efficiency of Drugs, Production, Quality Assessment and organization of finished drugs according to GMP requirements, conditions, medicines include working with current regulatory documents.

This manual plays an important role in mastering the science of organizing pharmaceutical production.

In the following times, a number of regulatory legal acts were adopted aimed at improving the supply of residents and health institutions with affordable medicines, medical supplies and medical techniques.

At the same time, the study of the current state of affairs in the pharmaceutical network showed that there is no systematic monitoring and control over the supply of medical institutions and the population with medicines, medical supplies, a necessary level of accounting and analysis of the state of medical equipment in state health institutions.

A single strategy for the sustainable development of the pharmaceutical network has not been developed and the necessary coordination of the activities of local pharmaceutical

enterprises, including the production of related products, taking into account the needs of the population and health institutions for them, is not ensured.

The widespread practice of producing medicines and medical products using imported raw materials, which are almost finished products, and the low level of technological processes prevent the organization of domestic production of high-quality and competitive Pharmaceuticals.

The main goals of the development of the production of pharmaceutical products

The main objectives of the further development of the pharmaceutical network are to transform it into a strategic network of the national economy and social sphere through the implementation of the following. This in turn is the improvement of the state system of quality control, registration and certification of pharmaceutical products and services, to transfer the domestic production network to an innovative model of development by coordination with the requirements of the "necessary production practice" (GMP) and create favorable conditions for improving its competitiveness, to organize the production of drug substations based on deep processing of plant raw materials and to develop technology for the synthesis of raw materials and the production of medicinal substances, to actively attract foreign.

The Republic of Uzbekistan defines the following main goals for the development of the pharmaceutical network these are ensuring the production of safe, efficient, hamabop and quality domestic medicines and medical products that satisfy the needs of health institutions and the population of the Republic, first of all, are included in the list of basic medicines (ADVR). The development of the pharmaceutical industry by expanding the range of pharmaceutical products produced taking into account advanced scientific experience and modern technologies, as well as promoting the creation and production of innovative pharmaceutical products, launching modern facilities and modernizing and strengthening the material and technical base of existing facilities. Development of the domestic pharmaceutical network by ensuring compliance of organizations and enterprises with the standards of standards harmonized with international requirements for the creation and production of medicines. To organize modern competitive production of medicines and medical products, including investments and advanced technologies of foreign pharmaceutical enterprises. Organization and localization of the production of substations based on raw materials of medicinal plants for the subsequent production of medicines. At the expense of modernizing operating production capacities, increasing and mastering new types of drugs, as well as reducing the import of drugs by attracting investments. Step-by-step implementation of practices aimed at regulating "necessary production practices" (GMP), "necessary pharmacological practices" (GVP), as well as quality and safety system management (GDP), klinikoldi (GLP) and clinical research conduct (GCP) in distribution activities at local enterprises. Improving the mechanisms of price formation, marking of drug preparations and the introduction of control systems. Strengthening the capacity of the national regulatory body by improving legislation in the field of development, production and quality control of medicines and medical products in accordance with modern international requirements, conducting clinical and clinical research. On the basis of Advanced International experience, ensuring high-quality training of specialists for the pharmaceutical network of the Republic, including in such important areas as biotechnology of drug preparations, Chemical Technology of medicines, technology of ready-made medicines and phytopreparations, pharmacy

economics and its management, pharmaceutical chemistry and microbiology. To create an effective system for retraining and professional development of personnel in the pharmaceutical network by international standards. To radically increase the effectiveness of fundamental, practical and innovative research aimed at developing and adapting new technologies for clinical and clinical research of pharmaceutical products, production, certification and standardization, through deep integration of Education, Science and production. The organization of modern educational laboratories and research centers aimed at the development of original drugs (generics) on the basis of original drugs, which are also in high demand.

The main directions of the development of the pharmaceutical network are those below, starting with the improvement of the regulatory framework. These are the improvement of the regulatory framework in order to create favorable conditions for the rapid development of the pharmaceutical network (amendments and additions to the law of the Republic of Uzbekistan "on medicines and pharmaceutical activities"), the implementation of international norms and standards. The implementation of international experiments, including the development of drugs with the participation of the World Health Organization, standardization, registration, production, control of their quality, coordination of the regulatory framework in the field of clinical and clinical research with the requirements of the GxP "necessary practices". Improving national legislation in terms of simplifying the requirements for the registration of medicinal substations, ensuring the high quality and safety of the product during the registration of the finished drug. Improving the mechanisms of ensuring compliance with the rules for the correct appointment and use of drugs by doctors and pharmacists in order to avoid inappropriate drug appointments, as well as conflict of interest and signs of corruption.

To implement the above, the development of methods for promoting the development of the pharmaceutical network and the creation of a new pharmaceutical product for implementation, as well as the implementation of state support measures in the form of reimbursement of the costs of its promotion in the process of registering a pharmaceutical product abroad. Encourage local pharmaceutical manufacturers to organize the production of imported substitute medicines and medical supplies that had not previously been produced in the country. Implementation of comprehensive measures for state support of scientific research aimed at the development and creation of innovative pharmaceutical products. It is necessary to develop an effective mechanism for attracting financial resources of commercial banks and other non-budgetary resources for the development of the pharmaceutical network.

In order for a domestic pharmaceutical product to be competitive, it is necessary to ensure the quality of pharmaceutical products in accordance with international standards. It is for GxP and ISO to create a quality management system for the entire cycle of pharmaceutical product by introducing the requirements of "necessary practices". Creation and publication of official methodological manuals for the introduction of the rules of "necessary pharmaceutical practice" of the GxP, Organization of training courses, consultations and other activities for their implementation. Making regulatory legal acts regulating the state registration of pharmaceutical products in accordance with international requirements, including the introduction of the practice of inspecting foreign productions. Active participation in the work of international and Interstate expert bodies, in particular, commissions for Standardization and registration of pharmaceutical products. To develop comprehensive measures for obtaining

international accreditation by domestic testing laboratories in order to improve the quality and competitiveness of manufactured pharmaceuticals.

In order to develop new types of pharmaceutical products, it is necessary to implement new technologies for obtaining biologically active substances from plants, microorganisms and animals intended for use in the pharmaceutical network. The expansion of the most effective types of generic drugs, the creation of new modern innovative drug forms with improved pharmacokinetic and pharmacodynamic properties, systems of targeted action of the active substance on the body. Development of pharmaceutical production, which requires scientific and technical potential and deep knowledge in order to effectively meet the requirements of the domestic and foreign market. Wide use in the implementation of mechanisms of Public-Private Partnership and its use in practice, including the organization of the production of pharmaceuticals that were not previously produced in our country. Vaccines, first of all, are immunodiagnosticums included in the national vaccination calendar, immunotropic drugs, the organization of the production of a new generation of immunobiological drugs with high efficiency against pathogens of dangerous infectious diseases (tuberculosis, AIDS, etc.) by local enterprises.

The production of medical products, medical equipment and medicines, including medicines made from raw materials of medicinal plants, today determine the priority list of generic drug import substitutes, the volume of imports of which occupies a large share in both monetary and natural forms. The introduction of modern technological processes for obtaining medicines from plant raw materials, the cultivation of the most promising plants on plantations and the development of their breeding. Development and introduction of a modern system of collection and primary processing of medicinal plants, determination of the reserve of medicinal plants growing in the wild. Implementation of targeted measures to attract foreign direct investment and leading manufacturers of foreign pharmaceutical products for the rapid development of the network.

It consists of the development of complex measures for the development of production, Road transport and other infrastructure necessary for the organization of production of pharmaceutical products in high demand in our country and abroad

Measures aimed at expanding the export potential are technological re-equipment of the production capacities of domestic manufacturers of the pharmaceutical industry at a competitive level in foreign markets. Development of an effective strategy for the promotion of domestic pharmaceutical products abroad. To develop the pharmaceutical network in the Republic and to establish joint enterprises producing pharmaceutical products with leading foreign manufacturers to increase the volume of exports. Encourage participation of local pharmaceutical manufacturers in international pharmaceutical activities (exhibitions, fairs, forums, advertising and image events) in promoting their products. To join the Pharmaceutical International Trade System with the aim of expanding trade markets, including participation in tenders in foreign countries for the supply of pharmaceuticals.

The role of highly qualified specialists in the production of a high-quality competitive product in the pharmaceutical industry is incomparable. One of the main ones in the training of highly qualified specialists is the improvement of the system of training of qualified personnel in Industrial Pharmacy, the development of advanced technologies on the basis of domestic and foreign educational institutions in the field, directing education to practice. Taking into account

the current trends and development needs in the pharmaceutical network, improving the scientific and educational and methodological support of the educational process, improving the quality of training of specialists for the pharmaceutical industry. Updating the material and technical base of educational institutions of the local network in order to comply with international standards. Extensive cooperation with foreign pharmaceutical educational institutions, including the opening of their branches and faculties in the Republic. Expanding educational opportunities due to the use of resources of foreign educational institutions through interaction and open courses in networks, as well as the development of national e-learning platforms and the formation of an e-learning environment.

The organization of an innovative scientific and practical pharmaceutical cluster provides for the creation and development of the necessary conditions and infrastructure for the integration of Education, Science, Practice and production in the pharmaceutical network, the creation of favorable conditions in the scientific research environment of the pharmaceutical network and its integration into international scientific research centers, promoting the quality of training of pharmaceutical professionals in, it consists in helping local enterprises in the pharmaceutical network to establish cooperation with leading foreign pharmaceutical companies, to master the production of new types of competitive high-quality pharmaceutical products in the domestic and foreign markets by creating a complete technological cycle of production of finished products on the basis of an innovative scientific and practical pharmaceutical cluster.

In accordance with the decree of the president of the Republic of Uzbekistan "on measures to radically improve the management of the pharmaceutical network" dated November 7, 2017, in order to improve the conditions for the development of pharmaceutical activities, to further increase the level of provision of cheap, quality medicines, medical products and medical equipment of population and health institutions, to introduce a unified system, The pharmaceutical Network Development Agency under the Ministry of health of the Republic of Uzbekistan was formed.

The main tasks and functions of the agency

it consists of: the development and implementation of a strategy for the sustainable development of the pharmaceutical network, including by introducing modern mechanisms of its state support;

Organization of the study of the pharmaceutical market structure, systematic analysis of the state of supply of pharmaceutical products of the population and health institutions and the development of proposals on its basis for further replenishment of the domestic market and localization of production;

assistance to Network Enterprises in establishing cooperation with leading foreign pharmaceutical enterprises in mastering the production of competitive, high-quality new types of pharmaceutical products in domestic and foreign markets;

state management of the pharmaceutical network, including pharmaceutical products through state registration, standardization, certification, technical regulation, as well as licensing of pharmaceutical activities (excluding retail sale of medicines and medical products;

coordination of work on the implementation of advanced foreign practices and international standards in the pharmaceutical network;

participation in the implementation of the Information System Of Control and accounting for the movement of pharmaceutical products, which provides for the collection of

complete information about pharmaceutical products imported and manufactured on the territory of the Republic.

The agency carries out the following functions in accordance with the tasks assigned to it:

a) in the field of development and implementation of a strategy for the sustainable development of the pharmaceutical network, including by introducing modern mechanisms of its state support:

 makes proposals for medium and long-term prospects for strategic areas of development of the pharmaceutical network;

 participates in the development and implementation of Republican and territorial programs for the development of the pharmaceutical network, including programs aimed at the territories of Free Economic Zones of the pharmaceutical network, using the mechanisms of public-private partnerships;

 promotes the activities of pharmaceutical enterprises and organizations, participates in the development and implementation of investment programs for the organization of import replacement productions of socially significant medicines and medical products;

b) in the field of organizing the study of the conjuncture of the pharmaceutical market, systematic analysis of the state of the supply of pharmaceutical products of the population and health institutions and the development of proposals for further replenishment of the domestic market and localization of production on its basis:

 organizes and carries out marketing research of the pharmaceutical market, identifies medicines, medical products and medical techniques that are in great demand, with the aim of mastering their production or making adjustments to existing productions;

 it promotes the release of domestic medicines, medical products and medical equipment to foreign markets, and also develops recommendations for domestic manufacturers for mastering the production of medicines, medical products and types of medical equipment that are in great demand in foreign countries;

 analyzes the level of availability of medicines, medical supplies and medical equipment of the population and state health institutions;

 organizes the development and implementation of programs for localization of the production of medicines, medical products and medical techniques;

 the import substitute makes proposals for the organization of the production of socially significant medicines and medical products;

C) in the field of assistance to Network Enterprises in establishing cooperation with leading foreign pharmaceutical enterprises, in mastering the production of competitive, high-quality new types of pharmaceutical products in domestic and foreign markets:

 monitors and analyzes the state of material and technical bases and technologies used in the production of medicines, medical products and medical equipment and develops programs for modernization, technical and technological re-equipment of production according to their results;

 develops a list of investment programs, which provides for the modernization, technical and technological re-equipment of production, annually by Regions and a separate enterprise, and makes it available to authorized bodies;

analyzes the innovative and high-tech production of medicines, medical products and medical equipment abroad and, on the basis of this analysis, makes proposals for the formation of new investment projects in the Ministry of investments and foreign trade of the Republic of Uzbekistan;

carries out measures aimed at attracting funds from foreign investments, including foreign and international financial institutions, to modernize existing production and carry out priority investment projects;

organizes R & D work on the creation of original and effective medicines and the development of their production;

provides cooperative relations between research institutions and pharmaceutical enterprises for the introduction of ready-made scientific developments into production and the beginning of new directions of research, including research aimed at the production of drugs from plants;

develops measures to stimulate innovative developments in the production of medicines, medical products and medical techniques;

organizes cooperation between domestic manufacturers and leading foreign companies;

ensures the participation of representatives of local organizations in international pharmaceutical exhibitions, forums, conferences, seminars and national exhibitions held in foreign countries;

participates in the work of international organizations, intergovernmental commissions (groups) and business forums;

g) in the field of state registration, standardization, certification, technical regulation of the pharmaceutical network, including pharmaceutical products, as well as state management by licensing of pharmaceutical activities:

provides for the implementation of state registration, quality control, standardization and certification of medicines, medical products and medical techniques. This ensures that the certification of medical products is carried out only by state certification bodies in the system of the Ministry of health of the Republic of Uzbekistan, accredited in the prescribed manner;

the State Register of medicines, medical supplies and medical equipment, which is allowed to be used in medical practice, ensures the maintenance and publication of a periodical;

ensures the formation of a state Pharmacopoeia;

organizes the examination of the results of clinical and clinical studies of pharmacological and/or medicinal products and medical products;

organizes the examination, Agreement and approval of Pharmacopoeia documents for medicines and medical products for "in vitro" diagnosis, as well as the examination and agreement of regulatory documents in the field of technical regulation of medical products (except for medical products for "in vitro" diagnosis) and medical equipment;

ensures the implementation of pharmacological control;

when the harmful effects of medicines and medical products are detected, it ensures the suspension of their manufacture, preparation, import and sale in the prescribed manner;

provides coordination and control of the activities of certification bodies of medicines, medical products and medical techniques, including testing laboratories;

provides an assessment of the conditions for the production of drugs and medical products to be certified;

carries out measures to improve the fund of regulatory documents on the technical regulation of medical equipment and medical equipment;

provides for the examination of medicines, medical supplies and medical equipment on the appeals of law enforcement agencies;

the pharmaceutical Network organizes the training of specialists in advanced training courses, including in foreign countries or with the involvement of foreign specialists;

controls the licensing of pharmaceutical activities as well as the procedure in which compliance with the requirements and conditions of the license is established;

d) in the field of coordination of work on the implementation of advanced foreign practices and international standards for the pharmaceutical network:

coordinates international cooperation in the field of drug production, regulation of circulation, quality control and implementation of ISO Quality Management Systems and the necessary style of practice (GxP);

the pharmaceutical network helps enterprises to introduce international standards;

Organizes an audit of compliance with the requirements of good production practice rules (GMP), Good distribution practice rules (GDP), good maintenance practice rules (GSP), good clinic practice rules (GCP), good laboratory practice rules (GLP), good Pharmacy Practice Rules (GPP), and the issuance of relevant conclusions and/or certificates.

e) in the field of participation in the implementation of the Information System Of Control and accounting for the movement of pharmaceutical products, which provides for the complete collection of information about pharmaceutical products imported and manufactured on the territory of the Republic:

The State Register of medicines, medical supplies and medical equipment, which are allowed to be used in medical practice, as well as information on certified medicines, medical supplies and medical equipment "<https://uzpharm-control.uz>" highlights on the Web page;

automates the business process in the field of registration and certification;

establishes information exchange of formed data electronic bases with systems of other government bodies;

The agency may also exercise other functions in accordance with the legislation.

We can see the increase in the number of pharmaceutical enterprises from year to year from the fact that the state gives special attention to enterprises producing pharmaceutical preparations. In this regard, the importance of the discipline "Organization of pharmaceutical production" within the Pharmaceutical Sciences as an educational discipline is incomparable.

Organization of the production of ready-made medicines produced on an industrial scale in them as educational subjects of the discipline" organization of pharmaceutical production", Organization of pharmaceutical production according to GMP requirements to guarantee the quality of finished products, regulatory technical documents necessary in pharmaceutical production, requirements for them, basic and auxiliary substances necessary for production, equipment and apparatus, correct Organization of pharmaceutical production, it turns out the correct selection of the starting materials used in it, the use of equipment and apparatus necessary for the preparation of the drug, adapting their respective parameters to the operating mode, increasing their productivity, documenting the production of

chemical technological and hardware schemes, production of drugs, material balance, statements of the technological process. Students apply their knowledge of the subject "Organization of pharmaceutical production" in the production of ready-made medicines. The chemical and pharmaceutical industry is one of the leading sectors of the national economy. It includes a complex of a number of enterprises, in which, in addition to chemical treatment of materials, biological synthesis of medicinal preparations is widely used.

Beginning in 1990, medical-related enterprises were tasked with producing a large number of drugs, antibiotics, vitamins, and hormones, which are produced on our own for the purpose of prevention and quality treatment of tuberculosis, viral diseases, acute bacterial, infectious, cardiovascular and other diseases.

Modern chemical and pharmaceutical enterprises have their own characteristics that determine the specifics of its development, including ensuring the chemical purity of the extracted product. It should also ensure complete sterility of drugs intended for intramuscular injection, intravenous injection, subcutaneous administration. The quality indicators of the product produced must comply with the requirements of the state standards of the pharmacopoeia of the Czech Republic.

The second distinctive feature of chemical-pharmaceutical enterprises is the small volume of production of most medicinal preparations. In chemical and pharmaceutical enterprises, only sulfonamides, salicylates, barbiturates, analgesics and some antibiotics, as well as anti-tuberculosis agents are developed in large quantities.

For these enterprises, it is characteristic that raw materials and other auxiliary materials are spent in large volumes, since the synthesis of Medicinal Products is fractional in its multi-stage and complexity:

That is characterized by the fact that chemical-pharmaceutical enterprises often exchange the nomenclature of medicinal preparations. This feature of the enterprise, as well as medicinal; the scarcity of the volume of production of preparations, - this is the reason for the widespread use of mixed technological schemes in enterprises, and this makes it possible to develop 2-3 or more types of drugs during the year. In addition, substances that will be developed in this area must be processed to obtain ready-made drug forms.

In the chemical-pharmaceutical industry, several groups of enterprises can be distinguished. Among them, the most basic are pharmaceutical plants for the manufacture of synthetic medicinal preparations, pharmaceutical plants for the production of antibiotics and pharmaceutical plants for the production of ready-made drug forms and preparations.

On the basis of the production of synthetic drugs on an industrial scale, there is a large-scale application of organic synthesis, which brings these enterprises closer to the enterprises of the main chemical industry.

Enterprises for the production of antibiotics form a separate group. This is due to the fact that the main technological process in obtaining these drugs is biological synthesis.

The characteristic features of pharmaceutical plants producing Galen preparations and ready-made drug forms are that the production of various medicinal products in them is characterized by the production of liquid extracts and decoctions, injection solutions, tablets, dragees, plasters.

In industrial enterprises of chemical and pharmaceutical production, various homogeneous preparations are produced based on plant and animal products and raw materials

obtained by chemical synthesis. Chemical raw materials are characterized by the most common type of product. Mineral raw materials are used as ingredients for the synthesis of inorganic salts, as well as various organic compounds. In this direction, mineral acid and alkalis are used in large quantities. Primary organic raw materials are supplied by toxochemistry, petrochemicals, aniline dye enterprises and Major Organic Synthesis enterprises.

In the production of drug preparations, animal products are widely used, including histidine from the blood of animals, adrenaline from the adrenal glands, insulin from the pancreas, thyroxine from the thyroid glands, etc. is obtained.

-Preparation of all types of technological operations in obtaining drugs, the process of obtaining direct drug preparations, can be on final and additional operations.

Preparation operations-storage of solid, liquid, gaseous materials, changing them to another type; grinding and mowing solid raw materials, extracting solids, processing them by using methods of tinning, filtering, centrifuging, cooling, converting them into crystals, vacuuming. It is made free of water and gases in its composition.

On the basis of the process of direct receipt of medicinal preparations lie such processes as exchange, thermal, electrochemical processing, biological processes, electrolysis. At this stage of the technological process: sulfation, nitration and halogenation, amination and oxidation, reductive and oxidation reactions are widely used.

At the final stage, drug preparations are subjected to drying, grinding or mashing, tablet reduction, ampouling and packing in containers.

Preparatory operations. Most of the primary raw materials used to obtain Galen and synthetic medicinal preparations are solid, and therefore the raw materials are ground and milled. The need to undergo this operation is that from them it is necessary to take mainly drug forms (Tablets, dragees, etc.) technology. Grinding raw materials; is carried out in flat, roller, conical, hammered and other grinding mechanisms. And milling is done with the help of spherical and clove grinders, Disintegrators. Small-scale medicinal products are milled using mechanisms such as mechanical kayaking Hoppers, Islamgulov mill, "Exselsior".

The system of production of ready-made medicines in the Republic of Uzbekistan.

Enterprises that produce drugs are divided into two types:

a) enterprises that produce substations. These, in turn, are divided into enterprises specializing in antibiotic, hormone, enzyme, vitamin, endocrine preparations and synthesis.

b) enterprises specializing in the production of Ready-Made drugs. It usually specializes in the production of ready-made medicines from substations produced in enterprises of the first type. Pharmaceutical enterprises, regardless of the form of ownership (a private enterprise, a joint venture or an open-type shareholder society (FTS)), they will be structured on the principle of sex. In large pharmaceutical enterprises, ampoules, tablets, Galens will also be available, which will pack ready-made products. Some private or joint ventures may also have one sex. In addition to these, there will also be additional workshops that will ensure the operation of the main workshops in one standard: cartonage, mechanics and workshops that provide heat to the enterprise. Nazorat bo'limi (NB).

To organize the work of pharmaceutical enterprises in one norm, the control department, analytical and bak laboratories operate at its disposal. NB's staff conducts step-by-step inspections of the processes from raw materials to the release of the finished product. At

what stage the technological process breaks down, it is straightened out. As a result, the output of unsuitable products is practically not observed. The head of the NB is an independent person, only bowing to the director of the enterprise. Ready-made products are given to the warehouse only when the seal of the NB is printed onmumkin.

Technical department. There are mainly mukhandis operating here. They help to properly organize production in workshops, obeying the head fan of the enterprise. In some firms, however, they are also referred to as the manufacturing division.

Central laboratory. Here, the technology of the product applied to the workshop is tested on small machines and its quality and quantitative methods of estimation are developed or the technology of the product produced at the enterprise is improved. In the laboratory of the central enterprise there are small gabarite countertops, in which a technological process is carried out.

Pharmaceutical enterprises are managed by the general director. At the same time, personnel and production deputies also operate in pharmaceutical enterprises. Enterprises or firms specializing in the production of ready-made drugs can have 1, 2 or even more sex. Enterprises that produce ready-made medicines obey the concern "Uzfarmsanoat". In turn, the concern is under the care of the Cabinet of Ministers.

Types of enterprises producing ready-made medicines and their disposal.

To date, there are more than 90 enterprises that produce ready-made drugs on the territory of the Republic of Uzbekistan, which in turn are divided into:

A) an open-type shareholder society, e.g. "Özkimyofarm" OTAJ.

B) joint venture, such as "Samsung" Uzbek-Turkish, "Adjanta" Uzbek-Indian, Uzbek-American joint venture specializing in the production of infusion solutions, etc.

V) private enterprise: for example "Zhurabek", "Dorishunos", "Galen", etc.

All of the above enterprises will be under the jurisdiction of the concern "Uzfarmsanoat".

Necessary terms

A" clean " camera is a device that creates a laminar flow of sterile air, in which the amount of a mechanical particle of a certain size is normalized.

"Clean" rooms are rooms or zones for the production of ready-made sterile medicines, the cleanliness of which is regulated by the amount of mechanical particles and microorganisms of a certain size.

aseptic conditions are conditions for the production of sterile medicinal substances or ready-made medicines that exclude the ingress of microorganisms or mechanical particles into the finished product.

one-way airflow (laminar flow) is a parallel airflow (linear flow) that runs one – way along a cross-section of homogeneous velocity.

Validation (validation): actions that prove that a specific router, process, equipment, raw materials, activity or system in accordance with the principles of good production practice will indeed bring the expected results. (see" qualification " concept).

Cleaning validation (cleaning validation): documented evidence that the approved cleaning process ensures the cleanliness of the level of equipment necessary for the production of medicines.

Process validation(process validation): documented evidence that a process carried out within the limits of specified parameters can be carried out with effective and reversible results, and on the basis of this process will be brought to the acquisition of a drug corresponding to pre-established specifications and quality classifications.

Prospective validation (prospective validation): validation conducted before the start of serial production of a product intended for sale.

Satellite validation (concurrent validation): validation conducted in the process of serial production of products intended for sale.

Retrospective validation(retrospective validation): a data-based process validation assembled about the production, testing and control of drug-status series with market sales.

Revalidation; repeated validation (re-validation): repetition of process validation in order to ensure that the change made to the process/equipment in accordance with the change control process does not adversely affect the nature of the process and the quality of the drug.

Valve (valve): a device for opening and closing containers.

Minimum pressure retaining valve(minimum pressure retention valve): a valve with reverse flow resistance, which maintains a set pressure (about 3-5 bar above atmospheric pressure) to prevent contamination during the use process.

Return (return): return the drug, manufacturer or distributor, regardless of whether or not there is a quality defect.

Airlock (airlock): a limited space between two or more rooms, for example, belonging to different cleanliness classes, with two or more doors that serve to control the air flow between them when access to these rooms is necessary. Air switches are designed and used for the movement of people and objects.

Damage (harm): damage caused to human health, including damage caused by loss of product quality or suitability.

Auxiliary substances and materials (process aids): intermediate product or

FFI-substances and materials in addition to solvents that are not involved in chemical or biological reactions on their own, which are auxiliary in the production of substations (e.g., filtering materials, activated charcoal v.b.).

Secondary packaging(outer packaging): external packaging in which the preparation in the primary packaging is placed.

Production by parameters (parametric release): a production system based on the data obtained at the time of the production process, which also applies to production by parameters, based on compliance with the established requirements of GMP, guaranteeing that the product has the required quality.

ventilated air-purified air coming from the fan to the ventilation system and ensuring the appropriate level of cleanliness of the production room.

generic drugs (generics) are drug preparations that are not inferior to those issued by a patent, but are prepared by another manufacturer;

homeopathic remedies - drugs that are used according to homeopathic rules and are included in a special section of the state register;

medicines are those that are formed on the basis of one or more medicinal substances (substance), both natural and artificial in origin, as well as auxiliary substances, which are allowed to be used for the prevention, diagnosis and treatment of the disease. They include

immunobiological, radiopharmaceutical and parapharmaceutical drugs, homeopathic, diagnostic and sterilizing agents, as well as medicinal substances (substances) intended for the production and preparation of medicines;

the State Register of medicines, medical items is an official document consisting of a list of medicines, medical items that are allowed to be used in medical practice;

medicinal substances (substance) - biologically active substances of natural and artificial origin, allowed to be used;

drug preparations-dosed, packaged in a container-wrapped, ready-to-use medicines;

a pharmacy is a medical institution that carries out the preparation, packaging of medicines, control over their quality, as well as the purchase, storage and sale of medicines, medical items, sanitary and hygienic items, Healing Foods, mineral waters, treatment-cosmetic products intended for treatment and Prevention of disease. Pharmacy institutions include pharmacies and their branches, pharmacies of treatment and disease prevention institutions;

auxiliary materials are substances or materials that are not intended for use as a separate drug, however, used in the production of finished products.

Manufacturing (production process) are tampons that involve the operations of the production of ready – made medicines, that is, when buying raw materials, primary packaging, marking materials and additional, semi-finished products, such as preparing them, wrapping them, obtaining proofs for sale, storing them, transporting them and controlling the quality of finished products.

production process control-the implementation of the types of step-by-step control of the introduction of correction into the relevant technological parameters in order to monitor the production process of the product being released in order to ensure the quality of the finished product complies with the requirements of the regulatory document. Environmental and equipment cleanliness control is part of production process control.

qalbakilashtirilgan dori vositasi - tarkibi va (yoki) ishlab chiqaruvchisi haqida yolg'on ma'lumot ilova qilingan dori vositasi;

quarantine is a legal situation in which raw materials, auxiliary, sickle, marking materials, semi-finished products are stored in a separate place or prohibited for sale and use until it is decided to use them: sale, separation or restoration of unsuitable.

coding is a system of records that allows you to compare the finished product in an automatic way that it is of the same type.

material balance-a comparison of the finished product, which can be obtained theoretically and obtained practically.

a prescription is a written instruction from a doctor about the preparation and delivery of a drug to a pharmacist, in which the method of using the drug will be noted;

certificate of registration-document confirming the permission of the Ministry of health of the Republic of Uzbekistan for the right to medical use of medicines;

series-a certain amount of homogeneous finished products prepared in one production process under constant conditions.

serial number-numeric lettered or letter-numeric characters that help compare the homogeneity of the series and determine the sequence of execution of production and control operations in obtaining the same series.

quality is a set of signs that determine the quality of the finished product and its compliance with the established standards for its use, that is, the basic parameters of the technological process included in the list.

a poor-quality drug is a drug that has become unusable and (or) a drug that has expired; standard recording-the composition of drug preparations after examination of the effectiveness of the treatment properties;

a ready-made drug is a drug that is prepared for sale in a form in which a drug form with a healing property is convenient for a private consumer to treat.

the finished product is a form of medicine that has passed all stages of production, including the winding and marking stage.

technological clothing – a complete set of clothing, which is designed to absorb raw materials, auxiliary and cutting materials, semi-finished and finished products, mechanical particles emitted by equipment and rooms, and microorganisms from secondary contamination.

medical items are items used in medicine to prevent, diagnose, and treat disease.

Illegal copies of drugs registered in the Republic of Uzbekistan-drugs that are entered into circulation in violation of intellectual property legislation

packaging-all stages and operations in the placement, branding and organization of medicines on the materials of the mower. In the production of sterile drugs, the primary winding filling (primary winding material, packaging or pouring), as a rule, does not enter the winding stage. A product that is filled, but not wrapped with primary wrapping material, should be considered a semi-finished product.

sickle materials-materials used in wrapping or dosing, as well as in the storage of ready-made medicines (except for the transport comb). They are divided into the following types: 1. Primary mowing materials that directly touch the drug forms. 2. Secondary wrapping materials used in wrapping ready-made medicines (boxes, cardboard, plenka, foil, etc.).

pharmacological agents-a mixture of substances or substances of a certain medicinal form, which have a defined pharmacological activity and are considered objects of clinical trial;

Pharmacopoeia is a set of state standards that determine the quality of medicines, their preparation, quality - quantitative control, storage conditions and naming;

Pharmacopoeia Committee - an official expert body confirming regulatory and technical documentation that sets out the requirements for the quality of medicines, medical products and methods of their control;

Pharmacopoeia article-regulatory and technical document approved by the pharmacopoeia Committee for the drug;

a pharmaceutical enterprise is an industrial enterprise for the production of medicines, medicines or forms.

pharmaceutical activities-activities that cover research, research on the creation of medicines, medical items, as well as their production, preparation, quality control, standardization, registration, storage, information, delivery and realization;

an air hose is a device that is installed in a contiguous area between rooms belonging to different levels of cleanliness in order to prevent mechanical particles and microorganisms from entering the “clean” room. The gateway can be used to transfer people, equipment and homogeneous materials from one room to another..

Quality unit (s)(quality unit (s)): an organizational unit that operates independently of production, as well as performing quality assurance as well as quality control obligations. Depending on the scope and structure of the organization, it can be in the form of separate quality assurance and quality control services, or in the case of a single person or group of individuals.

Deviation (deviation): deviation from an approved router or established standard.

Disposal (evacuate): by creating a vacuum in a container, from which the remaining gas is lost.

Risk evaluation (risk evaluation): determination of the importance of risk based on quantitative and qualitative indicators with the aim of comparing the predicted risk to the existing criteria of risk.

Primary packaging (immediate packaging): a container or other type of packaging that is in direct contact with a drug or a drug undergoing a research test.

Collision contamination (cross contamination): contamination of a raw material or product with another raw material or other product.

Processing (reprocessing): in the medium of one or more additional processes, at a certain stage of the technological process, the processing of a whole or part of a series of products, the quality of which is unsuitable for the suitability of the product.

Comprehensive contamination-the possibility of contamination by raw materials, semi-finished products, other types of raw materials, semi-finished products or finished products in the process of production of the finished product.

raw materials-the primary material used in obtaining finished products, in addition to plowing and marking materials.

room cleanliness level-the "clean" or "cleanliness" level of the room is determined by the amount of mechanical particles and microorganisms of a certain size in 1 m³ of air.

waste is a by-product that is obtained during the production of finished products.

a semi-finished product is a partially processed raw material or drug substance that must go through the next stages of the production process before becoming a medicinal product.

shelf life-the specified date, taking into account the stability of drugs in accordance with the requirements of the regulatory document. In addition, the label must have an indication of the expiration date in accordance with the expiration date (expiry, date).

unsuitable (a product deemed unfit) – a product that is issued without being followed by students of a technological document or does not comply with the established standard.

International requirements for the production of medicines. " Good Manufacturing Practice " (GMP) general rules and requirements.

DV (drugs) is a universal product that is required in all countries of the world, the quality of which is determined by its safety and effectiveness on the human body. DV's world market price has been estimated at over US \$ 600 billion (2009), with 12% of interethnic pharmaceutical companies covering 80% of the Old World pharmaceutical market with its product, and it continues to view DV as a product of secular importance. This assumes that it is necessary to harmonize all regulatory and legislative acts in the field of drug circulation between different regions and countries.

To date, several international and regional document regulation organizations operate in the field of drug circulation, such as the World Health Organization (WHO), the International Association for Pharmaceutical Engineering ("International Society for Pharmaceutical Engineering- ISPE)," pharmaceutical inspections (GMP inspectors) cooperation scheme ("Pharmaceutical Inspection Cooperation Scheme" - PIC/s), international pharmaceutical organization (FIP), regional: international conference on harmonization (harmonization) of technical requirements for registration of DV – ICH (International Conference of harmonization), International Organization of Southeast Asian Nations (Asean), Convention for the creation of European Pharmacopoeia .

In most countries of the world, the quality of DV, which is allowed and entering into use in medicine, is ensured by licensing the process of their production. In this case, the DV will have to be produced on the basis of the requirements of the principles of good production practice - GMP - Good Manufacturing Practice (Rules for organizing production and quality control of the DV).

It is necessary to carry out a certain certification process in order to confirm the compliance of drugs with the requirements of the world market. Certification in the field of DV circulation is associated with confirmation of their quality, safety and efficiency, as well as the suitability of quality assurance and Quality Management. The DV certification system for international market trade is developed by WHO, the main part of which is the compliance with GMP requirements. In addition to compliance with GMP requirements, it is necessary for manufacturers to have an inspection system established and operating in the country, which registers medicines and constantly checks them (no less than 1 time in 2 years).

The World Health Organization (who) was established as a special Agency of the United Nations in 1948. Today, 192 countries are members of this organization. Its activities are managed by the secretariat of the headquarters, which is made up of 6 regional bureaus located in some regions of the world. Significant work of the organization is carried out by member-states. This work is carried out by the ministries of health, centers, who experts and other interested organizations and specialists.

The WHO's strategic objective is to:

- reduction of mortality, morbidity and incapacity for work;
- support for a healthy lifestyle, reducing risk factors associated with atrophies and diseases;
- development of the health system;
- conduct and organize the policies of advanced health organizations.

According to the Charter (Constitution) of the WHO, its tasks include, above all, the development of international standards for food, medicine, biological and other products. Its regulatory acts are not considered mandatory, but the nature of their use is decided at the national level, that is, at the mandatory, tafsia level, according to the decision of each member state of the WHO. International Conference of harmonization (International Conference of harmonization) of expert committees that prepare proposals, methodological guidelines and lectures on the work carried out by the organization www.ich.org) organizes and leads their work.

To harmonize (harmonize) the requirements developed for DV, it is permissible to insist that the activities of the proposed organization, such as GMP and GCP regulations, proposals

for pharmaceutical product registration procedures, methods for studying stagnation and bioequivalence, inspection (inspection) of drug production enterprises and ways of their distribution, international Pharmacopoeia, drawing up International Biological Standards, are worth special attention.

International Conference on harmonization (harmonization) of technical requirements for registration of drugs for human use (ICH). The development of the globalization process in pharmaceutical production all over the world, the presence of homogeneous national standards in different states, led to the fact that it became difficult to register medicines, and this caused this issue to find its solution at the WHO conference on the regulation of medicines in Paris in 1989. In 1990, the International Conference on harmonization - ICH was organized by the Association of demonstrators and manufacturers of regulatory bodies of the United States, the European Community (EH) and the agency of Japanese States (ICH is located at the headquarters of the International Federation of Association of pharmaceutical manufacturers in Geneva). To date, the ICH has included 6 members, 3 supervisors (who do not have voting rights), and the International Federation of the Association of pharmaceutical manufacturers (IFPMA).

The ich governing body has two representatives from the EH, the United States and Japan, one from the state's regulatory body and the other from the Association of innovative pharmaceutical manufacturers of the state in question. Therefore, this organization is sometimes also called a "tripartite initiative".

1. EH dan:

- European agency for Drug assessment (EMA);
- Europa Federation of Pharmaceutical Manufacturers Association (EFPIA);

2. From the USA:

- administration of medicines and foodstuffs (FDA); (the use of essential medicines. Report of the WHO Expert Committee (including the 13th Model list of Essential medicine). Who Technical Report Series No. 920, 2004, 133 p.)
- U.S. Association of pharmaceutical developers and manufacturers (PhRMA);

3. From Japan:

- Japan SSV (MHW) agency for medicines and medical technology, labor and social issues and National Scientific Institute for health Sox;
- Japan Pharmaceutical Manufacturers Association (JPMA).

Observers of the ICH include the WHO, the European Association for free trade and the Canadian SSV. To date, the ich rajbariya operates on the following 4 main lines:

safety-S (Safety, bezopasnost)

efficiency-E (Efficacy, effektivnost)

quality-Q (Quality, kachestvo)

Inter-Saxon documents-M (mejditsiplinarnie document)

The main purpose of ICH:

- economical use of human, biological and material resources;
- elimination of difficulties in the process of applying innovative drugs;
- to carry out greater use of new drugs, adhering to quality, efficiency and safety.

Functions of ICH:

- Organization of forums for the purpose of conducting constructive dialogue between regulatory authorities and manufacturers in order to ensure that drugs quickly enter into practice and quickly reach patients (differences in the registration of drugs);

- monitoring of medicines and updating harmonized (harmonization) technical requirements;

- * registration of drugs for the purpose of therapy and development of new technologies using harmonization (harmonization) to remove the difference in technical requirements;

- explanation and distribution of harmonized (harmonization) instructions;

- * generalization of requirements.

Harmonization (harmonization) of the technical requirements for the registration of medicines for humans is carried out through technical regulations, state control, consultations within the framework of ICH, preparation and approval of texts, adoption of ICH decisions by national bodies. Within the framework of ICH, solutions are found to such questions as drug safety - pre-clinical trials (toxicity, carcinogenicity, pharmacokinetics, toxicokinetics, reproductive toxicity studies), clinical trials planning, safety monitoring, communication problems (activity) and quality (sustainability studies, analytical methods validation, alien testing, pharmaceutical production and specification).

Ich Q10 - objectives:

- "Product turnover in the market"- supply of production, consumer requirements (registratsionnoe dose)

- product quality and condition of control with respect to process

- * continuity effects of improvements

- * The relationship of GMP requirements with ICH. Quality control of medicines:

- ICH Q9 (upravlenie riskami kachestva) "quality: production of products and the level of demand response of the process until it reaches the consumer" (ICH Q6A

- ICH Q6A "Requirements: Requirements that give the results that patients are waiting for and requirements for the process before the production of the product and reaching the consumer".

- ICH Q6A "quality: the drug substance recommended for use and the suitability of the drug drug". Thus, when drawing up methodological manuals within the framework of the ICH, the rules for conducting clinical trials (GSP) of the WHO, Japan, EU states and the United States were mainly used, in which the harmonization of these documents was expressed.

International Organization of Standardization - ISO 3 was established by the United Nations (OON) in October 1946.

Its main task is to develop international standards (recommendations) that promote the development of international trade and scientific and technical development. In total, ISO has 100 committees-members, in addition to member-correspondents (for developing countries). A number of commissions and committees have been established and approved to develop international standards (recommendations). These include:

- The International Electrotechnical Commission (IEC) is a committee that develops standards that determine the safety of medical electrotechnical devices.

- European Committee for temperance (EKN,

- European Committee for electrotechnical normalization (EKEN), 3 International Organization of Standardization-ISO www.iso.org

- Includes the European Quality Control Organisation (EOKK) and others.

The MEK and ISO are collectively organized in:

14 technical committees for the standardization of medical products; secretariats - 7 are led by Germany, 3rd USA, 2nd UK, 1st Sweden and 1st Denmark.

ISO first developed the ISO 9000 quality system international standard based on the 1987 British Standard 5750. In 1994, 2000 and 2008, this standard was revised and it became regarded as a quality management system (SMT) and not as a standard.

The organizational system of the ISO consists of executive bodies and technical committees. The governing bodies include the General Assembly and the council, while the technical committees include the technical rajbar Bureau, sub-committees and technical consultative gurus.

The ISO 9000 series rules have been adopted by more than 190 countries.

ISO 9000 series rules include the entire life cycle of a product, in which quality requirements are developed with the personal participation of the consumer. In traditional methods of quality assurance, problems related to quality were solved using various homogeneous corrections. Now the requirements for solving problems have been introduced into these rules.

Changes were also made to the audit process. If the task of an auditor is only to verify that the quality complies with the requirements set out in the standard, a new revision of ISO standards has now become required to include a process of continuous quality perfection in the SMT content. Thus, the auditor was required not only to verify that the quality complies with the requirements presented in the imposed standard, but also to analyze the results obtained and constantly think about increasing the quality.

Today, a new ISO 15378: 2006 document has been developed. This standard was developed with the participation of experts from the pharmaceutical sector, which included GMP products for the development, production and supply of primary packaging materials of quality management ISO 9001:2000 and medical product.

ISO 9000-contains 3 basic standards and various different executive directives.

* ISO 9000: 2005 Quality Management System – Basic Rules and vocabulary;

* ISO 9001: 2008 Quality Management System-Requirements (international standard applied for certification);

* ISO 9004: 2009 Quality Management System - proposals for improving activities (expressed in how the management of the organization should use the quality management system to achieve permanent high achievements).

ISO 9004: 2009 proposed the use of ICHQ10, under which lay the PDCA (Plan-Plan, Do-bajar, Check-tekshir, and Act - act (vozdeystvuy)) complex.

1.2. Production of drugs GMP, GLP, GACP on the basis of international requirements.

There are certain rules that are tearful to control the quality of medicines based on international requirements . Cooperative Convention on pharmaceutical inspections (inspectors under GMP) (PIC). The convention was signed by 10 European countries and Australia's national health authorities in 1970. The main purpose of PIC:

- Mutual recognition of inspections under GMP;
- Harmonization of GMP requirements;
- ensure uniformity of pharmaceutical inspection system;
- Preparation of GMP inspectors;

- data sharing;
- mutual trust.

In the early 90s of the last century, disagreements arose between the European Union and the PIC. This was due to the fact that some EU states that were members of the PIC were not allowed to conclude agreements with non-European states that wanted to join the convention. At this time, the right to conclude an agreement with these states was granted only to the European Commission, which was not a member of the PIC.

Therefore, in order to expand PIC, in 1995, a cooperation scheme for pharmaceutical inspections –PIC/S– was formed. The PIC/S consisted of inspectors from 26 PIC / S member states that ensure compliance with GMP regulations rather than States.

Purpose of PIC/S:

- Strengthening interoperability between responsible government bodies in the field of inspections under GMP;
 - provision of information and exchange of experience between responsible government bodies;
 - Coordination of the training of GMP inspectors and experts;
 - harmonization and improvement of control in drug manufacturers inspection processes and technical standards, as well as in Drug Quality Control Laboratories;
 - Assistance in the development, harmonization and implementation of GMP;
- (Introduction to Quality Control. ISBN-13: 978-4906224616 ISBN-10: 490622461x Kaoru Ishikawa
- expansion of cooperation between responsible public bodies at the expense of equivalent standards and processes in order to harmonize globally.

PIC / S is a prestigious international body that inspects government bodies that verify that drug manufacturers meet GMP requirements, to draw conclusions about compliance with the inspection system, GMP requirements; provides control over the implementation of legal requirements, as well as the training of inspectors and experts.

Good Manufacturing Practice-GMP – Good Manufacturing Practice– is part of a quality assurance system that ensures continuous product production and control based on quality standards. GMP regulations are primarily aimed at reducing the risk that may be present in every pharmaceutical production and that cannot be lost with the help of inspections of the control batches of the finished product. Including the development of GASP - good cultivation and preparation practice rules regarding the quality of medicines obtained on the basis of medicinal plants.

The first rules of GMP were adopted and implemented in the United States in 1963. According to him:

- the quality of the drug is not provided only by the analysis of the finished product;
- it must be provided during the production process of the drug;
- this process must be monitored;
- GMP increases pharmacopoeic control.

GMP concept

(National policy on traditional medicine and herbal medicine regulation: JUST, Geneva, 2005, p.156.)

That is, GMP is:

- using only the best products;
- highly qualified personnel who fully and diligently fulfill their duties;
- quality assurance;
- formalize the processes to be performed, perform on their basis and finally formalize the work performed;
- * use of technologies that guarantee the production of a quality product in accordance with the document;
- risk prevention;
- to follow cleanliness and hygiene.

Today, GMP rules are used by more than 40 countries, and about 140 countries have recognized. Based on them, GLP DVni clinical trials GCP DVni clinical trials GMP DVni production GSP DVni storage GDP DVni wholesale GPP DVni retail GXP system drug (DV) pharmaceutical development during the entire life cycle of Consumer national standards, including guidelines for the use of medicinal plants, were developed. Local GMP regulations of participating countries also exist- "Soglasheniya po farm kontrolyu" (GMP PIC), GMP regulations of EU states (GMP EU), GMP ASEAN (Association of South East Asian states participants), as well as international who requirements (GMP who) are among them.

GMP elements are being implemented at all stages of the DV life cycle, i.e. good laboratory practice GLP - Good Laboratory Practice, G(Q)CLP - Good (Quality) Control Laboratories Practice, GCP-Good Clinical Practice - good clinic practice, GDP-Good Distribution Practice-good wholesale practice (raspredelenie), GSP // GTDP - // Good Storage Practice // Good Trade and Distribution Practice – good storage, sale and Distribution Practice distribution practice, GPP - good pharmaceutical practice - Good pharmaceutical practice (pharmacy), GRP - good regulation practice- good regulatory practice, GEP - Good Education Practice-good learning practice, and GxP-Good X Practice (code standard). Strict regulations of production on the basis of GMP requirements:

Ensuring the quality of medicines through the production (quality control, quality error management) of drug preparations based on GMP requirements;

1. • the presence of a quality assurance system, indicating that the product is being produced and controlled based on quality standards
2. This standard is considered the main part of the quality assurance system, ensuring the conduct of production and control at the enterprise based on the requirement of relevant documents. The rules will help to bring to a minimum dangerous errors in production, which cannot be lost by controlling the finished product. Most often, double-type errors occur:
- 3.all-round contamination
- 4.mixing or confusing finished products.

The rules provide for:

- all production and control processes, their clear regulation to confirm their readiness to release drugs of the desired quality;
- validation at all stages of production, which can affect the quality of the product, and all significant changes in it;

- ensuring the necessary rooms, appropriate equipment and service to them, the storage and necessary transportation of quality plows and marking materials with highly qualified personnel, which are properly trained by the production enterprise;
- the existence of an approved technological regulation written in a clear and homogeneous sense, woven on the basis of a standard and manual for the production of each specific product;
- to teach employees the appropriate level of technological operations;
- constant registration at all stages of production according to the requirements of the regulation, while the products obtained provide for compliance with the qualitatively and quantitatively established requirements.

- storage of typical production documents containing finished product sales documents for a certain period of time in a place where it is convenient to browse each series of products(Series reports, route maps, etc.);

- the likelihood of a decrease in quality when storing and selling finished products will be minimal;

- the procedure for withdrawal and warning measures are taken when the detected defects are returned when the reasons for the qualitative violation are identified at the stage of sale or sale of each series of finished drugs.

The World Health Organization created the “international commercial pharmaceutical drug quality approval system” to assess the technical level of production and quality of medicines, and the operating variant of the system was adopted in 1992.

The fact that there are three conditions in the country for participation in the system darkor:

- 1.The Office of state registration of medicines and the availability of the system.
- 2.Regular inspection of pharmaceutical enterprises by competent authorities.
- 3.Compliance of the existing enterprises with the requirements of GMP (Good manufacturing practice – Rules of good production practice).

Today, more than 140 countries have joined the system. Uzbekistan is not a member of the system due to the fact that not all drug production enterprises meet the requirements of GMP regulations. It should be noted that in the registration of new manufactured or imported drugs, a production certificate must be issued that complies with GMP regulations.

GMP is a general management rule that sets out the procedure for conducting production processes and control tests, and includes a minimum of practical instructions on the type of release, in a modern way.

In order to ensure the implementation of GMP regulations in different countries, documents and standards are being developed that regulate and determine the conditions for the organization and management of the process of issuing certain types of pharmaceutical products.

At the present stage of the development of the production of medicines, it is relevant to provide the population with quality products, to control enterprises by organizational, technological, personnel and other indicators. With this in mind, in the Republic of Uzbekistan, as in many other countries, formal requirements have been made to organize control over the production of drugs aimed at preventing errors and shortcomings that can lead to the production of poor-quality products. Such requirements are referred to as "good manufacturing practice (GMP).

GMP:

- this is a single system of requirements for the organization and quality control of the production process from raw materials to finished products
- it is not a production or technology, but a proof system that allows itself and the consumer to prove the quality that produces a quality, quality, efficient product in the factory.

- GMP rules general guide to the organization,

it is the proper management and control of the production process.GMP umumiy talablari:

1. Quality assurance
2. Personnel
3. Buildings and equipment
4. Documents
5. Production
6. Quality control
7. Conditions for the production and quality control of products.
8. Advertising and product reference
9. Check
10. Self-examination

GMP requirements were first adopted in the United States in 1963, and then in Canada in 1966, Italy in 1970, the United Kingdom, Australia in 1971 and another country .

Establishing uniform standards of drug quality

it became especially necessary with the expansion of international trade relations around the world. In this regard, in 1969, the World Health Organization (WHO) established similar rules and established the world's

More than 90 countries agreed.

They are periodically revised according to modern requirements.

In addition to GMP National and international regulations, regional regulations: European Economic Community countries GMP regulations (GMP EU) and GMP regulations participating countries "pharmaceutical control agreements" ("Pharmaceutical Inspection Convention") - GMP PIC also exists.

GMP pic unites Austria, United Kingdom, Hungary, Denmark, Iceland, Liechtenstein, Norway, Portugal,Romania, Sweden, Switzerland, Germany, Finland.

<<Within the contract...>> GMP PIC mutual control of the production of medicines between member states is carried out and is facilitated by free trade. GMP PIC provides regular company and pharmaceutical inspection information, conducts inspector - inspector meetings and seminars by participating countries to guarantee the fulfillment of GMP PIC requirements.

National requirements are dominated by regional, and regional requirements are dominated by international. All national and other provisions of GMP are collected in the " International Drug GMP's " collection and occasionally reprinted in the United States.

The collection consists of four parts and an appendix. The first part lists the countries with national GMP and details of the accession of other countries to regional or international regulations.

The second part contains comparative tables of the rules of GMP WHO, GMP PIC, GMP USA. The last is considered the most complete.

The third part contains the full texts of the WHO GMP, GMP PIC rules.

The fourth part contains texts from the National GMP.

The application lists the national regulatory authorities responsible for compliance with the rules for the production of medicines.

On April 10, 2019, Decree No. PF-5707 of the president of the Republic of Uzbekistan "on measures for the rapid development of the Republican pharmaceutical network in 2019-2021

was signed. According to it, all domestic drug manufacturers must be subject to mandatory certification for compliance with the National requirements of good production practice (GMP).

In order to ensure the implementation of the decree of the Cabinet of Ministers of the Republic of Uzbekistan No. 788 of September 18, 2019 "on additional measures for the introduction of relevant practice requirements into the pharmaceutical network", a plan of measures for the implementation of the inspection procedure in accordance with the relevant practice requirements of GMP, as well as the implementation of

List of GMP National certified businesses

SP ooo" Jurabek Laboratories", OOO"NIKA PHARM", IP ooo" Nobel Pharmsanoat", CHNPP" Radiks", SP OOO"Remedy Group", SP OOO"Samarkand England eco-medical", SP ooo"Uzgermed Pharm", OOO"Dentafill Plus", ooo"Merrymed Farm", SP ooo"Reka med Farm".

EXPECTATIONS FROM THE INTRODUCTION OF THE GMP CONTROL SYSTEM.

- change the approach to ensuring the quality and safety of pharmaceutical products, which reduces the losses caused by poor-quality products;
- clear determination of responsibility for ensuring the safety of pharmaceutical products;
- documentary confirmation of confidence in the safety of pharmaceutical products, which is especially important when working with the consumer, including during the trial;
- ensure a systematic approach that includes all parameters of the safety of pharmaceutical products from raw materials to the consumer;
- more cost-effective use of resources for security management;
- reduction of financial costs associated with the production of low-quality products;
- increase the consumer's confidence in the quality of pharmaceutical products;
- ensure the optimal mode of operation of the entire enterprise and control and inspection systems
- increase access to new trade markets and expand existing ones;
- possibility of exporting pharmaceutical products;
- attracting foreign investors;
- to raise the reputation of a manufacturer of high-quality and safe pharmaceutical products.

GMP includes national, regional, international sections: introduction, terminology, staff, buildings, equipment, manufacturing process, functions (OTK), registration and reporting.

In the introduction, the minimum practical recommendations for the organization of the production of medicines required are given.

The" terminology " part includes basic concepts: drug, drug form, finished product, powder "Angro", raw materials, semi-product, series, Serial part, component, active substance, inactive substance, theoretical output, practical Output, Quality Control Department, production process, quality control, shelf life, packaging materials and containers, labeling, packaging, cleaning, specification, inspection, sales, drug manufacturer, etc.

The" employees " section lists the requirements for the qualifications of employees working in production, as well as the main tasks of employees of pharmaceutical enterprises.

Leaders at all levels must have educational and practical experience to help organize the production of medicines. Employees must have training, training and work experience that allows them to perform production operations according to job descriptions. GMP, special and general rules should be taught to employees on a regular basis.

Employees of pharmaceutical enterprises are obliged to follow;

- clean and work in clothes in accordance with the work they do;
- strict adherence to the requirements of production discipline;

- training in specialty and related subjects, including knowledge that ensures the successful production of sterile products, including the basic elements of Hygiene and microbiology;
- strict adherence to health and hygiene requirements;
- to inform the head of any disease that can negatively affect the medication. It is not allowed until the carriers of infectious diseases, open wounds to the skin and pathogenic microflora are fully restored to work related to the production and storage of drugs;
- to inform the head of any disease that can negatively affect the medication. It is not allowed until the carriers of infectious diseases, open wounds to the skin and pathogenic microflora are fully restored to work related to the production and storage of drugs;
- periodic passage of retraining and medical examination;
- access to and from clean rooms is carried out according to written instructions. Access to clean rooms is limited;
- before entering a clean room, the staff removes all decorations, removes cosmetics and wears special or technological clothing;
- hygienic means before entering a clean room and changes in clothes and shoes occur in special rooms for changing clothes.

The Department of " buildings " determines the requirements for the planning and organization of production of production premises. The premises in which the preparation, processing, packaging and storage of medicines is carried out must have a size, design and order that ensures a rational production process and facilitates their cleaning. The planning of the premises should ensure a reasonable placement, the transfer of various raw materials, semi-products and ready-made medicines from one building to another should be carried out in a safe way. Each technological operation should be carried out in a separate room to prevent contamination and improper mixing of components.

In the " equipment " section, the basic requirements for the structure, size and location of the equipment are indicated.

Equipment for production, processing, packaging and storage

it is designed to facilitate the preparation, use and service of medicines and should be placed accordingly.

All the rules of the GMP " production process " describe the various stages of the production process: sample selection and quality control of raw materials and preliminary packaging materials; control of production processes; processing, packaging and labeling; processing of unsuitable drugs.

The " registration and reporting " section describes a set of registration and reporting requirements, which makes it possible to track the execution of the production process and, if necessary, to accurately determine the sequence of actions of employees.

The experience of applying GMP rules in the pharmaceutical industry shows that they are of particular importance in ensuring the appropriate conditions for the production and quality control of medicines at all stages of the technological process. Compliance with GMP rules will serve as a reliable guarantee of obtaining the necessary quality drugs. Approval of the country's GMP regulations is one of the mandatory conditions for full participation in the WHO-recommended "system for determining the quality of pharmaceutical preparations in international trade".

Lecture 2. Design of premises for pharmaceutical production. Requirements for buildings and buildings. Sex system in pharmaceutical production. Chemical, technological and hardware scheme of production.

Plan

1. Design of premises for pharmaceutical production.
2. Requirements for buildings and buildings.
3. Sex system in pharmaceutical production.
4. Chemical, technological and hardware scheme of production.

Base words and phrases: pharmaceutical activities, pharmacological agents, medical equipment, medical supplies, poor-quality medicine and medical item, prescription, medicinal plant raw materials.

The allotted time is 2 hours.

A pharmaceutical enterprise is understood as industrial premises that contain several zones: basic production, auxiliary, energy, transport and storage - each of these zones can be represented as a separate building. An integrated solution is required for the placement of buildings and structures on the territory of industrial production, the planning and improvement of the territory, the organization of engineering networks, economic and cultural service systems.

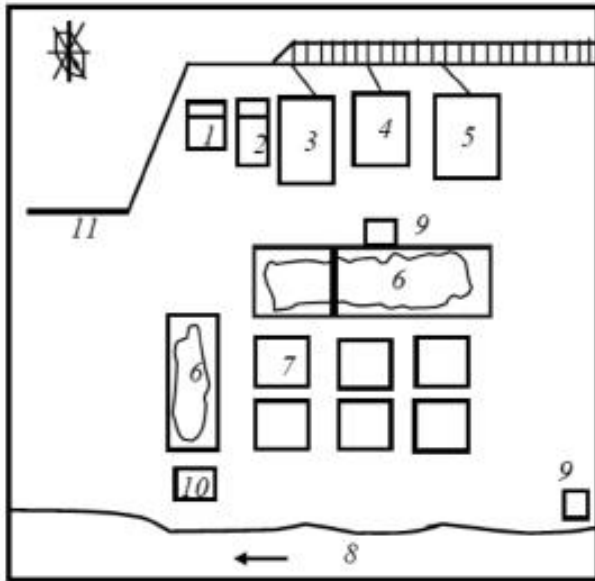
When choosing a place for pharmaceutical production buildings, the following criteria should be taken into account: the technical and economic indicators of the selected area; the possibility of placing the enterprise close to the source of raw materials and reducing the ways of exporting the finished product; sanitary and hygienic conditions and environmental issues.

When designing pharmaceutical enterprises, special requirements are imposed on compliance with environmental conditions: to reduce the impact on the environment, it is necessary to correctly place industrial enterprises in relation to residential buildings, public buildings and structures, recreational areas, and take into account the direction of the prevailing wind.

The location of the pharmaceutical production building along the direction of the wind in the direction of the government or at an angle of 45° ensures the removal of air masses from residential areas of settlements and public places with impurities from industrial waste. The fact that the pharmaceutical manufacturing enterprise is located on a softer slope also helps to ventilate the area well.

The ecology of pharmaceutical enterprises requires both the protection of the industrial facility from the influence of the external environment and the protection of the external environment from pharmaceutical production. The protection of the air of the pharmaceutical enterprise from emissions, odors and noise is ensured by the mandatory elimination of the sanitary protection zone around the territory of the production enterprise. On the other hand, the feasibility of reducing the amount of atmospheric pollution and reducing the load on domestic industrial air purification systems requires the placement of industrial buildings at the right

distance from large industrial and large transport routes (fig. 3.1).



Picture. 3.1. Situation Plan [1]: 1st passenger railway station; 2nd freight railway station; 3rd chemical pharmaceutical plant; 4th IES; 5th textile factory; 6th sanitary protection zone; 7th residential areas; 8th River; 9th water intake; 10th treatment facilities; 11th railway

When choosing a construction site for the organization of pharmaceutical production, architects and urban planners are required to approach this issue very carefully. It is necessary to take into account the direction of the prevailing wind blowing, the nature of the relief and the connection with the settlements.

The organization of the placement of industrial enterprises in the outer Hudu should be aimed at ensuring the most favorable conditions for the production process.

In ensuring the effectiveness of industrial production, it is necessary:

optimal functional placement of the territory taking into account the technological process;

compliance with sanitary and hygienic and fire safety requirements;

creating conditions for cargo turnover, transport and pedestrian routes;

Organization of a system of buildings for administrative, economic, domestic purposes;

Organization of the correct compositional solution of the building, and the need to moderate production in the future, it is desirable to place pharmaceutical enterprises in a larger area. Buildings, structures, workshops, warehouses and devices of the industrial complex are divided into groups in the regions of several zones according to their functional characteristics: territory up to a pharmaceutical plant, production, utilities, warehouses. According to the peculiarities of pharmaceutical enterprises, buildings on the production site are divided into

groups according to the degree of harmfulness of production: harmful, less harmful and harmless.

In modern world practice, the main concept of designing pharmaceutical pharmaceutical plants is to organize production that meets the requirements and regulations of GMP. GMP is one of the most important documents that define the requirements for the production and quality control of medicines. The liquidation of pharmaceutical enterprises under the requirements of GMP solves the issues of Environmental Protection, the use of new construction structures and materials, technological equipment.

According to the requirements of the concept of sterile production, buildings should be located in an environment that guarantees the minimum risk of cross-contamination. In production, storage or laboratory practice, the lighting, room temperature and humidity of the building should correspond to the functional purpose of the premises. At the same time, it is necessary to take all the necessary measures to protect against the penetration of insects or animals and the passage of unauthorized persons. For hazardous and other technological operations, all hygienic zones are divided by purity classes into zones A, B, C and D according to the permissible number of Fine aerosol particles.

The placement of buildings for pharmaceutical production according to their functionality is divided into two main parts: the production area itself and the technical support area; and the planning of the structure of the premises must correspond to the logical sequence of basic technological operations to eliminate cross-contamination and reduce errors in operations.

Taking into account the specifics of production when slurring a warehouse, storage areas should be divided into several sections, the light, temperature, relative humidity of which are different homogeneous indicators.

Auxiliary buildings , laboratories, warehouses should be separated from the main production zones with the help of buffer zones using air switches.

The composition, size and specifics of production, technological equipment, number of employees, connection with one is determined by the ratio of production facilities and engineering systems when silencing the external composition of pharmaceutical enterprises.

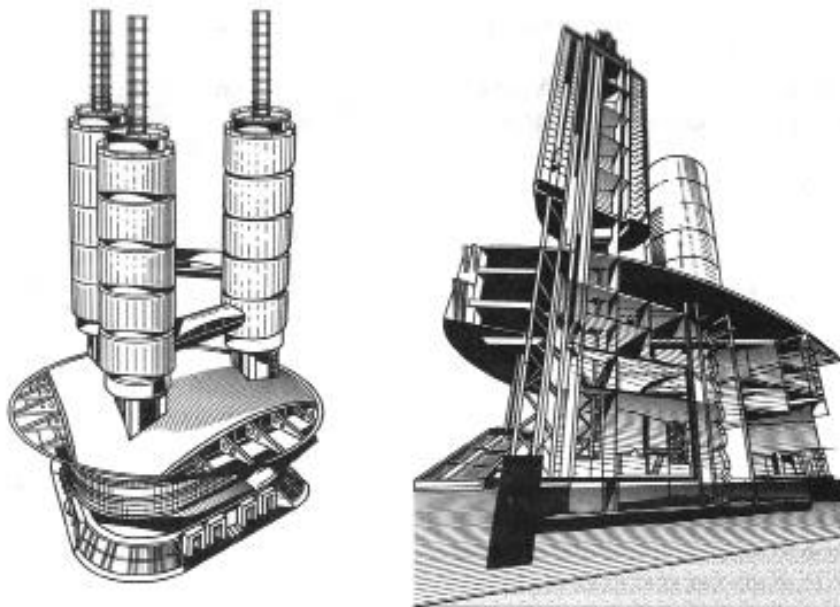
When designing a pharmaceutical production building, attention is paid to:" clean zone " - a place where production equipment is located and where basic technological operations are carried out;" clean room " - a place protected from the penetration of any contaminants, a barrier room separating the location of clean zones;" air gateway " - a buffer zone between clean rooms and barrier or auxiliary and administrative buildings.

The zones of the main "clean" production and auxiliary engineering systems are located in accordance with the principle of shell spaces, which are interconnected by a decrease in the purity class for the outer zone in relation to the interior: 1) Clean Zone-2) Clean Room - 3) buffer zone - 4) barrier that protects the building from environmental influences.

In the formation of the architecture of pharmaceutical pharmaceutical plants and factories, great importance is paid to solving aesthetic problems associated with the environment, increasing the number of buildings and improving landscaping . In further enriching the artistic aesthetic appearance of buildings, improving the air microclimate for workers, protecting nearby settlements from harmful gases, smoke, dust; in ensuring compliance with sanitary and hygienic standards, the following will help: the organization of

green zones on the territory of pharmaceutical enterprises, the provision of water devices, the presence of decorative small architectural devices, the organization of the enterprise God with informational signs for unhindered and safe movement, etc.

Compliance with the aesthetic laws of the construction of an industrial enterprise is formed depending on the nature and size of production, which is often determined by the size of industrial buildings, the forms of engineering structures and planning features. The main compositional elements of industrial development can be the largest and most expressive volumes with the subordination of other parts to them. The composition can be dominated by metro-rhythmic construction groups, technological and engineering structures, surrounding structures, vertical communication nodes, contrasting combinations of glazed and empty surfaces of fences, light with a bright silhouette and contours of aeration lamps. Extended low-industrial buildings that resist the multi-storey volumes of the administrative, landscaping and auxiliary zones of the complex will be an example of contrast (figure 3.2).



Picture.3.2. Project of a multi-storey building for the pharmaceutical production of finished drug forms

In the architecture of pharmaceutical facilities, issues of the internal environment of enterprises are also relevant. Interior design plays an important role in the design of industrial buildings, solving the problems of mutual and aesthetic location of buildings, placement of technological equipment, Organization of workplaces, air exchange and ventilation systems, ensuring the level of lighting. In the design of the enterprise, it is necessary to properly organize the direction of normal illumination of the workplace and the direction of Light Fall, focusing on the norms of natural and artificial lighting.

In the organization of workplaces - as a way to ensure optimal viewing conditions in the workplace, reduce the general fatigue of employees and increase the safety of workplaces, the color of interior rooms also plays an important functional role.

Thus, in the planning and design of pharmaceutical production buildings on the basis of GMP standards, and in the field of technology for the production of medicines for obtaining

high-quality finished products, a specialist in the field of technology is based on the joint work of a technologist and an architect who issues the correct formation of buildings.

The location, layout and construction of buildings and rooms should be designed to carry out production operations, as well as ensure that there are no possible errors of origin in production. Preparing rooms for work and catching them in working condition should give the opportunity to eliminate all kinds of contamination, dust and other impurities accumulations that negatively affect the quality of the finished product.

It is strictly forbidden to use it for the production of pesticides and herbicides in rooms where medicines are produced.

Pharmaceutical enterprises should be located in one or more production buildings. Its size, project and location must be ensured that the production processes are performed rationally.

Production buildings, structures and rooms should be designed in accordance with the current building standards and laws (QMVK) and the requirements of the instruction on the design and construction of enterprises of the medical industry.

Production buildings must be designed and built so that they prevent pollination, pollution, and insects and animals cannot enter.

The location of rooms in the production building should be planned in such a way that they should provide:

- technologically related, distances between rooms are extremely short, ensuring the continuity of processes;
- prevent people from intersecting transitions and technological flows;
- location near homogeneous rooms of the level of cleanliness as much as possible;
- rational placement of equipment and materials in order to prevent intermingling of primary raw materials, semi-finished products and finished drugs;
- full compliance with the conditions of the sanitary and hygienic regime:
- Prohibition of the use of production rooms as storage and household and sanitary rooms, the arrival of unauthorized personnel;
- protection against contamination when transporting primary raw materials, semi-finished products and finished medicines indoors and from one building to another;
- compliance with the norms and rules of Technical Safety and fire safety;
- the use of separate rooms in the production of betalactamine antibiotics in order to prevent cross-contamination of drugs of another group;
- the use of separate rooms in the production of highly active, toxic or volatile substances;

Production rooms must have:

- lighting, ventilation, electrical systems, water network and sewage, production waste removal systems, which favor the cleanliness of rooms, equipment and finished products
- air conditioning devices that ensure the quality of medicines during the production and storage period, as well as the fulfillment of the hygienic requirement imposed on employees and the necessary temperature and relative humidity for the exact operation of the equipment used
- clean and household-sanitary rooms located close to the production rooms.

The functional-technology should be integrated into the blocks, provided with a system of autonomy that works separately at the necessary points!

All production rooms are characterized by the degree of air pollution by microorganisms and mechanical particles. The degree of cleanliness of rooms or zones is determined by the nature of technological processes.

3.1.- table

Classification of "clean rooms" under GOST ISO 14644-1

Purity classes	1 M³ the number of particles allowed in air					
	0,1	0,2	0,3	0,5	1,0	5,0
1 ISO	10	2				
2 ISO	100	24	10	4		
3 ISO	1000	237	102	35	8	
4 ISO	10000	2370	1020	352	83	
5 ISO	100000	23700	10200	3520	832	29
6 ISO	1000000	237000	102000	35200	8320	293
7 ISO				352000	83200	2930
8 ISO				3520000	832000	29300
9 ISO				35200000	8320000	293000

3.2.- table

Classification of "clean rooms" under ISO and FED STD 209 (USA)

GOST ISO 14644-1	FED STD 209 D	FED STD 209 E
1 ISO		
2 ISO		
3 ISO	1	M 1,5
4 ISO	10	M 2,5
5 ISO	100	M 3,5
6 ISO	1000	M 4,5
7 ISO	10000	M 5,5
8 ISO	100000	M 6,5
9 ISO		M 7,5

In the production of sterile drugs, "clean" rooms are normalized depending on the amount of mechanical particles in the air. The detection of mechanical contamination of the room air and the nazortation of microbial reproduction is carried out in accordance with the document.

It is understood that all systems of a "clean" room are ready for work, technological equipment is installed and designed for work, the absence of an employee in the work zone is perfectly provided with a tool. By working condition, all systems and technological equipment in a "clean" room are in working condition, in accordance with the requirements of the

regulation; in order, as well as in the performance of their production tasks, it is understood that with the participation of a certain number of employees.

The fact that the dervors of rooms belonging to the B, C and D levels of cleanliness do not touch the walls of rooms belonging to external barriers is darkor (according to fire safety standards, the walls of rooms belonging to Category A and B should not be strong). The fact that the rooms belonging to the upper levels of cleanliness are located inside the rooms of the lower level is darcor.

3.3.- table

Classification of "clean rooms" under GMP (2004)

room	1 M3 the number of particles allowed in air			
	In the production process		In the process of exploitation	
	0,5 mkm	5,0 mkm	0,5 mkm	5,0 mkm
A	3500	1	3500	1
B	3500	1	350000	2000
C	350000	2000	3500000	20000
D	3500000	20000	Unspecified	Unspecified

3.4.- table

Classification of "clean rooms" under GMP (2009)

room	1 m ³ havoda ruxsat berilgan zarrachalar soni			
	1 M3 the number of particles allowed in air		In the process of exploitation	
	0,5 mkm	5,0 mkm	0,5 mkm	5,0 mkm
A	3520	20	3520	20
B	3520	29	352000	2900
C	352000	2900	3520000	29000
D	3520000	29000	Unspecified	Unspecified

Rooms belonging to Level B, C and D of cleanliness are prohibited from being placed in the basement of a building or on a semi - basement floor.

The following requirements are imposed on the rooms for the production and quality control of medicines:

- strictly necessary to use only for the intended purpose;
- wide enough to be equipped in such a way that it eliminates the mixing of various drugs and their components, contamination at the junction of roads, passing one of the stages in the process of preparation and quality control of drugs.
- the inner side should be smooth (walls, floors, ceilings, doors), there should be few pushed areas and racks;
- it is desirable that the liquid is impermeable and convenient to be treated with detergents and disinfectants. The materials used for finishing production rooms should be dust-free, easy to wash, non-combustible and resistant to the effects of disinfectants;

- it is necessary to design and place pipes, lighting elements in rooms with ventilation holes, etc., taking into account the ease of washing with disinfectants and water. Technical service should be carried out as far as possible outside the production rooms:

-they must be impeccably clean, necessarily collected every day and repaired from time to time

-it is possible to irradiate the air with UBN in order to neutralize it with the help of stationary or portable lighting (in the absence of people).;

- the rooms can store enough equipment and furniture to carry out production processes;

-the lighting, temperature regime, air and ventilation in the room should not directly or directly adversely affect the quality of the finished product during the production process, as well as the performance of equipment and the health of employees;

-to have small equipment to clean the landed dust in places darkor (when taking na'muna, when measuring, stirring, etc.k.

The following additional requirements are imposed on sterile medicine preparation rooms:

- it is forbidden to use wooden surfaces, unpainted surfaces;

- the ground where the walls, floors and ceilings are adjacent must be round in shape;

- suspended ceilings must be air-permeable (hermetized) in order to prevent dust from falling from the top;

- flexible and hermetic shrinkage materials are used, which do not emit dust to prevent air from entering and close densely from the junctions of the structural parts;

- cleaningnng communications (except natural gas) and airways should not be open in rooms belonging to Level B and C (usually, such a situation should not be in rooms belonging to Level D of cleanliness either);

- the pressure to give filtered air, higher than in other rooms that are nearby, should be. The main focus should be on zones with a greater risk of exposure directly to the product or to the purified primary wrap that will be in contact with the product, that is, the surrounding muchit. It is encouraged by the need to make appropriate changes in air supply and in accordance with the pressure difference when certain substances are involved, such as pathogenic, highly toxic, radioactive, as well as living viruses and bacteria. Decontamination of heating agents for certain operations may be the need to process the air coming out of the Clean Zone;

- there must be a system that warns that little air is being given. If the pressure difference between two rooms is calculated to be fundamental, an indicator must be installed in the two room intervals that determines the pressure difference; the level of the difference in pressure must be constantly checked;

- in rooms belonging to the D and C levels of cleanliness, the use of rakovina and water drainage pipes is prohibited in rooms belonging to the D-level of cleanliness, it is advisable not to use them. If this is not possible, the drain pipes should be conveniently placed for washing and processing, as well as provided with devices that do not reverse the flow of water darkor;

- air conditioning filters are maxkam compacted (hermetized) and must be placed in a place to provide air to a " clean " room or as close to it as possible;

- it is forbidden to use the sliding door;

-when transferring finished products from rooms with a higher level of cleanliness to rooms with a lower level of cleanliness, it is encouraged to use a transporter that passes between the walls. It is not recommended to use transporters when transmitting to the opposite side;

-it is necessary to have electromechanical speaking devices between rooms belonging to different levels of cleanliness;

- the entry of personnel through air ducts and the transfer of materials to "clean" rooms must be carried out. This is done using a "top-down" transmission of sterile air. In the gateway, it is forbidden to open all doors in one way; the doors themselves must be closed and compacted.

In the rooms of wrapping medicines:

-to properly organize technological operations and be wide enough so that the roads carrying the materials are not blocked;

-it is necessary to place the equipment, products, especially medicines, as well as the wrapping materials, in such a way that they prevent the risk of intermingling at different stages of wrapping;

-during wrapping, it should have light, temperature order, air humidity and ventilation capacity, which do not adversely affect the quality of the product, as well as the operation of the equipment

Storage rooms, warehouses must meet the following requirements:

- primary raw materials, auxiliary materials, semi-finished products, plows and marking materials, finished drug products and products deemed unsuitable should be wide enough to allow for orderly and separate storage;

- ensure reliable protection against unconscious or deliberate contamination or poisoning;

- compliance with the current rules for the storage and treatment of flammable and explosive products, poisoners and drugs of production;

- it must be dry, clean and have the necessary level of light, ventilation, temperature and air humidity.

Samples for control are selected in the prescribed manner, if necessary, in special rooms equipped with devices that create a laminar flow of sterile air.

To carry out the production process, it is necessary to carry out weighing on the scales in the specified order in special rooms in the production or product storage zone in order to evaluate the initial raw materials and auxiliary materials and the finished product obtained by practical means.

In the reception of products and materials, as well as in the shipment, protection against exposure to inclement weather conditions should be ensured.

It is encouraged to enter the storage room only to employees with the appropriate authority.

The composition of sanitary and household rooms is determined by the character of production processes.

There should be a dressing room (wardrobe) for storing clothes in different styles (wearable on the street and special clothing-head, transitional and technological). The street dresser and passageway storage wardrobe are placed at the entrance to the building. Technological clothing-head should be stored in special wardrobes. It is necessary that the toilets, and hand washing rooms and toilets are separated from the production and storage rooms.

Dining and rest rooms should be separated from other rooms.

For the training of personnel, rooms belonging to the C and D – level (separate for men and women) should be organized, which are provided with the necessary amount of ventilation and appropriate equipment.

Personnel training rooms should be placed in such a way and used in such a way that each stage of clothing change should be conducted separately, and thus the level of contamination of the technological clothing head with microorganisms and mechanical particles should be reduced. Staff training rooms should be placed adjacent to "clean" production rooms, especially outside the zones of production of sterile products. Rooms should be provided with cold and hot water. A sterile towel or air dryer that is used once or many times can be used to wipe the hand. In addition, the rooms must have containers with a top cover for storing the clothes used, as well as the necessary washers and disinfectants for washing and processing.

The technical control department and workshops must be additionally provided with accident showers, racoon or hand washers.

Mechanical workshops should be as isolated (separate) from production and storage rooms as possible. If any tools (equipment, tools) and instruments are needed to work directly in production or storage rooms, they must be stored in separate rooms or cabinets specially designated for the purpose.

Requirements for production buildings and rooms of pharmaceutical production enterprises

A pharmaceutical production enterprise should be located at a distance far enough from productions that adversely affect the quality of its product.

Construction, reconstruction and repair of buildings of enterprises of pharmaceutical production of the pharmaceutical industry should be carried out in accordance with the provisions of QMQ 3.01.02-00 "safety equipment in construction".

It is necessary to design and build production buildings in such a way that the level of pollination, pollution is reduced as much as possible and the fall of insects and animals on them is eliminated.

The entire territory of the enterprise should be kept clean. Effluent tanks designed to expel atmospheric precipitation must be cleaned and repaired regularly according to the approved schedule. Roads, passageways, and areas between buildings, structures, and structures are prohibited from being used to store materials, and from laying down equipment or manufacturing waste.

Smoking on the territory of the enterprise is allowed only in specially designated places, equipped in accordance with the "standard fire safety regulations in enterprises of industrial pharmaceutical production" SHMQ 2.01.02-04.

In production, production rooms and warehouses should be equipped with automatic fire extinguishers and automatic fire alarm.

The administration of the enterprise is obliged to carry out control over the maintenance, operation and repair of buildings and structures.

Production rooms should have air flow control equipment and an effective air flow intake and air traction ventilation system equipped with temperature, humidity, purification efficiency and pressure change measuring devices in filters.

The productivity of air traction ventilation systems should be 80-90% of the productivity of airflow intake ventilation systems to ensure the delivery (podporini) of air in "clean" rooms.

The air supply systems of antibiotics should be completely insulated from the air systems of the production of medicines for other medical purposes.

In the manufacture of sterile medicines, horizontal or vertical laminar flows can be created using special equipment throughout the room or in certain local zones to protect particularly important plots or operations, depending on the production need.

Production rooms can be equipped with an air flow one-stop storage system if necessary, and this system must ensure the proper purification of air from mechanical particles and microorganisms, automatically coordinate climatic parameters (air temperature, humidity) to create reasonable conditions for the technological process and service personnel.

In production rooms, it is forbidden to combine production effluent with farm-fecal effluent.

Filters are installed on the pipes of the water supply system, depending on the need.

The pipes are made of materials that allow them to be sterilized using steam, they must be installed obliquely so that the liquid flows completely, and there must be no parts in it in which the liquid will remain standing.

Requirements for the location of rooms, number of them, status of household and additional premises

In accordance with the requirements of QMQ 2.09.12-98 "administrative and household rooms of enterprises of pharmaceutical production", the rules for the design of enterprises of pharmaceutical production, buildings and structures of the food industry and the rules for the construction of sanitary and additional rooms shall be established in each pharmaceutical production enterprise.

The design and construction of domestic and additional buildings should be carried out taking into account the need to simultaneously launch them with production facilities.

The composition of special household rooms and devices is determined depending on the groups of the production process.

Household rooms should be placed as close to work as possible.

It is forbidden to organize general sanitary and household rooms for employees of sterile and nosteril production.

Special household rooms should be created for employees working on plots in an environment that creates a large degree of pollution of clothing and the body.

The inclusion of personnel in aseptic rooms is carried out through special household rooms (showers, changing rooms, etc.) — sanpropusknics.

Wardrobes, toilets, washrooms and bathing rooms where home and work clothes are stored should be separate for men and women.

The number of changing rooms, shower sizes, shower sets, foot baths, bet hand washers, consumer water supply devices, toilets and the like should be determined especially taking into account the number of shift handlers that make up the majority.

Tarnovs, channels, traps, pissuars and unitases in toilets and toilets should be cleaned, washed and disinfected regularly. The floors of toilets should be kept dry.

Depending on the nature of the production, 40% of the calculated number of bet hand washers can be placed next to the working areas of the production rooms (on the drum in the toilet).

Each washbasin must be connected to pipes from which hot and cold water comes. In the washing rooms there should be electric towels, mirrors, clothes hangers, containers for liquid soap and solid soap hangers, as well as a hand washer in a solution of chlorine, which is due to the expense of one device per 40 people in the maximum number of shifts.

Laundry rooms should be established at enterprises of pharmaceutical production for washing special clothes. The composition and area of laundry rooms should be determined by the standards and rules of construction for the design of enterprises of pharmaceutical production of household services for workers.

Wardrobes should be designed to store Street, home and work clothes.

Wardrobes designed for work clothes should be placed separately from street and home clothing wardrobes. Household rooms should be equipped with flow and suction ventilation in accordance with the requirements of QMQ 2.09.12-98 "household and administrative premises of the Enterprise".

Catering points must meet the requirements of sanitary rules established for enterprises of pharmaceutical production of catering.

Requirements for the protection of the surrounding natural environment

Conditions for the formation of wastewater and discharge into water bodies QMQ 2.04-01-98 " drain. Design standards "and QMQ 2.04-03-97" drain. External systems and structures must comply with the requirements of" and be coordinated with the state sanitary supervision authorities, with each individual receipt.

The entire external drain system must be closed. Branches (lotocks) can be installed in open areas designed to exclude precipitation (rain) water and water that serves for washing.

The sewage should be closed for the sewage of contaminated production inside the workshops.

Open rods (lotocks) can be built to allow for floor washing as well as the water generated by washing the apparatus and pipes with clean water.

The leaking systems of production waste in liquid state should be adapted to eliminate the leaking of liquid into the back. The places where these waste passes should be equipped with appropriate ventilation.

Effluent that cannot be cleared of specific contamination is destroyed or discharged into specially designated areas.

The enterprise is obliged to provide regular laboratory control over the efficiency of purification of production and household wastewater.

Sex system in pharmaceutical production. Chemical, technological and hardware scheme of production

The following conditions are necessary for the serial production of drugs in industrial enterprises:

- 1) to ensure profitability, the mass demand for the medicinal product must be adjusted;
- 2) the starting materials and the finished product must be stable, because a certain time will pass until the raw materials for production and the finished medicines from the production are delivered to the consumer. In addition, in order to meet the demand for medicinal products in a timely manner, there must be reserves of finished products. With the use of various types of

stabilizers to increase the shelf life of the medicinal product, lyophilization, micro-encapsulation, application of protective shells, development of special packaging types, etc., these issues are solved;

3) in order to ensure the release of homogeneous products that meet the requirements of regulatory and technical documentation, which is achieved through the use of modern technologies, improvement of production, raw materials and medicines must be standardized. At the same time. The fact that there are several standards for a single-name product produced in the pharmaceutical industry is that it uses several different dosages in the treatment of patients of different ages

The organization of the production of medicines in pharmaceutical enterprises has its own characteristics. The work of industrial enterprises is characterized by strict regulation and planning of production, since a large amount is handled with raw materials and auxiliary materials, and any errors in production technology can lead to significant material damage and the development of braces. In order to prevent accidental adverse events, the production process is carried out according to specific standard instructions, and the instructions are grouped into a single document, which is a document development regulation.

- 1) The high quality of products produced at pharmaceutical enterprises and the improvement of technological operations of the profitability of production is achieved by the principle of proper distribution of Labor. Comprehensive pharmaceutical production consists of a complex of specialized workshops.
- 2) Pharmaceutical pharmaceutical plants are built according to the principle of sex, which usually have four main sex :

galen sex;



3) tablet production sex;



4)

3) sex of ampula;



4) packing shop.



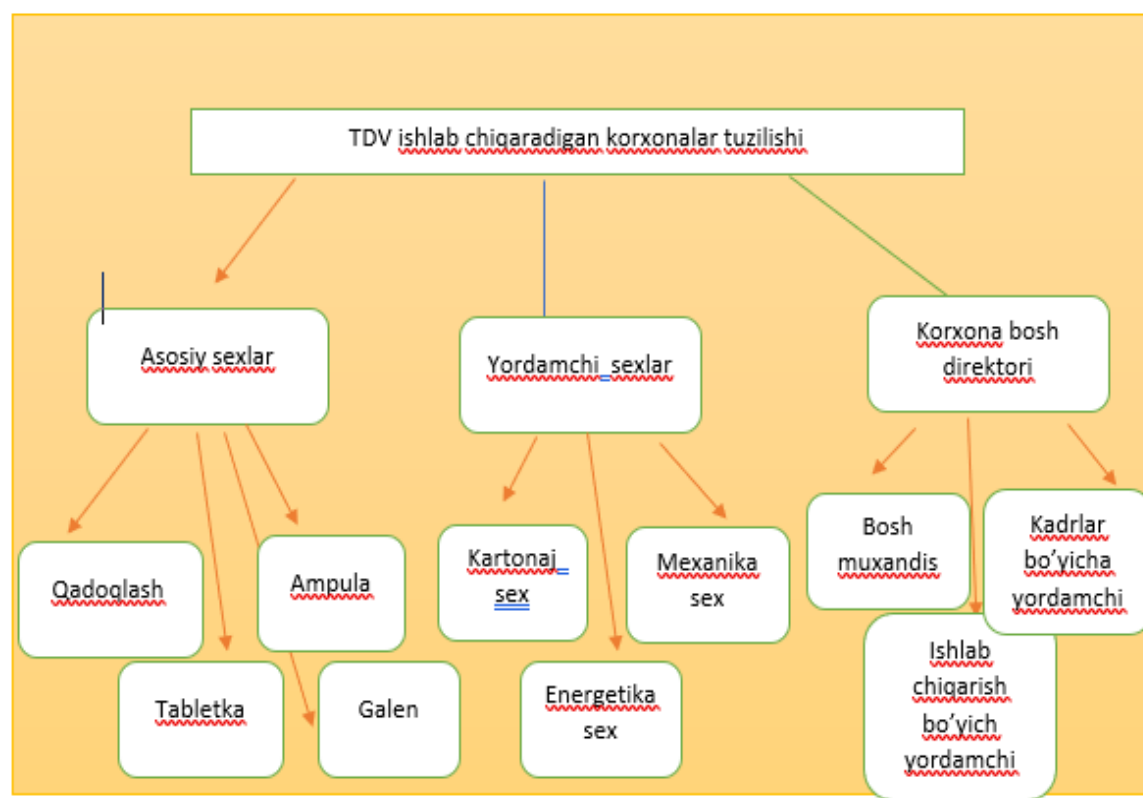
In the Galen workshop, extracts and decoctions are produced, as well as novogalen preparations, biogenic stimulants, etc. In this workshop, it is used to extract plant materials by various methods (maceration, percolation, circulation, etc.), liquid and solid phase separation operations (immersion, filtration, centrifugation, pressing), alcohol and other extractions for treatment, evaporation, vacuum drying, melting, mixing and other processes.

In the workshop where the tablets are produced, preslab tablets are taken from different powder mixtures. The main production operations in this workshop are grinding, mixing, mass granulation and tablet preparation of starting materials.

In the workshop where the ampoule is produced, ampoules are made that are used for injection. Here, the production cycle consists of smelting starting materials, filtering solutions, making ampoules, preparing them for filling (washing and other operations), filling, labeling, sterilizing and marking.

In the packaging shop, products produced at the enterprise are packaged.

In addition to the main workshops, each pharmaceutical Plant has auxiliary workshops and departments involved in the implementation of production by servicing the main workshops. This includes repair workshop, heating units, cardboard shop, warehouse, pharmaceutical factory transport standing garage, container workshop, etc.



A special place in the pharmaceutical plant is occupied by the experimental laboratory, which deals with issues related to the improvement of production, and the control is an analysis laboratory, the functions of which are to exercise control over all areas of production and allow the release of finished products from the pharmaceutical plant.

Quality control, not limited only to laboratory work, it will be necessary to participate in the processes and conclusions related to the quality of all products. At enterprises of the manufacturing industry, ensuring the independence of the quality control system, this control-analysis is the main basis and main criterion for the satisfactory functioning of laboratories.

Every licensed pharmaceutical manufacturing enterprise must have a quality control department. This department is composed of one or more control-analysis laboratories that become independent of other departments. The quality control department should only be headed by a specialist with relevant information, level and experience.

In order to ensure the effectiveness and reliability of all quality control activities, it is necessary that the quality control department has sufficient resources. The Department of quality control organizes its activities based on state and network documents.

When assessing the quality of finished products at a production enterprise, all factors are covered, starting from the conditions of production, ending with the results of internal control of the semi-finished product, a set of documents related to production (both on packaging), compliance with specifications and control of the finished product.

Control-analysis laboratories must be isolated from production zones. Employees of the quality control department must have access to production zones, samples and research.

It is considered very important for the control laboratories of biological, microbiological and radioisotope preparations. All such laboratories must also be designed in an isolated state.

Control and analysis all conditions must be met in order to fully carry out the work intended for the disposal of laboratories. In order to avoid confusion and contamination, it is advisable that the rooms of the laboratories are spacious enough. Separate rooms are allocated for storing samples and analysis results. Rooms are organized in Alexi for high-sensitivity priors, vibration, humidity, temperature and other influencing works.

Laboratories that work with biological, microbiological and radioactive samples are silenced according to special requirements.

The purpose of the quality control system at drug manufacturing enterprises will be to ensure that all series of drugs that are marketed mainly comply with approved specifications. From the date of production, until the expiration of the shelf life, each series of the drug, in order to guarantee compliance with the approved official requirements (Pharmacopoeia article), it is necessary for the enterprise to establish at a high level the requirements of quality indicators for itself. Therefore, production specifications can be distinguished by certain indicators, despite the fact that they are created on the basis of fitting the approved Pharmacopoeia article. In enterprises that normally comply with GMP requirements, the requirements of production specifications are a number higher than the requirements of general Pharmacopoeia articles. Thus, the main goal of controlling the quality of drugs in pharmaceutical enterprises will be to ensure that the quality of the drug being created, produced and marketed is consistent with the constantly established meiori requirements. This task is performed by the Department of quality assurance in industrial enterprises (fig. The shelf life of documents on drug analysis in enterprise control analysis laboratories is set as the shelf life of drugs and plus one year

Manufacturing or manufacturing process are tamouls that involve the production operations of ready-made medicines, i.e. from the purchase of raw materials, primary packaging, labeling materials and additional, semi-finished products, to their preparation, wrapping, obtaining

proofs for sale, storage, transportation and quality control of finished products. The production process is necessarily carried out under strict control. It carries out the types of step-by-step control of the introduction of amendments-corrections to the relevant technological indicators in order to monitor the production process of the product being released in order to ensure the quality of the finished product complies with the requirements of the regulatory document. Environmental and equipment cleanliness control is part of production process control.

The technological process is the process of large-scale (unlike the laboratory) production of finished products for consumption from natural and synthetic materials. The pharmaceutical industry, on the other hand, is a specific category of material goods necessary for the healthy survival of society as a result of certain processes, that is, the development of drugs and drug preparations.

The main factors that regulate the course of technological processes in pharmaceutical production are the following: a) mechanical processes - related to the processing of solids, which are subject to the laws of mechanics; b) hydrodynamic processes subject to the laws of hydrodynamics; c) heating processes subject to the laws of heat transfer; g) cooling processes subject to the laws of low temperatures; e) diffusion processes; f) chemical processes related to the chemical transformation of processed materials and subject to the laws of chemical reactions.

All these processes occur in the production of galen preparations and drugs in pharmaceutical enterprises.

The factors that will be needed to carry out each technological process of production are: 1) raw materials; 2) equipment; 3) Energy; 4) Labor.

The production process consists of production stages, which consist of separate technological operations.

The technological process should be carried out in accordance with all the requirements of regulatory technical documentation and on the basis of technological regulations in order to ensure the production of finished products. Particular attention should be paid to the issues of improvement and modernization of the production process. Technological process operations should be carried out and monitored by qualified personnel in special rooms allocated for these purposes, using the necessary equipment and equipment. Processing of raw materials, auxiliary materials, primary cutting materials and finished products, as well as all types of use, including acceptance, quarantine, sample selection and analysis, storage, marking and wrapping, it is necessary to carry out and register on the basis of written instructions and the standard of the enterprise. Any deviations from the technological process must be listed in the order established at the enterprise. Any deviations in the performance of production operations should be noted.

The technological process is the sum of the individual stages that are carried out in series. They can be: continuous, semi-continuous and continuous.

Continuous (periodic) processes are carried out in stationary devices and equipment. In this case, the final product is unloaded from the equipment after a certain period of time, after which a new part of the starting materials is loaded into the equipment, and the production cycle is repeated. Most of the technological processes in galenopharmaceutical production are periodic.

Continuous processes that occur in stationary equipment are characterized by continuous loading and continuous production of equipment with raw materials. These processes, which allow maximum mechanization, are now more often introduced into the practice of large pharmaceutical manufacturing enterprises. As an example of a continuous process, we can cite drying extracts in valli or spray dryers. Continuous processes have a number of advantages over bulk processes. Continuous processes make it possible to fully mechanize and automate production, which reduces the use of manual labor to a minimum

In a semi-continuous (unified) process, only certain stages are carried out periodically, Colgan processes are carried out without interruption, without interruption. An example of a semi-continuous process is tabulation, in which pressing is a continuous process, with periodic loading of the granule into the equipment funnel.

Various technology processes are used in the pharmaceutical industry. Depending on certain characteristics, such processes are smeared into several classes. The main processes are divided into 5 groups, depending on the power that harms technological processes: 1. Mechanical processes. 2. Hydromechanical processes. 3. Heat exchange processes; 4. Substance exchange processes; 5. Chemical processes.

At the final stage, each technological process is completed with the release of a finished product - a consumer product. Such finished products are both galen preparations and medicines obtained as a result of a certain technological process.

To obtain the finished product, you will need all the starting materials and raw materials indicated in the instruction (for example, alcohol for obtaining decoctions and extracts from plant raw materials, sugar for syrups, iron achchio stone for Burrow liquid, chalk and acetic acid, etc.). In some cases, herbal preparations may be among the starting materials in the production of more complex herbal preparations (e.g. camphor alcohol in the production of a arsenic solution of Fauler, coriander aromatic water in the production of chuchik Apple - iron nastoyka, etc.).

If the technological process consists of several stages, the products obtained in intermediate stages are usually called intermediate products or semi-finished products (for example, Adonis grass crushed in one of the stages of production of adonizide). In some cases, semi-finished products can be considered a finished product: for example, from a pharmaceutical enterprise, the same medicinal plants can be released as a finished product for pharmacy needs, crushed or powdered.

At the end of the production of the finished product, raw auxiliary materials will be needed: they are materials that are not directly part of the preparation, but without which it cannot be removed from the enterprise. Auxiliary materials include, in particular, containers and packaging materials.

At the same time as the release of the finished product during the production process, waste Ham appears. For example, in the production of Valeriana nastoyka, the waste of the valeriana Root remains. Development it is necessary to distinguish waste from production garbage. In this case, the valerian root, divided by use, cannot be considered garbage, since it retains a certain amount of alcohol in its composition, it can be washed with water or distilled with water vapor, and in the future, separated alcohol can be used. Therefore, washing water and distillates should be considered as by-products, and the "empty" plant mass left after them should be considered waste (waste that does not have a consumption value). To reduce the cost

of production, it is always necessary to try to make the most of the waste and reduce the waste to a minimum.

The technological process or the use of non-standard raw materials carried out by improper error leads to poaching, that is, to the production of a product that does not comply with the established standard.

Classification of technological processes

According to the unified system of technological documents (GOST 3.1109-82), there are three types of technological processes (TJ): single, simple and general. Technological processes are developed to produce a new product or to improve the existing ones. Bitality TJ-is formed for the manufacture or repair of a product of the same name, size and design, regardless of the type of production. Bitalik (TJ) is formed at the enterprise to produce original products (parts, assembly units) that do not have a common structure and technological characteristics with previously produced products.

A simple TJ is a structure for the production of a group of products with a common structure and technological characteristics, characterized by a general content, processes and a sequence of their execution. When constructing a working TJ, a simple TJ is used as a source of information, provided that all the necessary information is available to produce the product, and a simple TJ is used as a working TJ. On the basis of these technological processes, enterprise standards (TJS) are developed for simple technological processes.

General TJ is a single batch of products that have a different structure, but have common technological characteristics, and are formed for the production of rice. Common TJS are developed for all types of industry only at the enterprise level.

Simple and general TJS are unified TJS belonging to a group of products with common structure and (or) technological properties. This TJ is widely used in small scale and serial production and is used in less large scale production.

According to the txyat classification, each of the TJS under consideration may be a prospective or online worker. A promising process is such a technological process that it is the complete or partial implementation of modern achievements of Science and technology into the methods and equipment used in the enterprise.

Working TJ is a technological process that is performed according to the working technological and (or) project documentation. Working TJS are developed at enterprises to produce a wide variety of products. Working TJ can be promising, standard and temporary. Promising TJ-is performed in the initial design of technological documents. The standard is carried out on the Xol, which is compiled by the TJ-standard (TST, TJS) and is associated with an orderly processing and a planned technological process, which is performed on certain equipment.

Temporary TJ-this applies to the absence of the necessary equipment at the enterprise for a limited period of time or until the replacement of worn-out jixozes with more modern and more economical equipment .The basis for the development of TP bqlib typically uses existing standard or common TJS, while in the absence of them a single TJ is applied available to produce similar products.

technology is a Greek word,techne means art, skill, mastery and logos - doctrine, knowledge; Technology-a set of methods for processing, preparing, changing the state, properties and shape of raw materials, materials or semi-finished products in the production process.

The technological process (TJ) is part of the production process, which involves scientifically based actions aimed at obtaining a finished product. Consists of technological stages.

The technological stage is a set of technological operations that lead to the production of an intermediate - semi-finished product (at the final stage of the finished product), which has its own qualitative characteristics.

Technological operation is part of the technological process associated with the maintenance of a type of equipment.

Technological regulation (TR) is a document that defines production methods, technological standards, technical means, conditions and procedures for TJ, provides the production of a standard drug, and also determines the procedure for achieving the safety and goals of the work, which is the main technological MX that will complete the indicators of optimal technical and economic production.

Chemical scheme of production.

This section is compiled for industrial enterprises associated with chemical reactions in the production of drugs, which is a technological process, which gives the sequence of chemical reactions and chemical changes as a scheme with formulas. Chemical formulas of substances that do not dissociate during the production process are given in square brackets. With chemical reactions, it is recommended to describe the sequence of change of substances with vertical and horizontal linear axes between formulas (depending on the location of the circuit).

At the top of the linear axis (or on the left side of it) are the chemical formulas of the substances included in the reaction, the conditions for the chemical reaction to occur under the linear axis (or on the right side of it) are indicated by the sign. (in square brackets, the determination of the catalyst, temperature, pressure, pH value of the medium, etc.) and in percentage terms, the practical and theoretical output of substances is given. Under the structural chemical formula, the name of the product and its relative molecular weight are indicated.

Technological scheme of production.

The technological scheme of production should clearly (in the form of a graphic scheme) clearly indicate in the scheme the stages of the technological process and their division into different operations the sequence of works in obtaining the manufactured mausoleum, which should indicate the main material objects (introduction of raw materials, chemicals, obtaining intermediate products in production) and the places of The technological operation was described separately, indicating that it belongs to a certain stage

Each step and operation should be characterized by a name consisting of a character and a serial number, and an index denoting them. The numbering of stages is carried out according to the procedure for their implementation during the technological process, from the reception and preparation of raw materials to the shipment of finished products.

Drawing of the technological process in pharmaceutical development

If auxiliary work for one stage of the main technological process (smelting and drying of raw materials, preparation of solutions of a given concentration, etc.) is carried out on separate equipment, such auxiliary work enters the stage of this main technological process. Auxiliary work performed on separate equipment for several stages of one production or several productions is brought into stages in an independent technological scheme (for example, the preparation of demineralized water, the preparation of solutions of acids or alkalis of a certain concentration for the entire workshop, etc.). .

If waste processing or their disinfection is carried out as independent work, they may not be included in the technological scheme of production. In this case, the technological scheme indicates the place taken for waste processing (decontamination) with a linear Arrow (Arrow).

Hardware scheme of production and specification of equipment.

The drawing of the hardware scheme of production should clearly indicate all technological equipment, including auxiliary equipment (storage-collectors, measuring equipment, heat exchangers and handle apparatus, containers used in non-standard cases, pumps, compressors, Special Vehicles, etc.).

The equipment used in the productions of several enterprises is not specified in the hardware scheme. (E.g.: storage tanks of a workshop or pharmaceutical plant, centrally stages for the production of inert gas, hydrogen, oxygen, etc.). In this case, the place where raw materials, compressed air, nitrogen, etc. came to the drawing is recorded with a drawing arrow.

In technological processes where a large number of tools and measuring instruments are used, a drawing of a hardware scheme can be drawn up for each stage separately, without disrupting indexing.

Equipment and measuring instruments must be described and numbered in a drawing in a sequence that reflects the course of the technological process.

When combined circuits are used, nodes based on the numbering are allowed. The symbols of equipment and measuring instruments must comply with the standards of the unified system of design documentation (TXYAT). In the absence of a standard symbolic graphic designation of the equipment, if possible, a free designation of the design features of the product based on it is applied.

The hardware circuit drawing of production should indicate the pipes necessary for the correct and safe conduct of the technological process, as well as other types of pipes, equipment and safety devices, the amendments to which should be formalized as changes to the regulation. Places for the supply of steam, compressed air to the device, etc., are marked with conditional signs.

Control-measuring instruments and automation systems are displayed on all apparatus and pipes. Sampling points must also be specified for analysis in order to ensure control and control of the technological process. In graphical representations of hardware circuits, the pulse lines must display the working values of the measured parameters of the instruments.

The signs and dimensions of the graphic images of the devices must comply with the requirements of GOST 21.404-85. In the drawing, it is allowed to display the indicated equipment and devices above the main inscription in the form of a table.

Table 1.

Mark	Designation	Quantity	Note
1	2	3	4

Technical inspection of equipment specification 2 is presented in Table

Table 2.

Mark	Designation	Unit quantity	Working material	Zone	Technical description	Note number
1	2	3	4		5	6

Column 1 shows the state of the equipment or device according to the hardware scheme.

Column 2 lists the name of the equipment corresponding to the current regulatory document rsatilgan.To ' the single case for installations such as rectification, molecular distillation, vacuum evaporation, water desalination, granule drying, etc, followed by a list of the names of the components included in this installation.

Column 4 shows the working area of the equipment and the material of the measuring instrument (sensor), that is, the components of equipment and measuring instruments that are in direct contact with substances, reaction masses or products that are released during the production process.If corrosion protection is used in the workplace, a brief description of this protection will be given.

Column 5 shows: for standard equipment and measuring instruments - the type, brand or code of regulatory documents is determined; for non - standard equipment - the drawing number, the name of the organization that developed and produced the equipment; imported-brand, code, name of the company and the country of the supplier. Next, a brief technical description of the equipment and measuring instruments is given, indicating the availability of certificates for them and indicating the device of electric motors in terms of explosion protection.

For a separate group of equipment and measuring instruments, it is recommended to provide the following information:

- 1) storage-for collectors and measuring containers - type (structural features), capacity, method of receiving the product (filling, vacuum filling, pump, etc.), method of transferring the product to another apparatus (with gravity descent, compression, compressed gas, etc.); if the containers are working under pressure, working pressure is indicated; the type of viewing or measuring device is quoted. If, instead of a mernik, an automatic device installed directly on the pipeline is used to measure the fluids that pour into the device, then in the classification of such a device, performance and overall dimensions are given;
- 2) for autoclaves, reactors, dividing apparatus - heating or cooling method, mixer type and frequency, indicating the type (structure specificity) of the reactor, working pressure, working capacity (for continuous devices), heat exchange surface or temperature measurement method;
- 3) for heat exchangers (heaters and refrigerators) - type of structure (Serpentine, tubular, "pipe in the pipe", etc.), heat exchanging surface;
- 4) for filtration equipment - filter construction, filtration material, filtration surface area, maximum mass (volume) of filtered product, processing power for continuous filters;

- 5) for distillation columns - the height, diameter, number and shape of lycopchalap for structure type (vessel, packed, Rotary, etc., continuous or continuous operation), lycopchalap for lycopchali columns(column); diameter, height for film columns (column), film forming method, heat exchange surface, heating and cooling method with indicating working pressure;
 - 6) for dryers - construction type (chamber, vacuum, liquid layer, etc.), heating method and heating surface area, loading and unloading method, gabarite dimensions;
 - 7) for grinding equipment-construction, operation, loading and unloading method, gabarite dimensions; device to prevent dust;
 - 8) for auxiliary standard equipment - compressors, blowers, pumps for weighing products, vacuum pumps, cooling equipment - type (building characteristics), pressure;
 - 9) ready-made forms of medicinal product-for equipment used in the manufacture of tablets, dragees, ampoules, etc., as well as for filling and packaging of products - type, brand, capacity;
 - 10) control-for measuring and control instruments-type (regulation type), measurement range, accuracy class, instrument characteristics and its performance;
- Note for serial control and measuring instruments repeatedly applied in this production, diagrams for serial control and measuring instruments are allowed to provide a separate specification showing their markings without numbering these devices.
- 11) for transport devices-construction, operation;
 - 12) for electrical and electrified devices and devices installed in blocks of all categories of explosion hazard, it is necessary to additionally specify the version of the product for explosion protection in Column 5;
 - 13) for laboratory measuring instruments used in the process of technological process - type, measurement range, measurement error (precision class), performance characteristics.

Requirements for production (technological) processes

Technological processes in enterprises of pharmaceutical production OST own 19-02-96 " products of the medical and microbiological industry. Technological regulations of production. The procedure for content, development, coordination and approval is carried out taking into account sanitary rules for the organization of technological processes in accordance with the requirements" and hygienic requirements for production equipment, requirements for labor safety standards and other legislative acts on safety equipment.

Temperature, pressure and other parameters of the technological process, as well as the amount of raw materials being loaded, serial numbers, output data and individual comments should be reflected in technological notebooks and operating sheets. In the workplace and the head of the workshop, there should be technological instructions and instructions on safety equipment, fire safety and industrial sanitation.

Requirements for ensuring the safety of employees in case of violation of the technological process

The work of technological apparatus is stopped immediately in the following cases:

- a) on the alarm signal about the accident;
- b) in case of damage to the Hermeticism of equipment and pipes;
- C) in the appearance of a sudden smell or visible amount of harmful production products;
- g) in a fire;
- d) in an accident.

In the workplaces of production rooms, the amount of harmful gases, vapors and dust should not exceed the maximum permissible concentrations.

When working in areas of soldering ampoules, it is forbidden to work on the machine when the gorelka is faulty or the gas trunk is punctured.

Leaving the working gorelka unattended and keeping the quick-firing materials close to the gorelka

The main technological processes in chemical-pharmaceutical enterprises

Occupational damage to primary raw materials crushing, mowing, and disassembly are dust, intensive noise, and general vibration. Powders are observed at the places of unloading primary raw materials, grinding and mowing them, and at the exit of crushed, milled products.

The most inappropriate operation is characterized by the separation of materials into fractions (components). The air separators and mechanical sieves used in it serve as the main source of dust separation. In the manufacture of small - volume medicinal preparations (harmonic preparations) - through a sieve of products, when passing, it is often necessary to rub manually, which in its place causes the separation of dust and contamination of the body skins and special clothing of workers.

To combat dust separation, it is necessary to properly dispose of technological processes and equipment, aspirate pollinated air with the concealment of places where dust is formed. In the mechanisms of crushing and milling of drug raw materials, the level of noise and vibration can exceed the permissible values. Therefore, the placement of these mechanisms in separately allocated production rooms should not be associated with the construction of a fundamental building under the equipment. Among the anti-noise and anti-vibration activities, it is possible to include the installation of noise absorbers and vibration dampers in the rooms. It is advisable to control the mechanisms of grinding and mowing raw materials by distance.

At the preparatory stage, the degree of pollution of the air of production zones is significantly influenced by the process of transportation of primary components. This is due to the fact that the loads on the communications facilities in a large hajm fall, the presence of mechanisms and equipment for transferring raw materials from one place to another, hermetically tightening of the mechanism and equipment and the effective non-functioning of the air absorption mechanisms.

When transporting raw materials in obtaining a drug, workers are not only in contact with steam and gases, but also in contact with liquid and non-woven harmful substances. In some cases, it is necessary to manually increase, unload products (raw materials on plants).

The transfer of liquid substances from one place to another is carried out by means of pumps, air pressure or compressed steam through the pipelines, the flow of liquids and the vacuum solution. Compression and vacuum are used when transporting gaseous substances. Transmission of primary products using compressed air is associated with increased pressure in the communication network, which can cause the separation of harmful vapors and gases due to malfunctions (hermetic non-shutdown) in the transmission tubes, apparatus and storage containers. It should be noted that from a hygienic point of view, the transportation of liquid products using pumps is an additional factor that leads to contamination of the air environment with chemicals. Therefore, transporting liquid products using their own flow or vacuum is the most appropriate method. Among the main hygienic requirements for these processes can be included such as the tightness of the pipes, the resistance to the liquid action of the pads placed

in the connection range of the pipes, the replacement of the swing pumps with non-swing pumps.

The transfer of solid-state drug raw materials from raw materials warehouses to preparatory workshops (plant products, organic and mineral substances), the transfer from one type of warehouse to the second warehouse is carried out through tape transporters, elevators, shnekli and pneumatic and hydraulic systems. Methods for transporting raw materials are determined depending on the aggregate state of the substances, their toxicity, the nature of the enterprise.

Judging by the technological processes in question, the transmission of products through tape transporters and schnecks is associated with the separation of large amounts of dust. Transmission of dry primary products using pneumotransporters is the most improved method.

The process of direct extraction of medicinal substances, obtaining medicinal preparations at this technological stage, is characterized by the fragility of technological processes and operations, the variety of chemicals and chemicals used. In the industrial synthesis of medicinal substances and semi-finished products, nitrolyzation and halogenation, amination and oxidation, recurrence and oxidation reactions are widely used, which involve excitation of hydrogen atoms in the nucleus of aromatic compounds using one or another group of atoms, giving new properties to the changed compound that occurs in the organic compound molecule and changing the carbon content of the.

At the final stage, drug preparations are subjected to drying, grinding or mashing, tablet reduction, ampouling and packing in containers.

Preparatory operations. Most of the primary raw materials used to obtain Galenic and synthetic medicinal preparations are solid, and therefore the raw materials are ground and milled. The necessity of this operation is that from them it is necessary to take mainly drug forms (Tablets, dragees, etc.k.) technology. Grinding raw materials; is carried out in flat, roller, conical, hammered and other grinding mechanisms. And milling is done with the help of spherical and clove grinders, Disintegrators. Medicinal products in small khajm are milled using mechanisms such as mechanical kayaks, Islamqulov mill, "Exselsyor".

Occupational damage to primary raw materials crushing, mowing and disassembling components is characterized by dust, intensive noise and general vibration. Powders are observed at the places of unloading primary raw materials, grinding and mowing them, and at the exit of ground milled products.

Reactors can operate under conditions of increased, normal, or thinned atmospheric pressures. They feature intermittent and continuous operation. These reactors are steel, cast-iron, or lead vessels, and are equipped with special mixers, heaters, or refrigerators. Depending on the processes that go in the reactor, it is possible to apply different types of mixers: parracl, vincimon, Rhombus, anchor, etc.chemicals in the K reactor compartment are the main harmful factor. The separation sites of toxic substances that are excreted from reactors can be stirrer's salnics, reactor product injection and release holes, measurement player, observation mirrors, flange Fusion sites. In this case, the composition and level of harmful substances contained in the air of the good zone depends on the refinement of the hostels being used, the type of ready-made drug preparations or semi-products to be taken, the procedure for using the tools and other factors. The origin of inappropriate hygienic situations will depend on manual operations, for example, measuring the amount of fluid in the reactor, transferring apparatus such as sampling to a vacuum process, applying a closed reactor with shielded mixer engines, as well

as using methods for automatic control of their work will significantly reduce harmful substances released into the air of the working zone in.

At this stage, the process of separation of chemical components takes up a large working charge. The main equipment for conducting such operations is provided by haidash apparatus and retrieval devices. The maintenance of these chemicals is associated with the possible connection of workers with harmful chemicals, since through communication systems, caps, faucets, sampling sites, chemical separation and air permeability can occur.

Filtration and centrifugation processes are widely used to divide suspensions into solid and liquid phases. Filtering is carried out in filters that periodically work or work continuously. Intermittent filters include notch filters, filter presses, listed filters, and continuous-acting filters include drum, disc, and tape filters. In the operation of notch filters and filter-presses, there is often a state of release of toxic substances into the air of the working zone, this is due to the fact that the application of hand cocktails and hands, special clothes can be seriously contaminated with chemicals. From a hygienic point of view, drum filters are most suitable, since they have hermetic compaction and are provided with air pushers.

Centrifuges that work periodically or continuously are used to quickly separate medicinal semi-finished products. Intermittent centrifuges are poorly refined and have a number of disadvantages, the main of which are the inconvenience of distancing materials from which the liquid is squeezed, the use of hand cocktails, the lack of reliable Hermeticism is noted. These deficiencies are responsible for the separation of harmful chemicals into the air of the working zone and the contamination of the body's skin.

Mechanized and closed filters, filters that self-pump and release products into the centrifuge, drum-vacuum filters and automatic filter-presses are reliably qualified.

The bulk of semi-products and ready-made medicines are subjected to drying. This process involves the use of Galenic, synthetic drugs, antibiotics, vitamins, etc. it is necessary to take. The moisture contained in the product is removed mechanically (filtration, pressing, centrifugation), physicochemically (absorption into hygroscopic materials) and using heat (evaporation, condensation) methods.

In the production of medicinal preparations, chamber, drum, pollinator, shaft and other dryers are widely used. Many go to the drywall with a high level of heat and the release of toxic substances directly in the workplaces on the service ceiling.

The main disadvantage of dryers is the insufficient mechanization and the failure to ensure the Hermeticism of the processes of application of substances to them, as well as release. As a result, pollution of the air of the working zone with finished product dust is observed. In the use of continuous working dryers, the air of the working zone is polluted to a lesser extent by harmful substances (such as OARs, pollinators, drying drums), since the processes of laying and releasing products in these mechanisms have complete germetization and mechanization.

Vaporization and curing (crystallization) processes are common in the production of drug preparations. The steaming process is used to obtain solutions of higher concentrations (such as synthetic and Galenic preparations, antibiotics) from less concentrated solutions. Multi-hull steaming machines are used for this purpose. In terms of hygiene, when working with these mechanisms, the process of transferring solutions to the apparatus and releasing finished products is assessed as Inappropriate, operations, since these processes are carried out with the separation of harmful compounds into the air of the working zone.

The crystallization process is used when separating medicinal substances from various mixtures or their liquids. These processes are performed in crystallizers of an open or closed series. Their main disadvantage is the insufficient supply of Hermeticism in these equipment and the complete, mechanized nature of the processes of introduction and release of medicinal substances. In the service of vacuum-crystallizers, the most appropriate sanitary conditions are created in the workplace.

Obtaining ready - made drug forms in the form of tablets, dragees, ampoules is made up of a lot of preparation and basic processes and operations, and accordingly-in the case of smokers, work of a certain order and sequence is carried out.

Final operations. At the final stage of the technological process, medicinal substances are sent for pouring, placing in containers and packaging. The drug forms are placed in plastic, paper and glass containers, a lot of operations at this stage are mechanized. At the same time, hand cocktails in some enterprises still remain.

At this stage of the production of drug preparations, drug dust can be included among the main incompatible factor from the point of view of hygiene. Workers are exposed to dust with a complex composition, since several types of drug preparations are packaged and placed in containers at the same time. In semi-mechanized work and especially in the packaging and manual placement of tablets, ampoules, dragees in containers, as well as the gluing of paper corobs with convalescent clay cellophanes and a number of other operations are associated with the obligatory state of the body.

Lecture 3. Documents. Internal and external documents. State standards and enterprise standards. Regulations and their types. Drawing up regulations.

Plan

1. Documents. Internal and external documents.
2. State standards and enterprise standards.
3. Regulations and their types.
4. Drawing up regulations.

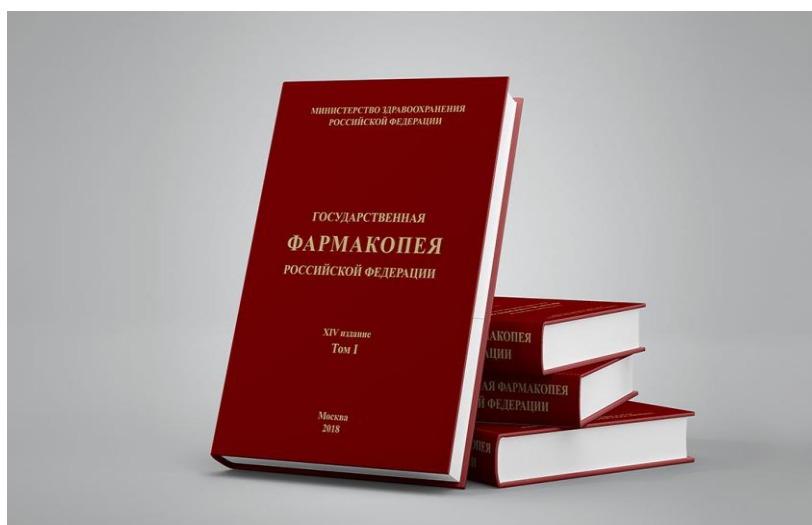
Base words and phrases: pharmaceutical activities, pharmacological agents, medical equipment, medical supplies, poor-quality medicine and medical item, prescription, medicinal plant raw materials.

The allotted time is - 2 hours.

The state Pharmacopoeia is an official publication with a set of documents that include requirements for medicines and medical items, General Pharmacopoeia articles, Pharmacopoeia articles, methods for controlling the quality of medicines and medical items.

Pharmacopoeia (yun. pharmakon-drug and poieo — I prepare)-a set of state standards that determine the preparation, quality quantitative control, storage conditions and naming of medicines. The pharmacopoeia highlights the methods of qualitative and quantitative analysis of drug substances and drug types in chemical, physical, biological and other ways, a list of toxic and strongly affecting drugs, a single intake of drugs for children and adults, as well as a

table of their daily amounts. The "Minibelu", issued in China in 502, is the first official Pharmacopoeia documents of the "Antidotory" collections published in Europe in 1130. The first Pharmacopoeia was printed in Florence in 1498 as "Ricettario Fiopentino". Abu Ali Ibn Sina's "laws of Tib" can be judged as a pharmacopoeia of his time with his information on the preparation, quality assessment and application of medicines used during his lifetime. Today, there are national and territorial pharmacopoeia of most countries, of which Yey.R. Such as (community Pharmacopoeia in Europe), LJSP (U.S. Pharmacopoeia), VR (British Pharmacopoeia), GF XI (11th edition of the state Pharmacopoeia), DP (German Pharmacopoeia) are internationally recognized pharmacopoeia, and in most cases quality control of drugs is based on the above.



According to the order of the Ministry of Health No. 227 of August 28, 2020, the first edition, the first volume of the state pharmacopoeia of the Republic of Uzbekistan was approved.



The quality of drugs is examined in accordance with the established procedure and assessed by compliance with the requirements of approved standards, and it is carried out in a complex of sequences of processes for the creation, production organization, storage, transportation and application of drugs in the prescribed way.

According to the World Health Organization, a total of 56 National, 4 territorial and international pharmacopoeias are recorded today. The structure of existing pharmacopoeias is

distinguished by the extent to which the articles covered in them are widely expressed, the requirements for standards, the degree of established norms are different.

The basis for the publication of the state pharmacopoeia of the Republic of Uzbekistan is reflected in the law of the Republic of Uzbekistan “on medicines and pharmaceutical activities”(No. 399 of January 5, 2016), which states in Article 8 “the state Pharmacopoeia is the official publication of the Republic of Uzbekistan with a set of documents containing requirements for medicines and medical products, general Pharmacopoeia articles, Pharmacopoeia articles.

According to the decree of the president of the Republic of Uzbekistan dated April 10, 2019 “on measures for the further rapid development of the Republican pharmaceutical network in 2019-2021”PF-5707, the task of developing and approving the state pharmacopoeia of the Republic of Uzbekistan by September 2020 is established. In order to ensure the implementation of this task, the pharmaceutical network development agency signed Order No. 24 “on the organization of work on the development and preparation of the state pharmacopoeia of the Republic of Uzbekistan for publication (reprint)”from July 17, 2019, and a number of current activities are carried out on the implementation of the order.

The European Pharmacopoeia is a territorial Pharmacopoeia that maximally concentrates in itself the methods of quality control of modern medicines and medical products. The European Pharmacopoeia is accepted today in 38 countries, including the countries of the European community, in addition, its main Monographs are used in more than 100 countries.

The Pharmacopeial Discussion Group (PDG), a pharmacopoeia discussion group, has been established by the World Health Organization and is tasked with harmonizing European, U.S., and Japanese pharmacopoeias. This is primarily to use the European Pharmacopoeia as the main source for the development of the state pharmacopoeia of the Republic of Uzbekistan, which in many ways means that the pharmacopoeia of our state is also coordinated with the pharmacopoeia of the United States and Japan.

Taking into account the international modern requirements for the quality of pharmaceutical products, the pharmaceutical network development agency “medicines, according to the bilateral agreement signed on March 20, 2019 between the Dok and the European Union Directorate for the quality of medicines and medical care (EDQM)” State Center for medical products and medical equipment examination and standardization", its texts were harmonized with the 8th-10th editions of the European Pharmacopoeia as the main source for the development and publication of the state pharmacopoeia of the Republic of Uzbekistan.

In order to improve the methods of quality control of medicines and medical products, taking into account the globalization processes taking place internationally in the field of pharmaceuticals, to facilitate the export of domestic pharmaceuticals to foreign markets, the texts of the main monographs included in the state pharmacopoeia and included in the future were also recognized at a number of international levels, – the emphasis is on further harmonisation with international Pharmacopoeia, U.S. Pharmacopoeia (USP), British Pharmacopoeia (BP), Japanese Pharmacopoeia (JP), Russian Pharmacopoeia (GF RF),

Belarusian Pharmacopoeia (GF RB), Kazakh Pharmacopoeia (GF RK), Ukrainian Pharmacopoeia (DFU), etc.

The first volume, the first volume of the state pharmacopoeia of the Republic of Uzbekistan is made up of 5 chapters, 40 sections and texts of monographs developed in the Uzbek language and, accordingly, in the Russian language, about 1200 pages.

In pharmaceutical industrial production, cells serve two main functions:

- 1) control of the production and quality of finished products set the requirements
- 2) indicates to what extent the work done was done.

In the first case, it fully covers the production chain by specifying what, when and how to carry out products, methods for checking the quality of primary raw materials and finished products, and so on.

There are the following types of regulatory documents that determine the demand for the quality of medicines:

State Pharmacopoeia-DF (GF).

General Pharmacopoeia article-UFM (OFS).

Provisional Pharmacopoeia article-VFM (VFS).

Pharmacopoeia article-FM (FS).

Network standard-TS (OS

Regulations

Provisional Pharmacopoeia article (VFM) - compiled for the initial range of new drugs and medicinal plant raw materials produced on a large scale, approved by the pharmacopoeia committee of the General Directorate of OERSSVDVTTSNA-is a state Quality Standard. The validity period is 3 years, after which VFM is revised and registered as FM.

Enterprise Pharmacopoeia article, KFM (FSP) is a quality standard approved by the pharmacopoeia committee, consisting of methods and indicators for monitoring the quality of a drug, taking into account the technology of some enterprise and the exact composition of the drug.

The general Pharmacopoeia article defines the general requirements for the quality of medicines, medical products, medicinal plant raw materials, methods of their quality control, standard samples used in the quality control of medicines, reagents, packaging materials used in the manufacture of medicines.

The pharmacopoeia article defines the requirements for the quality of a particular drug, medical item, medicinal plant raw materials, auxiliary substance.

The development of general Pharmacopoeia articles, Pharmacopoeia articles and their inclusion in the state Pharmacopoeia are carried out in the manner prescribed by the pharmacopoeia committee. The pharmacopoeia committee is the official expert body of the Ministry of health of the Republic of Uzbekistan.

The state Pharmacopoeia is published by the Ministry of health of the Republic of Uzbekistan at least once every five years. In the period between the reprints of the state Pharmacopoeia, applications to the state Pharmacopoeia are published

A general Pharmacopoeia article is a state quality standard that contains the basic requirements for the form of a drug or describes the standard methods of control. Includes the following: the quality for medicines consists of the requirements for indicators, inspection

methods, chemical, physical, physico –chemical, biological, biochemical, microbiological methods of laying drugs, titrated solutions used in chemical laying, reagents, indicators.

The pharmacopoeia article (FM) is the state quality standard for large - scale manufactured drugs approved by the pharmacopoeia committee of the General Directorate of ozr SSVDVTTsNA. The pharmacopoeia article has a validity period of 5 years, after which the pharmacopoeia article is revised to extend its validity to the next term. Pharmacopoeia is the sum of state standards that determine the qualitative preparation, quality and quantitative control of drugs, indicate the naming and storage conditions.

The state Pharmacopoeia is a set of data on Pharmacopoeia articles, general physical-chemical, chemical and biological methods of analysis, general requirements and regulatory documents for Applied reagents, titrated solutions, indicators and medicines, a document of legal status.

Regulation(limitation) is the Basic Laws of the production of drugs, which is divided into the following types:

1. Laboratory regulation (LR;
2. Experimental industrial regulation (TSR;
3. Industrial regulations (SR;

LR-includes the safety of methods, conditions and equipment for the preparation of the product, ensuring the stagnation of technological processes of production in laboratory conditions.

Experimental-industrial regulation-the drug is developed into a new product at the same time as the pharmacopoeia article, for the purpose of preparing experimental samples of a new type of product and entering the initial data when designing a new industrial production.

Industrial regulation is a document in the serial production of medicines containing the stages of the process, tasks to be performed, requirements for equipment, methods of quality control, in which each technological process is described in detail.

Standard, this is a normative document approved by the recognized office, developed on the basis of the consent of the majority of interested parties and established for the purpose of general and multiple use of rules, general principles, descriptions, requirements and methods related to various types of activities aimed at the dissolution of regulation in a particular area to a moderate level.

State standards of the Republic of Uzbekistan (Qz Dst) – defined for popular products, are obliged to be used on the territory of the Republic of Uzbekistan, that is, by state management agencies, economic entities.

Network standards are mandatory for all enterprises of this industry, as well as enterprises using industry products and organizations belonging to other industries.

Enterprise standard-prepared and accepted by the enterprise. It is a document that reflects the specifics of the process of production of goods, and in itself embodies the requirements for its quality.

Technical conditions-a document that defines the technical requirements approved by a specialist on specific products.

The State Register of medicines and medical products is an official document consisting of a list of medicines and medical products allowed for use in medical practice

Documents form an integral part of the quality assurance system. Clearly written documents prevent errors that arise in oral circulation

and makes it possible to track the history of the series. In order to avoid errors in specifications, production receptors and instructions, styles and statements, it is necessary that they are available in written form. The accuracy of the documents is important.

General requirements

In the specifications, the requirements are expressed in detail, these requirements must comply with the raw materials and materials used during production or the products to be obtained. They serve as the basis for quality assessment.

Production receptors, technological instructions, enclosing instructions store in themselves information about all the raw materials used and define all technological processes and enclosing processes.

Instructions (standard technological processes) provide guidance for performing certain processes, such as: cleaning, wearing work clothes, environmental control, sample selection, testing, equipment use,.

On the basis of statements, the product is confirmed by the history of each series, including its distribution, as well as all other circumstances that depend on the quality of the finished product.

Documents must be carefully developed, prepared, revised and distributed in accordance with this standard.

Documents must be approved, signed and dated by persons with approval authority. The content of documents must be unambiguous; their name, type and purpose must be clearly indicated. Documents should be placed in order to be light to transfer their control. A copy of the documents should be clear and understandable. When copying from the original of work documents, no errors that occur during the copying process should be allowed.

It is necessary to regularly revise the documents and ensure compliance with modern requirements. If the document is revised, then measures must have been taken to eliminate the error application of documents that have lost their power.

Documents should not be in a manuscript state, so that if it is envisaged to include information in documents, for example, in a manuscript, then the notes written by the manuscript should be clear and clear, in such a way that it is impossible to delete them. For such records, there should be enough space on the blanks.

Any changes to the document, confirmed by the signature

and the date must be set; the change must allow the primary information to be read. If necessary, a statement is drawn up about the reason for the change. In the course of each act carried out, it is necessary to draw up statements, collect them, and through this, it is possible to observe important activities related to the production of drugs. They should be stored for at least a year after the expiration of the shelf life of the finished product. Data recording can be done using electronic data processing systems, photography, or other reliable tools. This requires a detailed guide to the application of the system used, while checking the accuracy of the records. If documentation is carried out using data processing electronic systems, then only a person authorized to do so can enter data into a computer or change them; changing the information or deleting it must be recorded using statements; access to the information base must be protected by password or other means. The results of entering significant data should

be under independent control. Serial statements must be protected by electronic memory storage, paper copying, or another way of storing information. It is very important to ensure that the use of information during storage is light.

Required documents.

Specifications. It is necessary that there are specifications for raw materials, enclosing materials and finished products, and, if necessary, for intermediate and unpackaged products, which are allowed (approved) and dated in the appropriate way.

Specifications of raw materials and enclosing materials

Specifications of raw materials and primary and/or enclosing materials should include the following:

a) description of raw materials and materials:

- naming and / or internal code;
- instruction to the pharmacopoeia article, or to another regulatory document, in its presence;
- approved suppliers and, if possible, the name of the manufacturer of the product;
- sample of printed materials;

b) reference to instructions or methods for sample selection and testing;

C) qualitative and quantitative analysis, showing the allowed limits (deviations) of pointers;

g) storage conditions and precautions;

d) shelf life or maximum storage time up to repeated control.

Intermediate and unpackaged product specifications

If an intermediate and unpackaged product is purchased or sold, or foaled to evaluate the finished product from the information about intermediate products, intermediate and unpackaged product specifications must be available.

These specifications should be similar to the specifications of raw materials or finished products respectively.

Finished product specifications

The finished product specifications should express the following:

a) the name and code of the drug, if it is possible to use);

b) content or link to the document;

C) description of the form of the drug, as well as detailed information about its packaging and labeling;

g) reference to instructions or techniques for sample selection and testing;

d) requirements established for qualitative and quantitative analysis, indicating the permissible limits;

e) any special precautions in terms of storage conditions and in circulation when necessary;

C) shelf life.

Production receptor and technological instructions

It is necessary to have an officially approved production receptor and technological instructions for each production preparation and each series. It is allowed to combine the production receptor and technological instructions into one document. The production receptor will consist of:

a) reference to the product name and its code in accordance with the product specification;

b) description of the form of the drug, the dosage of the drug and the amount of the series;

C) with the registration of all used raw materials and the amount of each; as well as the name of any substance that may be lost during the technological process must be cited;
g) information about the expected output of finished products, with the allowed limits indicated and where possible, the corresponding intermediate products output is provided.

Technological instructions should include:

- a) information about the place of conduct of the process and the main equipment used;
- b) references to methods and methods used to prepare the most necessary equipment for work (e.g. cleaning, Assembly, calibration, sterilization;
- C) technological instructions that describe each action in detail (for example, inspection of raw materials, preliminary processing, procedure for loading raw materials, mixing time, temperature);
- g) any control instructions in the production process, with limit values indicated;
- d) requirements for the storage of unpackaged products, tara, labeling if necessary and including special storage conditions (if required);
- e) all special precautions that must be followed.

Wrapping instructions

For each drug, type and amount of packaging, there must be officially approved instructions for packaging. Typically, they should include the following information or links to them:

- a) the name of the drug;
- b) its drug form and dosage, if necessary;
- C) the amount of the drug indicated in the final packaging in pieces, mass or volume;
- g) A complete list of all enclosing materials, showing the code or number applicable to each enclosing material specifications, quantity, dimensions and the types are listed;
- d) if necessary, sample or copy of appropriate wrapping printing materials and samples of the product with the serial number and place of application of the shelf life;
- e) to ensure the cleanliness of the line before starting work, the areas are and instructions for a thorough inspection of equipment and special precautions that must be followed;
- j) description of the winding process, along with all the main auxiliary processes and the equipment used;
- z) a detailed description of the control in the production process, along with sample selection instructions and permissible limit values.

Series production minutes

To each manufactured product series, the production statements of the series must be kept. They are a proven production receptor and should be based on the relevant parts of the technological instructions.

The procedure for preparing these statements should be such that there are no errors in copying. The statement must indicate the serial number produced.

Before starting any technological process, the equipment and work area, the previous product, documents that are not required for the planned process

and it is necessary to check that the material has been emptied and the equipment is clean and ready for use, and draw up a statement.

When the technological process is going, during each executable action, information about it will have to be recorded in the minutes; after the completion of the processes, the statement will be agreed upon by the person responsible for the technological process, the date will be set and it must be signed and contain the following information:

- a) product name;
- b) the start and end date and time of the technological process, as well as the main, intermediate processes;
- c) surname of the person responsible for each stage of the technological process;
- g) the surname of the operator in various important stages of the technological process, the person who, if necessary, checked each of these processes (for example, determining the severity) ;
- d) the serial number of each raw material and/or the number of analysis control, as well as the amount actually weighed on the scales, (including the amount added and serial number of each raw material regenerated or processed);
- e) any technological process or situations that depend on the work, as well as information about the important equipment used;
- j) control statements in the production process and the surnames of the person (s) who performed them, as well as the results obtained;
- z) product output at different stages of production;
- i) detailed information about specific problems; production receptors and a signed permit allowing any deviations from technological directives.

Series wrap-around minutes

To a part of each produced series or series, a series wrapping statement must be kept. It should be based on the relevant parts of the enclosing instructions, and the method of preparing these statements should provide an opportunity to prevent errors from being made during copying. In the statement, the serial number of the Unpacked product, which must be wrapped and the amount, as well as the serial number of the finished product to be obtained and the planned amount should be indicated.

Before starting any technological process for wrapping, the equipment and it is necessary to check the work area, the release of previous products, documents and materials that are not required for the planned process, and the cleanliness of the equipment, as well as its readiness for use, and draw up a statement.

During each act performed, the information about him shall be drawn up in the manner of a statement; after the completion of the processes, the statement shall be agreed upon, the date shall be laid and signed by the person responsible for the encapsulation, and it shall contain the following information:

- a) product name;
- b) the date and time of the enclosing processes;
- c) surname of the person responsible for carrying out the enclosing process;
- g) surnames of operators of various milestones;
- d) it is precisely these specifics and statements of verification of compliance with the enclosing instructions, including the results of production control;

- e) detailed information on the equipment used and the operations performed on the enclosures, with instructions to the enclosures lines;
- j) if possible, samples of the printed wrapping materials used, along with samples indicating the serial number, shelf life, and other additional printing records to be placed;
- z) detailed information about certain problems or unusual situations; any deviations from the production receptor and enclosing instructions are allowed, signed permission;
- i) a reference to the number and quantity of all printed wrapping materials and unwrapped product issued, used, destroyed or returned to the warehouse, as well as information on the amount of product produced to draw up the appropriate balance sheet.

Style (instructions) and statements

Reception

Each delivered raw materials must have written style (instruction)S and statements to accept primary and printed cutting materials.

Acceptance statements must contain the following information:

- a) the name of the material in the shipping letter and in the comb;
- b) the naming and/or code of the material at the enterprise (if it differs from the naming by item " a;
- C) date of admission;
- g) the name of the supplier and, if possible, the manufacturer;
- d) manufacturer serial number or reference number;
- e) the total amount and number of received Phoram units;
- j) serial number issued upon acceptance;
- i) any comments related to the case (e.g. by the case of the scales).

Inside the enterprise, raw materials, wrapping materials and, if necessary, other written style for labeling, quarantine and storage of materials there must be (routers).

Regulations and their types. Regulation formation

Regulation(regulation) – Being the Basic Laws of production, it will be up to the Department of technical control (OTK-TNB)to monitor compliance with it in the entire technological process. TNB gives a conclusion about the quality of homoshyo,whether it is possible to use the finished product or not.If the industrial regulation directive is being violated during the production process,TNB also has the right to stop production.So; TNB is responsible for ensuring the output of a quality product from the enterprise.Regulation content-the entire production process is divided into separate stages,while each stage consists of certain operations.Each operation is performed at a specific standardized,fixed time interval,which is amalgam-enhanced using specific rules.These regulations will describe the appearance,quality and once-removable quantity of the housing,the processing time and the order,the amount and types of machine tools and tools used,auxiliary substances and the properties of the finished product.

Industrial regulation (TD) – Production is carried out by means of an industrial regulation. The industrial regulation is used not only without a technological document, but also in the design of enterprises that produce drugs from it (if it is being introduced into production for the first time) or in the modification of production. Also, on the basis of the regulation, the following will be determined:

technical and economic normatives, including raw materials and the amount of material consumption;

1. Technical Safety, industrial sanitary hygiene and fire prevention measures;
2. the use of production waste, measures to harm industrial wastewater and hakazo.

Industrial regulations are developed in experimental workshops and industrial enterprises, or by their assignment in network research and verification universities or in the Departments of oily educational institutions. Industrial regulation TST 64-2-72 will be developed according to the procedure “development of industrial regulation of Chemical and pharmaceutical products” and it will consist of 3 stages.

1. Laboratory regulation – this is a technological document, the appearance of the results of scientific work in the production of drugs, completed in laboratory conditions. Based on the laboratory regulation, experimental industrial devices are designed and used. New technology for the production of medicinal products in the yard of these devices will be studied.

2. Industrial experience regulation – this is a technological document, the study of the new technology in which drugs are produced in experimental industrial devices will be completed. This stage serves as the basis for the design of industrial-scale production of a drug product in the manufacturer's laboratory.

3. Commissioning regulation – this is also a technological document, on the basis of which the technology of production of a new drug product is studied and used. The commissioning regulation is drawn up on the basis of the industrial experimental regulation and project documentation and serves to produce this product. Production of galen preparations (tinctures, juices) of the same group or types of ready-made drugs (ampoules, tablets, grease drugs, capsules) usually, a group regulation is also drawn up so that it is released on the same type of instrument.

Regulation approval – Scientific Head of the enterprise who developed the laboratory regulation-the same regulation; the industrial-experimental regulation is approved by the technical head of the enterprise who developed the technological process in industrial experimental devices in agreement with the general authorities of the organization and the industry that design the production of the product on an industrial scale.

Launch regulation project - the technical head of the enterprise, who prepared the technical documentation and provided the production capacity after the agreement with the head of State, confirms.

Industrial regulation - the technical head of the enterprise, which provides production capacity, confirms after agreeing with the head of the department in this area. The regulation of pharmaceutical factories is approved by the Ministry of health of the Republic. The main difference between launch and industrial regulations is that the launch regulation is tested and made appropriate modifications in industrial production equipment of large designed and installed capacity, while the industrial regulation will make production possible.

Commissioning regulation - if the requirements of FM as well as the technical and economic and project indicators of production are fully satisfied, it is transferred to the industrial regulation.

The industrial regulation is an important document, and just as it is not possible to violate the DF and DST (gost) rules, no one has the right to violate it. The implementation of the regulation

is assigned to the technical-Control Department of the enterprise (OTK), which is directly subordinate to the director of the enterprise. Changes and fillings relevant to the regulation are made and reaffirmed as needed.

The main document in controlling the technology and quality of medicines being serialized (in the category) in pharmaceutical production enterprises is the production regulation. This regulation is developed with the cooperation of research institutes of the industry with the manufacturing enterprise. The regulation provides for the requirements for the quality of the drug and is considered to be a legal document, just like FM, VFM and KFM. The fulfillment of the specified requirements is entrusted to the quality control department. The industrial regulation will be developed in stages: 1. Laboratory regulation (production in laboratory conditions). 2. On the basis of experimental – industrial regulations and regulations (production of a drug at the experimental site and assessment of its quality). 3. Development of a new drug substance or drug form according to project documentation based on the experimental-industrial regulation and technical-economic indicators (puskavoy regulation). 4. Industrial regulation. The industrial regulation consists of several parts, including the technical and analytical control conducting part. In this part, the procedure for quality control is clearly defined, that is, the object and means of control, the dimensions that must be controlled, their norms, methods of cleaning and reproducibility. The “production control” section of this Regulation describes the procedure and sequence of the gradual transfer of control. For the analysis of the technological process, a list of sampling points and methods of sample analysis is presented, as well as the dimensions that must be checked. The regulation again illuminates the system of control of raw materials, semi-finished, intermediate products, auxiliary tools and finished products, control of raw materials and auxiliary tools is carried out before production. The most important place in the noted cases is occupied by methods of analytical analysis. In particular, we can see that many modern methods have been used in the analysis of plant products used in India⁷. In the “final (finished) product description” section of the regulation, the properties, type and packaging forms of the product, factors affecting stagnation (light, moisture, oxygen and carbonate anhydride, pressure, RN and x.k.) and b. is explained.

All internal meyor-technical documents are developed and approved by The Specialists of the korkhana. The regulation and KFM are carried out only by a supervisory organization, the examination and approval of which is under the authority of the state.

The main documents used in the production process include:

- - industrial regulations;
- - production record sheets;
- - analytical methods, quality details and other enterprise standards.
- According to the approved industrial regulation, the production process of each drug should be covered in special instructions. These instructions should contain at least the following information:
 - - appearance, name and dosage of the drug form;
 - - the authenticity and quantity of raw materials at all stages of production;
 - - description of technological processes for the production and storage of semi-finished products and ready-made medicines;

- - the theoretical amount of the output of the finished product at different stages of production and the given amount of the product being extracted from reality;
- - description of the methods of wrapping and labeling the drug;
- - a description of the name of the control analyzes and control departments that must be carried out at each stage of production.
- In terms of application, technological regulations are divided into the following types:
 - - Laboratory regulation (LR;
 - - Experimental industrial regulation (TSR;
 - - Commissioning regulation (ITR;
 - - Industrial regulations (SR;
 - - Model industry regulation (NSR).

The procedure for the development, examination, Agreement and approval of any technological regulations must be considered by the responsible person who approves or agrees, who is competent and qualified at the appropriate level.

1. The laboratory regulation is developed by regulations in accordance with the industrial regulation. The laboratory regulation also and just as it consists of sections in the industrial regulation, includes the safety of methods, conditions and techniques for the preparation of the product, ensuring the stagnation of technological processes of production in laboratory conditions. Instead of the Department of technical and economic norms (TIM), it is allowed to include a table with experimental data on technical and economic norms.

2. The experimental-industrial regulation is developed into a new product at the same time as the pharmacopoeia article of the drug and is an integral part of the set of technical documentation

The experimental-industrial regulation is a technological document, according to which tests of a new type of product technology are carried out and experimental-technological work of a new (improved) technology is carried out.

The experimental-industrial regulation normative-technix is used for the purpose of testing the quality indicators included in the documentation, Preparing experimental samples of a new type of product and entering the initial data when designing a new industrial production.

The experimental-industrial regulation or technological process of a new type of product, carried out at enterprises with serial production capacity, must be bilateral, that is, approved by the developer organization and the manufacturing enterprise.

3. The launch regulation is a technological document, according to which the establishment and development of the production of the newly created product on an industrial scale is carried out.

The launch regulation is drawn up on the basis of project documentation and an experimental-industrial regulation. Or to establish the addition of additional capacities to the current production, which will be compiled on the basis of documents and experimental and industrial regulations or when mastering the product produced by another enterprise.

The launch regulation is also approved by the head of the manufacturing enterprise after agreeing with the developer organization on technological processes, with the design organization (in the case of new/reconstructed fields or equipment used) and with the poor expert organization on product standardization requirements.

4. The industrial regulation is a technological document, according to which the product is produced in series.

1. The industrial regulation is drawn up on the basis of changes made to it in the process of mastering production in the start-up regulation and the start-up regulation.
2. The industrial regulation on explosion - prone production under the control of the relevant regulatory authorities-the environmental risk of industry and production, as well as the part of compliance with sanitary and hygienic standards, should also be additionally agreed with these organizations.
3. Industrial regulation TSt 19-02: 2003 " product of the medical and microbiological industry. The procedure for content, creation and approval of production technological regulations"- consists of 14 sections and 28 tables based on the network standard.
4. 1. Description of the final product in the output of production.
5. 2. Chemical scheme of production.
6. 3. Technological scheme of production.
7. 4. Hardware scheme and equipment specifications of production.
8. 5. Description of raw materials, materials and intermediate products.
9. 6. A statement of technological processes.
10. 7. Material balance.
11. 8. Processing and decontamination of production waste.
12. 9. Production control and technological process control.
13. 10. Technical Safety, Fire Safety and production sanitation.
14. 11. Environmental Protection.
15. 12. List of production instructions.
16. 13. Technical and economic norms.
17. 14. Information materials.

The regulation is in turn drawn up by interested persons, employees of the Department, laboratory or technical department. To date, there are laboratory, experimental, industrial and manufacturing regulations.

The laboratory regulation is approved by the head of the laboratory, and the production regulation is approved by the head of the enterprise.

When drawing up a regulation, the equipment of the instrument at the enterprise and local conditions are taken into account. Each enterprise will have a regulation that it has drawn up for each drug, which may not be recognized by another enterprise. Regulation is a mandatory document only for the same enterprise.

Production recording records (Series reports, route charts, writing logs), should contain the following information on all stages of production and control of each series of drugs and indicate that the series is prepared in accordance with industrial regulations and written instructions:

- - name of pharmaceutical manufacturing enterprise;
- - name and dosage of the drug;
- - date of preparation of the series;

- - complete chemical formula of the active substance;
 - - serial number of each ingredient used in the preparation of the drug (or control number of the analysis);
 - - theoretical output quantity of the finished product at different stages of production;
 - - production sequence compiled and signed records, precautions and special measures taken in the preparation of the series;
 - - records of all analyzes and results obtained during the production of the drug;
 - - an example of the labels used in this series;
 - - primary Reagent material serial number;
 - - signature of a specialist who monitors the conduct of technological processes and the date of signing;
1. - quality certificate of compliance of drugs in the series with applicable regulatory documents;
 2. - instruction on the processing or destruction of the series of the drug released to the unfit.
 3. Normative havolas
 4. 1. GOST 12.1.005-88 "general sanitary and hygienic requirements for air in the working zone"
 5. 2. Gost R 50766-95 "clean rooms. Classification. Attestation style. Basic requirements " M.Gosstandart Rossii. 1995.
 6. 3. TST 19-02:2003 "product of the medical and microbiology industry. Production technological regulations. Content, creation, Agreement and approval procedure"
 7. 4. AST 42-505-96. "Natural industrial products. Production technological regulations. Content, creation procedure, agreement, approval"
 8. 5. AST 42-506-96. "Procedure for the development, agreement and approval of a regulatory document for medicines and medicinal plant raw materials".
 9. 6. AST 42-507-96. "The procedure for organizing work on the creation and application of new drugs in the industry. Basic Rules"
 10. 7. Gost 2874-82 " Consumer water. Hygiene requirements and quality control".
 11. 8. AST 42-504-96. "Quality control of medicines in industrial enterprises and organizations. Basic Rules".

Lecture 4. Compilation of a pharmacopoeia article for substance and drug forms.

Plan

- 1 drawing up a pharmacopoeia article for substance.
2. Drawing up a pharmacopoeia article for drug forms.

Base words and phrases: Compilation of Pharmacopoeia articles for medicines, state standards, rules, substance, drug forms

Allocated time - 2 hours.

Rules for drawing up state standards for medicines. Compilation of Pharmacopoeia

articles for substance and drug forms

There are the following types of regulatory documents that determine the demand for the quality of medicines: state Pharmacopoeia - DF (GF). General Pharmacopoeia article-UFM (OFS). Pharmacopoeia article-FM (FS). Provisional Pharmacopoeia article-VFM (VFS). Enterprise Pharmacopoeia article-KFM (FSP). Network standarda - ' GS (OST). Enterprise standard KSt (StP). Management regulatory document (referrer document).

Pharmacopoeia - a set of state standards that determine the quality of medicines, their preparation, quality-quantitative control, storage conditions and naming.

The state Pharmacopoeia is a set of data on Pharmacopoeia articles, general physical-chemical, chemical and biological methods of analysis, general requirements and regulatory documents for Applied reagents, titrated solutions, indicators and medicines, a document of legal status.

Pharmacopoeia committee (FQ)- the official expert body confirming the regulatory documents that determine the requirements for the quality of medicines, medical products and methods of their control.

General Pharmacopoeia article (UFM)- State Quality Standard, which includes the basic requirements poured into the drug or describes the standard methods of control.

Pharmacopoeia article (FM) - regulatory document approved by the pharmacopoeia Committee for the drug. The pharmacopoeia article has a validity period of 5 years, after which the FM is re-viewed and the validity period is extended to the next term.

Provisional Pharmacopoeia article (VFM)- created for the initial range of new drugs and medicinal plant raw materials produced on a large scale, it is a state Quality Standard approved by the pharmacopoeia committee of the General Directorate for quality control of medicines and medical equipment of the Ministry of health of the Republic of Uzbekistan. The provisional Pharmacopoeia article has a validity of 3 years, after which the VFM is re-curable and the FM registered in the style.

Enterprise Pharmacopoeia article, KFM (FSP) - some enterprise taking into account the technology and the exact composition of the drug from methods and indications for monitoring the quality of the drug composed of, Quality approved by the pharmacopoeia committee standard..

Specification of normative document of foreign enterprises (Normativniy dokument-ND) – quality standard for control of the drug developed abroad, approved by the pharmacopoeia committee, consisting of methods and indicators for monitoring the quality of the drug, taking into account the technology of a foreign enterprise and the exact composition of the drug.

Network standards and other regulatory documents - development in the field of refinement, product development, product sales scientific technical terms, general technical documentation and technical norms general rules of development, safety techniques norm and the document in which the requirements are developed.

State standard example (DSN) - approved in the appropriate order, the quality dimensions are the standard sample listed in the pharmacopoeia article.

Working standard example - appropriate quality standard of the drug

(VFM, FM, TS, KFM) is a sample of substation that meets the requirements.

Control regulatory and technical documents should ensure an objective assessment of the quality of pharmaceutical and medical products, good returnability, reliability and accuracy of product quality control methods, competitiveness of the product and expansion of opportunities to enter the foreign pharmaceutical market, they should comply with the high level of requirements poured into the quality of medicines corresponding to the advanced achievements of pharmaceutical science and harmonization of

The examination of the quality control standard of medicines focuses on the scientific and technical level of the project, its compliance with modern requirements for regulatory documents of medicines:

- - compliance of the quality standards of the drug and the packaging for the consumer with the requirement of DF and other standards;
- - the basis of the values of quality standards, the listed indicators and the shelf life;
 - - chemical nomenclature, values of physical units, accuracy and uniformity of the terms cited.

Persons participating in the examination of the regulatory technical document are responsible for the confidentiality of the information received in the process of this work. General Pharmacopoeia articles, provisional Pharmacopoeia articles and Pharmacopoeia articles of the enterprise are approved by the pharmacopoeia Committee, and the state Pharmacopoeia is approved on the side of the Ministry of health of the Republic of Uzbekistan.

Creation, printing and implementation of state standards of medicines "standards of drug quality. The Basic Rules are implemented under the " TST 42-01: 2002 network standard. All quality standards documents of these drugs determine the procedure for the development of documents, their content, rules of formalization, examination, Agreement and general rules of procedure for approval.

Based on this regulatory document, the quality indicators of the pharmacopoeia article are established on the drug form of each drug.

Structure of MH for drug substance (substance)

1. The name of the drug in Latin, state and Russian.
2. Ring is an unpatented name.
3. Chemical name on IYUPAK students.
4. Structure and empirical formulas, as well as molecular mass.
5. The amount of the acting substance. (in percentage or unit of effect).
6. Description.
7. Solubility.
8. Integrity.
9. Melting (decay), hardening or boiling temperature. 10.Density.
- 11.Hyp break indicator.
- 12.Comparative absorption indicator.
- 13.Comparative angle of inclination.
- 14.Clarity of solution.

15. Solution color.
16. Ph medium, acidic or alkaline.
17. Mechanical attachments.
18. Foreign substances (similar compounds).
19. Purity (chlorides, sulfates, etc).
20. Sulfate ash and heavy metals.
21. Mass or water lost when dried. K. By Fisher's method identified.
22. Residual organic solvents (if in the final technological process if used).
23. Pyrogenicity or presence of bacterial endotoxins (LAL-test).
- 24.3 morality.
25. Acting compounds similar to histamine.
26. Microbiological purity (sterility).
27. Quantitative analysis.
28. Packaging.
29. Tagging.
30. Transportation.
31. Preservation.
32. Shelf life.
33. Main pharmacological effects.

*Due to the development of new drug forms, the introduction of modern methods of quality control, the use of new materials for packaging, new sections can be included in this list. Additional: 1,3-8, 18, 20, 21, 26-33 sections are necessary. The introduction of the remaining sections depends on the nature of the drug substance (substantia), the technology of obtaining and the forms of drugs obtained from this substance.

In the development of all types of quality control regulatory documents (Pharmacopoeia articles), the following information is based on:

- ensuring the modern level of quality indicators and control methods of medicines;
- Requirements of the state Pharmacopoeia, pharmacopoeia of foreign countries, pharmaceutical science and industry on the quality of medicines;
- requirements of quality control, packaging and regulatory documents of medicines;
- the quality of drugs identified in laboratory and production enterprises to the data;

The title of the standard gives the naming of the drug. The text must be short, non-reversible, anic-written, and word abbreviations are not allowed. The terms, concepts and processes used should correspond to those adopted by the state pharmacopoeia and other standards.

In some cases it should be found that muxime is introduced into the substance (acid number, soapy number, iodine number, ether number, toxicity, pyrogenicity, bacterial endotoxins, histamine-like acting substances, sterility, etc.).

In the introduction of the standard, the chemical name of the acting substance (for one-component preparations), the Latin, Uzbek, Russian name of the medicinal plant raw materials, the name and family of the plant (for nastoyka and extracts) are indicated.

When the composition of the drug is brought, the mixer of the acting and additional substances is written in the list style, giving an indication of the corresponding MH.

In the "description" section, organoleptic indicators of the appearance of the finished drug are given, and the color of the drug is brought at the end of the sentence.

It is brought to the corresponding regulatory document (indication) on the substance (substance) of the drug, which is part of the drug.

The name of the drug substance (substance) is written in Latin, state language and Russian, and the chemical name based on IUPAC standards is given. In the empirical formula of the drug substance, first carbon, then hydrogen is written in order.

For example: S6N8O6. When the relative molecular mass of a drug substance is less than 400, two rooms are written in accuracy after the whole, one room is written in accuracy after the whole "Appearance" section, information is given about the external appearance of the drug (physical condition, color, smell, taste), the possibility of changing under the influence of air and light during the storage process, hygroscopicity. It is not recommended to determine the smell and taste for toxic and strongly acting drugs. Currently, a reversible spectrophotometric method is also used to determine the degree of whiteness and glare of a drug substance (discoloration).

When the validity of complex-containing preparations is determined, the identifying ingredient is brought in parentheses after the analysis style statement.

In the sections "dry residue", "alcohol mixer", "boiling temperature", "density", "light refractive index", "turning angle", "viscosity", the lower and upper values of these regulatory indicators are indicated in the corresponding units of measurement.

In the "quantification" section, a statement of the method for determining the mixer of the acting substance in the drug is written, indicating their percentage amount or unit of action in milligrams (TB/mg, mkg/mg).

In the "determination of authenticity", 2-3 chemical quality reactions characteristic of the drug substance are brought, as well as ultraviolet and infrared light absorption spectra and other data.

The "solubility" indicates the relative solubility of the drug in water, 95% alcohol, chloroform and ether, and other solvents may be indicated if necessary. When assessing solubility, the terms solubility, which are presented in the state Pharmacopoeia, are used.

The driving, liquefaction and hardening temperature of the drug, as well as the density, the angle of comparative deflection, the index of light refraction, the index of specific light absorption and the physical constants of the head are given in the case of certain sections, and lower and higher values of regulatory indicators are given.

The clarity and discoloration of the solution of the drug substance is analyzed for a certain concentration of the solution, and for colored and muddy solutions, the degree of turbidity or the number of degrees of coloring, or the light absorption spectra of these solutions, is given.

When the acidity or alkalinity of a solution of a drug substance is determined using indicators, the Potentiometric method of the solution is measured using solutions of acid or alkalis at a concentration of 0.01 mol/L to 0.1 mol/L.

The section "detection of foreign private mixtures" should specify the normative Etalons or other modern methods, such as chromatographic, in which the compounds formed during the process of conservation of a technological mixture or substance can be allowed. If

the chromatographic method is used for this purpose, the sorbent type, the excitable phase composition, the amount of chromatographic Examiner substance and the standard sample (witness), the time of chromatography, the type of opener reagent and all the conditions that determine the process are brought.

The "organic solvent residue" section is injected into the MH if toxic solvents are used in the drug preparation technology or if an organic solvent is used at the final stage of obtaining the drug substance.

In the sections "chlorides", "sulfates" and others, the permissible regulatory limits of these mixtures are indicated.

In the sections "reduced mass when dried" and "water", the drawer of the drug substance, the norm of drying conditions or the amount of moisture and K. In the case of Fisher, the titration method is shown.

In the section "sulfate ash and heavy metals", quantitative norms of the drug substance drawer, sulfate ash and heavy metals are presented.

The "arsenic" section specifies the allowable mycorrhial intervals of arsenic in the case of a foreign mixture, or the requirement that it not be contained in a medicinal substance.

The sections "toxicity", "pyrogenicity", "substances with histamine action" indicate the type of animal experimented with, the test dose, the method of sending the substance to the animal and the duration of the experiment.

The "sterility" section is introduced if sterilization of certain drug forms is required.

In the section "microbiological purity", methods for detecting microorganisms and their permissible quantitative limits are indicated.

In the "quantification" section, the method of quantitative analysis of the main substance in the drug is presented and the unit of action of its percentage mictor or activity in milligrams is indicated.

In the "packaging" section, the initial packaging (jar, ampoule, vial, package, etc.) with the indication of a regulatory document is indicated.), information about the amount of the product in the primary packaging, the secondary packaging (with the indication of the regulatory document, the primary packaging mixer and hermetic routes, etc.) are provided. When the carriage packaging (tara) is displayed, a reference is given to the relevant regulatory document. The packaging must ensure the preservation of the drug during the specified shelf life.

The regulatory document on graphic equipment of medicines of the "labeling" department is issued on the basis of the requirements of RH 19-11, and for microbiological and immunobiological preparations-on the basis of the requirements of RD 42-28-86.

In the "transportation" section, a reference is given to the current standard and, if necessary, the conditions for loading and unloading the product on transport and the requirements for the post-transportation attitude are indicated.

In the "storage" section, the storage conditions that ensure the quality and commodity condition of the product are indicated, and when necessary, the requirements for the care of the product from the influence of external factors (humidity, sunlight, temperature) are indicated. For drugs that are toxic, strongly acting, psychotropic, enter the group of narcotic agents and precursors, specific aspects of their storage are cited (according to the current list).

In the "shelf life" section, the period of time during which the drug can be used is

indicated.

In the section "basic pharmacological effects", the pharmacological effects of the drug substance are indicated.

- - The temporary Pharmacopoeia article (VFM) was developed by the author-organization along with the technology of preparation of the drug, the shelf life of which should not be less than 3 years. And the pharmacopoeia article will be developed by the development enterprise after the expiration of the corresponding VFM.
- A pharmacopoeia article in takdir, where the drug is produced by several enterprises, is developed by the main enterprise with the participation of partners.
- In the case of the use of the state standard sample (DSN) in the quality control of the drug, a pharmacopoeia article or a temporary Pharmacopoeia article was compiled at the same time to the DSN,
- must be approved. The pharmacopoeia article will be reviewed by the manufacturing enterprise before it expires.
- The draft of VFM, FM, KFM and ND (hereinafter the pharmacopoeia article) is signed by the following persons:
 - - by the head of the enterprise who developed MH for medicinal or medicinal plant raw materials;
 - - By the person who developed the MH clay;
 - - by the head of the enterprise for the production of medicinal or medicinal plant raw materials;
 - - by the scientific secretary of the pharmacopoeia committee;
- The pharmacopoeia article will be examined and checked for compliance with the scientific and technical level of the project and the modern requirements of the MH poured into the regulatory documents of medicines, focusing on:
 - - compliance of drug quality indicators and packaging with the requirements and standards of pharmacopoeia and international Pharmacopoeia;
 - - based on all indicators, quality standards and shelf life;
 - - Metrological level of quality control of the drug and the correct selection of measuring instruments;
 - - accuracy of units of applied scientific terms, methods, chemical terms and physical magnitudes;
 - - the formalization of the tugri of the article of the pharmacopoeia article and the fullness of the complex of documents to be transferred to it;
- The pharmacopoeia article will be published in 5 copies, an application for approval of this MH, an explanatory note, documents confirming the stagnation and shelf life of the drug, an analysis certificate, a table of the results of the analysis (at least in 5 series of the drug), patent formularies confirming the patent purity of the drug, a table of comparison, the Metrological description of the quality control of the drug is submitted along with documents such as the schedule.

An explanatory note to the draft Drug Quality Standard provides the following

information:

- - The name of the enterprise that developed MH;
- - information up to the sleeve about the receipt or technology of the drug substance;
- - detailed information about the methods of analysis presented in the project, the justification of the norm indicators, as well as this drug
- alternative methods of analysis of the remedy or drug substance are widely described;
- - information on how much the draft quality standard was developed according to the amount of samples and what technological documents;
- - when a deviation from the general requirements of the state Pharmacopoeia is observed, it is indicated in the Halat alox;
- - information about the fact that this drug is noted in foreign pharmacopoeias or other literary sources similar;
 - - if the drug is being applied to medical practice for the new and first time, special information will be given about it.

Examination of state standards, methods of analysis, standardization and examination of medicines is carried out by the pharmacopoeia committee after examination in the laboratories of the State center.

Projects of MHS are considered by the specialized committee of Pharmacopoeia at a committee meeting.

After the approval of the general Pharmacopoeia article, Pharmacopoeia article, provisional famacopoeia article and Pharmacopoeia articles of the enterprise, the pharmacopoeia committee of the Ministry of health of the Republic of Uzbekistan gives the corresponding designation and lists.

When they are assigned a mark, they are first shown the index of the Ministry of health of the Republic of Uzbekistan, then the number of procedures assigned to the document and the year of approval.

For example: UFM (OFS), VFM (VFS), FM (FS).

42Uz-0985-2010, in which:

42-the index established by the Ministry of health of the Republic of Uzbekistan on standardization; 0985-the number of the document in the register, 2010-the year the document was approved.

For example: ND 42uz - 4584-2010.

In this sign 14346847-the code of the enterprise.

When the pharmacopoeia article of the enterprise is specified, the code of the enterprise is also indicated.

For example: KFM (FSP)- 42uz - 14346847-0183-2010.

In this sign 14346847-the code of the enterprise

Description of quality standards for drug preparations, content and structure.

Creation, printing and implementation of state standards of medicines "standards of drug quality. The Basic Rules are implemented under the " TST 42-01: 2002 network standard. All quality standards documents of these drugs determine the procedure for the development of

documents, their content, rules of formalization, examination, Agreement and general rules of procedure for approval.

In the statement of quality standards for drug preparations, the title is given to the name of the drug in Latin, state and Russian, in which the name of the substance of the drug acting (in general agreement) is written, followed by the name of the type of drug (in general agreement), dosage (concentration), hajmi.

For example: Analgin tablets 0.5 g or analgin solution for injection 25% 1ml.

Some sections are combined, and when they are found, other sections are introduced (acid number, soapy number, iodine number, ether number, toxicity, pyrogenicity, bacterial endotoxins, histamine-like irritants, sterility, etc.).

In the introduction of the standard, the chemical name of the acting substance (for one-component preparations), the Latin, Uzbek and Russian name of the raw material of the medicinal plant, the name and family of the plant (for nastoyka and extracts) are indicated.

When the composition of the drug is given, the amount of the acting and additional substances is written in the list style, giving an indication of the corresponding MX.

In the "description" section, organoleptic indicators of the appearance of the finished drug are given, and the color of the drug is brought at the end of the sentence.

For example: blue-green color.

In the "fragility" section, a full-fledged fragmentation of a tablet or capsule in a bone munit is indicated.

When the validity of preparations with a complex composition is determined, an identifiable ingredient is brought in kavs after the analysis method statement.

In the sections "dry residue", "amount of alcohol", "boiling point", "density", "light absorption indicator", "angle of rotation", "viscosity", the lower and higher values of these regulatory indicators are indicated in the corresponding units of share.

Under the conditions given in the "solubility" section, the percentage of the acting substance, which must be absorbed into the solution at a certain vacuum interval, is indicated.

In the "quantification" section, a statement of the method for determining the amount of the acting substance in the drug is written, indicating their percentage amount or the unit of action in milligrams (ED/mg, mkg/mg).

For tablets, the amount of the main substance in one tablet, for suppositories – the amount of the main substance in one suppository, for dragees, the amount of the main substance in one dragee in grams. And for injectable solutions, the gram content of the substance in 1 ml of solution is indicated.

Description, content and structure of the standard for medicinal plant raw materials

The title of the standard is given the Latin, Uzbek and Russian names of medicinal plant raw materials.

The name of the medicinal plant raw materials is written in the plural in the general agreement. In the introduction, the use of plant raw materials, the Latin, state-language and Russian name of the plant and which family the plant belongs to are listed.

In the "external signs" section, a summary of the morphological signs of raw materials in whole and ground chole is given.

In the "microscopy" section, diagnostic signs of raw materials and a microfoto or image confirming these signs are displayed.

The "quality reactions" provide information about the percentage or biological activity of the acting substances (pharmacological substances), the norm of moisture (reduced mass when dried), total ash and insoluble ash residue in 10% hydrochloric acid, permissible foreign impurities and use.

In the "quantification" section, the method of determining the amount of active substances acting is indicated.

Recommendation and approval of drug quality standards for examination

The drug is submitted by adding the following documents to the registry signed by the head of the enterprise who developed the quality standard:

1. application for the title of head of the General Directorate for quality control of medicines and medical equipment;
2. clarification letter;
3. analytical tables confirming the number indicators listed in the quality standard loixa (in at least 5 series of the drug, and in 3 series of the sample for immunobiological drugs);
4. a writ on the use of the drug (for a new drug);
5. patent formulations confirming the patent purity of the drug or a certificate confirming that it is not necessary to check the patent purity of this quality standard (for a new drug);
6. table of comparison of indicators presented in the loixa of the quality standard, with indicators presented in the state pharmacopoeia and foreign Pharmacopoeia;
7. samples of packaged and labeled drug preparation.

The clarification letter to loixa, the quality standard of the drug, describes the following information:

1. name of the enterprise that developed the quality standard;
2. brief information about the synthesis or technology of the drug;
3. an extended description of the methods for determining indications and norms presented in the loixa of the quality standard of the drug or substation;
4. information about how many series of samples were developed on the basis of what technological documents the loiha of the quality standard;
5. In the event of a deviation from the general requirements of the state Pharmacopoeia, this condition is fully justified;

In the case of analogues (analogs) of the drug used abroad, information is provided that they were determined by comparing their quality, indicating in which foreign Pharmacopoeia or other literary source this drug was brought.

This is also indicated if the medication is new.

The clarification letter and the table of the results of the analysis are signed by the head of the enterprise who developed the quality standard loixa.

The quality standard of the drug is checked by the State center of the examination of medicines, and in case of need, other specialty institutions are also involved.

The examination of the quality standard examines the scientific and technical level of loixa, its compliance with modern requirements for regulatory documents of medicines and focuses on:

quality standards and consumer packaging of the drug compliance with the requirement of GF and other standards;

the basis of the values of quality standards, the listed indicators and the shelf life;

chemical nomenclature, values of physical units, accuracy and uniformity of the terms cited.

Persons participating in the examination of the regulatory document are responsible for the confidentiality of the information received in the process of this work. UFM, FM and KFM are approved by the pharmacopoeia Committee, and the state Pharmacopoeia is approved by the Minister of health of the Republic of Uzbekistan.

Procedure for making changes to drug quality standards

When there is an opportunity to use the achievements of Science and technology in order to improve the quality of the drug, or when it is necessary to clarify the quality indicators, changes are made to quality standards.

But this change should not lead to a deterioration in the quality of the product.

The first set of changes to the quality standard is formalized in the appropriate form.

The texts of the sections in old and new redaction are brought in full. Examination of the modification included in the quality standard is carried out in such a way that it is established for the standards.

1. Injection drug forms

(injection solution, suspension and emulsions)

1. The name of the drug in Latin, state and Russian languages.
2. Chalcara is a nonpotent name.
3. Composition.
4. Sterilization and pouring conditions.
5. Integrity.
6. Clarity.
7. Colouring.
8. PH muxite or acidity, performance.
9. Mechanical attachments.
10. Density.
11. Calyx.
12. Foreign mixtures (similar compounds).
13. Osmolarity.
14. Filling hajmi (ampoule, vials and x.k.).
15. Pyrogenicity or bacterial endotoxins (lal-test).
16. Toxicity.
17. Histominic acting substances.
18. Sterility.
19. Particle size (in case of suspension).
20. Myclorium analysis.

21. Packaging.
22. Label.
23. Transportation.
24. Preservation.
25. Shelf life.
26. Main pharmacological effects.

Additional: sections 1-10, 13, 15, 19-27 are necessary. The addition of the remaining sections will depend on the nature of the drug substance (substance), the technology of obtaining and the method of use.

2. Dry injection drug forms.

1. The name of the drug in Latin, state and Russian languages.
2. Chalcro is a nonpotent name.
3. The composition of one vial (ampoule).
4. Description.
5. Integrity.
6. The average mass is and the mass is uniform.
7. Clarity.
8. Colouring.
9. PH mixture or acidity, performance.
10. Mechanical attachments
11. Foreign mixtures (similar compounds).
12. Pyrogenicity or bacterial endotoxins (LAL-test).
13. Toxicity.
14. Chlorides, sulfates and other mixtures.
15. Decrease in mass when heated. K.Water detectable by the Fisher method.
16. Sulfate ash and heavy metals.
17. The mass of the substance in the ampoule.
18. Histamine-acting substances.
19. Sterility.
20. The same dosage.
21. Quantitative analysis.
22. Packaging.
23. Label.
24. Transportation.
25. Preservation.
26. Shelf life.
27. Main pharmacological effects.

Note. 1-8, 10, 11, 17, 19, 21-27 sections are necessary. The addition of the remaining sections will depend on the nature of the drug substance (substance), the technology of obtaining and the method of use. Solubility indicator is added as needed.

3. Eye drops.

1. The name of the drug in Latin, state and Russian languages.
2. Chalcro is a nonpatent name.
3. Composition.
4. Sterilization and pouring conditions.
5. Integrity.
6. Clarity.
7. Colouring.
8. PH mixture or acidity, alkalinity.
9. Mechanical attachments.
10. Density.
11. Calyx.
12. Osmolarity.
13. Foreign mixtures (similar compounds).
14. Bag filling is hajmi.
15. Sterility.
16. Quantitative analysis.
17. Packaging.
18. Label.
19. Transportation.
20. Preservation.
21. Shelf life.
22. Main pharmacological effects.

**4. Solutions intended for drinking and rubbing use
(granules and powders used to prepare suspension, emulsion and solution)**

1. The name of the drug in Latin, state and Russian languages.
2. Chalcro is the name of a nonpatent.
3. Composition.
4. Description.
5. Integrity.
6. PH mixture or acidic, alkaline.
7. Density.
8. Calyx.
9. Foreign mixtures (similar compounds).
10. Particle size. (for suspension).
11. Filling khajmi.
12. Microbiological purity.
13. Quantitative analysis.
14. Packaging.
15. Label.
16. Transportation.
17. Preservation.
18. Shelf life.

19. Main pharmacological effects.

Note: sections 1-5, 11, 19 are necessary. The addition of the remaining indicators will depend on the nature of the drug substance (substance), the method of use.

5. Aerosols

1. The name of the drug in Latin, state and Russian languages.
2. Chalcara is the name of a nonpatent (for a type of one-component drug).
3. Composition.
4. Description.
5. Integrity.
6. Checking the pressure.
7. Checking the germicity of the container.
8. Checking the juiciness of the jumraq.
9. The mass of the dose.
10. The number of doses in the container.
11. The amount of substance in the packaging.
12. Particle size.
13. Water.
14. Foreign mixtures (similar compounds).
15. Microbiological purity.
16. The same dosage.
17. Quantitative analysis.
18. Packaging.
19. Label.
20. Transportation.
21. Preservation.
22. Shelf life.
23. Main pharmacological effects.

Note: sections 1-8, 11-14, 15, 17-23 are necessary. The addition of the remaining indicators will depend on the nature and dosage of the drug substance (substance).

6. Grease drugs (creams, gels, liniments, pastes).

1. The name of the drug in Latin, state and Russian languages.
2. Chalcara is the name of a nonpatent.
3. Composition.
4. Description.
5. Integrity.
6. The mass of the substance in the packaging.
7. Muxit of water separation.
8. Particle size.

9. Uniformity.
10. Foreign mixtures (similar compounds).
11. Microbiological purity and Sterility.
12. Quantitative analysis.
13. Packaging.
14. Mark.
15. Transportation.
16. Preservation.
17. Shelf life.
18. Main pharmacological effects.

Note: sections 1-8, 11-18 are necessary. the addition of the remaining indicators depends on the nature of the drug substance (substance).

7. Capsules.

1. The name of the drug in Latin, state and Russian languages.
2. Chalcro is the name of a nonpatent.
3. Composition.
4. Description.
5. Integrity.
6. The average mass is and the mass is the same.
7. Thaw.
8. Decomposition.
9. Yacht mixtures.
10. Microbiological purity.
11. Uniformly dosed.
12. Numerical composition.
13. Packaging.
14. Labeling.
15. Transportation.
16. Preservation.
17. Shelf life.
18. Basic pharmacological property.

Note: parts 1-10, 12-18 are the main ones. the remaining indicators depend on the nature of the drug (substance and dosage).

8. Drug substance (substance)

1. The name of the drug in Latin, state and Russian languages.
2. Chalcro is the name of a non-patented.
3. Chemical name on IYUPAK students.
4. Structure and empirical formulas, as well as molecular mass.
5. The amount of the acting substance (in percentage or unit of action).
6. Description.

7. Solubility.
8. Integrity.
9. Melting (decay), hardening or boiling temperature.
10. Density.
11. Light breaking indicator.
12. Comparative absorption indicator.
13. Comparative angle of inclination.
14. The clarity of the solution.
15. Solution color.
16. PH muxite, acidic or functional.
17. Mechanical attachments.
18. Foreign substances (similar compounds).
19. Purity (chlorides, sulfates, etc.
20. Sulfate ash and heavy metals.
21. Mass or water lost when dried, K. The Fisher method has been defined.
22. Residual organic solvents (if used in the final technological process).
23. Pyrogenicity or the presence of bacterial endotoxins (LAL-test).
24. Toxicity.
25. Gitsamine-like acting compounds.
26. Microbiological purity (sterility).
27. Quantitative analysis.
28. Packaging.
29. Label.
30. Transportation (transportation).
31. Preservation.
32. Shelf life.
33. Main pharmacological effects.

Thanks to the development of new drug forms, the introduction of modern methods of quality control, the use of new materials for packaging, new sections can be included in this list.

Structure, development and review of regulatory documents

The development of all types of Pharmacopoeia articles is based on:

- to the advances of Medical Sciences, Biology, Chemistry, Physics and other fundamental sciences in order to ensure the modern level of quality indicators and control methods of medicines;
- State Pharmacopoeia, pharmacopoeia of foreign countries, requirements for the quality of medicines produced in industry;
- Quality control of medicines, packaging and labeling indicators, State and network MX requirements;
- To information on the quality and dynamics of drugs identified in laboratory and production enterprises;

VFM is developed by the author – organization along with the technology of preparation of the drug, the shelf life of which should not be less than 2 years. The FM, on the other hand,

will be developed by the manufacturing enterprise after the expiration of the corresponding VFM.

In the event that the drug is produced by several enterprises, the pharmacopoeia article is developed by the main enterprise with the participation of partners.

At the same time, DSN should be used to control the quality of the drug, a pharmacopoeia article or a pharmacopoeia article should be compiled and approved to the DSN in the face of one vaccine. Kayta will be considered by the manufacturing enterprise before the expiration of the FMI.

- The pharmacopoeia article is signed by the following individuals:
- - by the head of the enterprise who developed MX for medicinal or medicinal plant raw materials;
- - By the person who developed the MX lens;
- - By the head of the enterprise for the production of medicinal or medicinal plant raw materials;
- - By the scientific secretary of the pharmacopoeia committee.
- The FM or VFM will be examined and checked for compliance with the modern requirements of the scientific and technical level of the chemical and the regulatory documents of the MX of drugs, focusing on:
- - compliance of drug quality indicators and packaging with pharmacopoeia and halcaro Pharmacopoeia requirements and standards;
- - based on all indicators, quality standards and shelf life;
- - metrologically ensured level of control over the quality of the drug and the birth selection of measuring instruments;
- accuracy of units of applied scientific terms, methods, chemical terms and physical magnitudes;

- the correct formalization of the pharmacopoeia article or Pharmacopoeia article of the vaccine and the completeness of the set of documents to be added to it;

The Fuze of FM or VFM is 5 copies, an application for approval of this MX, a clarification letter, documents confirming the stagnation and shelf life of the drug, an analysis certificate ,an analysis results table (at least 5 series of drugs), patent formulas confirming the patent purity of the drug, a table comparing the indicators provided for by the quality standard, the Metrological description of the quality control of the drug is submitted along with documents such as the schedule.

The following information is provided about clarification of the drug quality standard:

- The name of the enterprise that developed MX;
- Summary of drug substance withdrawal or technology;
- Detailed information about the methods of analysis presented in loixa, the justification of the indicators of the norm, as well as methods of mucosal analysis of this drug or drug substance are widely described;
- Data on how much the loixa of the quality standard is developed according to the amount of samples and what technological documents;
- When a deviation from the general requirements of the state Pharmacopoeia is observed, this condition is given separately;

- Information about the use of this drug in foreign pharmacopoeias or other literary sources of analogues;

- If the drug is being introduced into medical practice for the new and first time, special information will be given about it.

Examination of state standards, methods of analysis; standardization and examination of medicines; carried out by the pharmacopoeia committee upon examination in the laboratories of the State center.

Loixas of mxs are considered at a committee meeting by the specialized paper of the pharmacopoeia committee.

Rules for drawing up drug quality standards

The title of the standard gives the designation of the drug. The text should be short, without the shedding of the isxar of thoughts, clearly written, and the shrinkage of the Otters is not allowed. The terms, concepts and magnitudes used should correspond to the terms adopted by the state pharmacopoeia and other standards.

An indication (indication) is brought to the relevant regulatory document on the substance (substance) of the drug, which is part of the drug.

The name of the drug substance (substance) is written in Latin, state and Russian in its empirical formula, first carbon, then hydrogen in order.

For example: C. When the relative molecular mass of a drug substance is less than 400, two rooms after the whole are written in accuracy, and one room after the whole is written in accuracy if it is greater than 400. The "description" section provides information on the external appearance of the drug (physical condition, color, KHIDI), the possibility of changing under the influence of air and light light during the storage process, hygroscopicity. It is not recommended to determine the smell for toxic and strongly acting drugs. The current vaccine also uses a reversible spectrophotometric method to determine the degree of whiteness and glare of the drug (discoloration).

In the "determination of authenticity" Section, 2-3 chemical quality reactions characteristic of the drug substance, as well as ultraviolet and infrared absorption spectra and other data are cited.

In the "solubility" section, the relative solubility of the drug substance in water, 95% alcohol, chloroform and ether can be indicated, as well as other solvents if necessary. In the elimination of solubility, the terms solubility, which are presented in the state Pharmacopoeia, are used.

The boiling, cooling and hardening temperature of the drug substance, as well as the density, the angle of comparative deflection, the beam break indicator, the specific beam absorption indicator and other physical constants are given in some section, and the lower and higher values of the regulatory indicators are given.

The clarity and discoloration of the solution of the drug substance is determined for a certain concentration of the solution, and the number of degrees of turbidity or degree of colouring for colored and fuzzy solutions or the corresponding absorption spectra of these solutions are given.

The acidity or alkalinity of a solution of a drug substance is measured by pH potentiometric method of solution using solutions of acid or alkalis at concentrations of up to 0.01 mol/l when determined using indicators.

The section "determination of foreign private mixtures" should specify the normative colorability étallons or other modern methods, such as chromatographic method, which can be allowed for the compounds formed during the process of substance storage. When the chromatographic method is used for this purpose, the sorbent type, the laminated phase composition, the amount of the Examiner substance and the standard sample (guvox), the time of chromatography, the type of opener reagent and all the conditions that determine the process are cited.

The "organic solvent residue" section is introduced into MTX if toxic solvents are used in the drug preparation technology or if an organic solvent is used at the final stage of obtaining the drug substance.

In the sections "chlorides", "sulfates" and others, the permissible regulatory limits of these mixtures are indicated.

In the section "sulfate ash and heavy metals", quantitative norms of the drug substance drawer, sulfate ash and heavy metals are presented.

The "Margimush" section specifies the permissible quantitative ranges of arsenic in the case of a foreign mixture, or the requirements that it is not contained in the drug substance.

The sections "toxicity", "pyrogenicity", "substances with histamine action" indicate the type of animal being experimented on, the test dose, the method of sending the substance to the animal, and the duration of the experiment.

The "sterility" section is introduced when the drug form cannot be sterilized.

In the section "microbiological purity", methods for detecting microorganisms and their permissible quantitative limits are indicated.

In the "quantification" section, the method of quantitative analysis of the main substance in the drug is given and the unit of action of its percentage amount or activity in milligrams is given.

In the "packaging" section, the initial packaging (jar, ampoule, vial, package, etc.) with the indication of a regulatory document is indicated.), information about the amount of the product in the primary packaging (for example: the amount of the tablet in the container), the secondary packaging (with the indication of the regulatory document, the amount of the primary packaging and the ways of hermeticization, etc.) are provided. When the carriage packaging (tara) is displayed, a reference is given to the relevant regulatory document. Dosage to ensure that the packaging is maintained during the specified shelf life of the drug.

The "labeling" section is formalized under the requirements of RN 19-11 for graphic drug labeling, and RD 42-28-36 for Mibps.

In the "transportation" section, a reference is given to the current standard and, if necessary, the requirements for the conditions of loading and unloading the product for transportation and the attitude after transportation are indicated.

In the "storage" section, the storage conditions that ensure the quality of the product and the condition of the brand are indicated, and when it is necessary, the requirements for the expiry of the product from the influence of external factors (humidity, groom's light, temperature) are indicated. For drugs that are toxic, strongly irritating, psychotropic, drug and precursor groups, specific aspects of their maintenance are cited (according to the current list, List A and List B).

In the "shelf life" section, the duration of the vaccine for which the drug can be used is indicated.

In the section "basic pharmacological effects", the pharmacological effects of the drug substance are indicated.

Description, content and structure of quality standards for drug preparations.

The title is given to the name of the drug in Latin, state and Russian, in which the name of the substance of the drug acting (in the general agreement), then the name of the type of drug (in the general agreement), the dosage (concentration), the name are written.

For example: Analgin tablets 0.5 g or solution for Analgin Injection 25% 1ml.

Some sections are combined, and when they are found, other sections are introduced (acid number, soapy number, iodine number, ether number, toxicity, pyrogenicity, bacterial endotoxins, histamine-like irritants, sterility, etc.).

In the introduction of the standard, the chemical name of the acting substance (for one-component preparations), the Latin, Uzbek and Russian name of the raw material of the medicinal plant, the name and family of the plant (for nastoyka and extracts) are indicated.

When the composition of the drug is given, the amount of the acting and additional substances is written in the list style and a reference is given to the corresponding MX.

In the "description" section, organoleptic indicators of the appearance of the finished drug are given, and the color of the drug is brought at the end of the sentence.

For example: blue-green.

In the "fragility" section, a full-fledged fragmentation of a tablet or capsule in a bone muller is indicated.

When the validity of preparations with a complex composition is determined, an identifiable ingredient is brought in after the analysis method statement.

In the sections "dry residue", "amount of alcohol", "boiling point", "density", "light absorption indicator", "angle of rotation", "viscosity", the lower and higher values of these regulatory indicators are indicated in the corresponding units of share.

Under the conditions given in the "solubility" section, the percentage of the acting substance, which must be absorbed into the solution at a certain vacuum interval, is indicated.

In the "quantification" section, a statement of the method for determining the amount of the acting substance in the drug is written, indicating their percentage amount or the unit of action in milligrams (ED/mg, mkg/mg).

For tablets, the amount of the main substance in one tablet, for suppositories – the amount of the main substance in one suppository, for dragees, the amount of the main substance in one dragee in grams. For injection solutions, however, the gram content of the substance in 1 ml of solution is indicated.

Description, content and structure of the standard for medicinal plant raw materials.

The title of the standard is given the Latin, Uzbek and Russian names of medicinal plant raw materials.

The name of the medicinal plant raw materials is written in the plural in the general agreement. In the introduction, the use of plant raw materials, the Latin, state-language and Russian name of the plant and which family the plant belongs to are listed.

In the "external signs" section, a summary of the morphological signs of raw materials in whole and ground chole is given.

In the "microscopy" section, diagnostic signs of raw materials and a microfoto or image confirming these signs are displayed.

The "quality reactions" provide information on the percentage or biological activity of the acting substances (pharmacological substances), the norm of moisture (reduced mass when dried), total ash and insoluble ash residue in 10% hydrochloric acid, permissible foreign impurities and use.

In the "quantification" section, the method of determining the amount of active substances acting is indicated.

General Pharmacopoeia article title sheet form

APPENDIX B

(required)

The form of the title page of the general pharmacopoeia article

MINISTRY OF HEALTH OF THE REPUBLIC OF UZBEKISTAN
GENERAL DIRECTORATE FOR QUALITY CONTROL
MEDICINES AND MEDICAL EQUIPMENT
PHARMACOPOEIA COMMITTEE

I APPROVE

Head of the Main Department
for Quality Control
of Medicines and Medical Equipment
_____. F. I. O.
" ____ " _____. y.

STATE QUALITY STANDARD
MEDICINAL PRODUCTS

GENERAL PHARMACOPOEIA ARTICLE

Name	OFS 42 Uz-0001-0000
of the general pharmacopoeia article	Introduced for the first time
	The term of introduction is set
с	" ____ " _____. y.
до	" ____ " _____. y.

text

APPENDIX D
(required)

The form of the title page of the pharmacopoeia article

I APPROVE

Head of the Main Department
for Quality Control
of Medicines and Medical Equipment

_____ Ф. И. О.

“ ” _____ г.

STATE QUALITY STANDARD
MEDICINAL PRODUCTS

PHARMACOPOEIA ARTICLE

Name	FS 42 Uz-0001-0000
of the medicinal product	Instead of

The term of introduction is set

с “ ” _____ Г.
до “ ” _____ Г.

TEKCT

ИЗДАНИЕ ОФИЦИАЛЬНОЕ

ПЕРЕПЕЧАТКА ВОСПРЕЩЕНА

ПРИЛОЖЕНИЕ Д

(обязательное)

Форма титульного листа временной фармакопейной статьи

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ УЗБЕКИСТАН
ГЛАВНОЕ УПРАВЛЕНИЕ ПО КОНТРОЛЮ КАЧЕСТВА
ЛЕКАРСТВЕННЫХ СРЕДСТВ И МЕДИЦИНСКОЙ ТЕХНИКИ

ФАРМАКОПЕЙНЫЙ КОМИТЕТ

УТВЕРЖДАЮ

Начальник Главного управления
по контролю качества лекарственных
средств и медицинской техники

_____ Ф. И. О.
“ ____ ” _____ г.

ГОСУДАРСТВЕННЫЙ СТАНДАРТ КАЧЕСТВА
ЛЕКАРСТВЕННОГО СРЕДСТВА
ВРЕМЕННАЯ ФАРМАКОПЕЙНАЯ СТАТЬЯ

Название

ВФС 42 Уз-0001-0000

лекарственного средства

Вводится впервые

Срок введения установлен

с “ ____ ” _____ г.

до “ ____ ” _____ г.

ТЕКСТ

ИЗДАНИЕ ОФИЦИАЛЬНОЕ

ПЕРЕПЕЧАТКА ВОСПРЕЩЕНА

ПРИЛОЖЕНИЕ Е

(обязательное)

Форма титульного листа фармакопейной статьи предприятия

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ УЗБЕКИСТАН
ГЛАВНОЕ УПРАВЛЕНИЕ ПО КОНТРОЛЮ КАЧЕСТВА
ЛЕКАРСТВЕННЫХ СРЕДСТВ И МЕДИЦИНСКОЙ ТЕХНИКИ
ФАРМАКОПЕЙНЫЙ КОМИТЕТ

УТВЕРЖДАЮ

Начальник Главного управления
по контролю качества лекарственных
средств и медицинской техники

Ф. И. О.

“ ____ ” _____ г.

СТАНДАРТ КАЧЕСТВА ЛЕКАРСТВЕННОГО СРЕДСТВА

ФАРМАКОПЕЙНАЯ СТАТЬЯ ПРЕДПРИЯТИЯ

(Наименование предприятия-производителя (разработчика) лекарственного средства;
указывается в именительном падеже)

Название

ФСП 42-00000000-0001-0000

лекарственного средства

Вводится впервые

Срок введения установлен

с “ ____ ” _____ г.

до “ ____ ” _____ г.

ТЕКСТ

ПРИЛОЖЕНИЕ Ж
(обязательное)Форма последнего листа ВФС, ФС, ФСП
ТЕКСТРуководитель предприятия-производителя _____ Ф.И.О.
(организации-разработчика) М.П. “___” _____ г.Основные разработчики: _____ Ф.И.О.
М.П. “___” _____ г.

Согласовано:

Председатель _____ Ф.И.О.
Фармакопейного комитета М.П. “___” _____ г.Ученый секретарь _____ Ф.И.О.
Фармакопейного комитета М.П. “___” _____ г.

ПРИЛОЖЕНИЕ И

(обязательное)

Форма титульного листа изменения ВФС, ФС и ФСП

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ УЗБЕКИСТАН
ГЛАВНОЕ УПРАВЛЕНИЕ ПО КОНТРОЛЮ КАЧЕСТВА
ЛЕКАРСТВЕННЫХ СРЕДСТВ И МЕДИЦИНСКОЙ ТЕХНИКИ
ФАРМАКОПЕЙНЫЙ КОМИТЕТ
УТВЕРЖДАЮ

Начальник Главного управления
по контролю качества лекарственных
средств и медицинской техники
_____ Ф. И. О.

“ ____ ” _____ г.

(Обозначение ВФС, ФС, ФСП)

(Наименование ВФС, ФС, ФСП)

(Наименование предприятия-производителя (разработчика) лекарственного средства;
указывается в именительном падеже)

ИЗМЕНЕНИЕ N _____

Срок введения изменений с " ____ " _____ г.

Старая редакция

ТЕКСТ

Новая редакция

ТЕКСТ

Lecture 5. Technique and fire safety. Pharmaceutical production sanitation.

Plan

- 1 technique and fire safety..
2. Pharmaceutical production sanitation.
3. Control meiori-application of technical documents

Base words and phrases: Technique and fire safety. Pharmaceutical production sanitation. Control meiori-application of technical documents

Allocated time - 2 hours.

Labor protection and security at the enterprise is a set of activities necessary to protect workers when performing the task of the employer.

At any enterprise, measures are taken to ensure the safety of workers, and large funds are allocated for the implementation of these goals. The pharmacist has a special security service subordinate to the chief engineer of the plant, which must ensure safe working conditions for the worker, monitor the state of industrial safety and ensure that all workers entering the enterprise are trained in safe working methods.

Pharmaceutical plants regularly carry out activities to reduce injuries and prevent car accidents. This activity is mainly reduced to:

- improving the design of existing equipment to protect workers from injury; - designing and improving new protective equipment for countertops, countertops and heating devices to prevent injury;

- improving working conditions: adequate light, good ventilation, pulling dust from cleaning areas, timely disposal of production waste, maintaining normal temperatures in workshops, workplaces and heat-releasing devices;

- accidents during the use of equipment, breakage of grinding wheels, accelerating circular sawing, splashing of acids, explosion of containers and high-pressure pipes, flare from heating appliances or the firing of molten metals and salts, electroweaking, electrocoachiurishivos. t.;

- to regularly familiarize all those who come to work with the rules for working on the territory of the enterprise and the Basic Rules of safety, to regularly train and test the rules of work safety management for working knowledge;

- to provide workers with posters that clearly show safety regulations, dangerous places in workplaces and accident prevention measures.

However, accidents can occur as a result of workers themselves not paying attention to safety. To protect yourself from an accident, you need to learn the safety rules and follow them constantly. General requirements for industrial safety.

When a new (unfamiliar) job is found, request additional safety training from the master.

When doing work, you need to be careful not to be distracted by external objects and conversations and not to distract others.

3. On the territory of the pharmaceutical plant (yard, building, access roads), follow the following rules::

- do not unnecessarily go to other departments of the enterprise;

- bypass loading and unloading areas;

- do not cross conveyors and roller tables in unknown places and do not lean under them, do not enter without permission without obstacles;

- do not touch electrical appliances, terminals and wires, general lighting devices and do not open the doors of electrical cabinets;

do not turn on and stop machines, machines and mechanisms that the administration of your workshop has not entrusted to you (except in case of emergency).

4. In case of injury or injury, stop working, inform the boss and contact the Medical Center.

Below are the special security requirements.

Before you start:

Place your work clothes in Series: secure or wrap the elastic band with a wide elastic band; tie the garment so that the clothes do not have curly ends: take off the ends of a tie, scarf or scarf; put on a tight hat and take hair under it.

Wear work shoes. Due to the possibility of injury to the feet with a sharp and hot metal scraper, it is forbidden to work on light shoes (slippers, sandals, sandals).

Carefully inspect the workplace, arrange it, remove all obstructions and obstacles. Place equipment, utensils, necessary materials and parts in a convenient and safe way to use. Make sure the working tools and accessories work.

Check that the workplace is sufficiently illuminated and that the light does not blind the eyes.

If you need to use a portable electric lamp, check if the lamp has a protective net, the position of the cord, and the insulating rubber tube. The voltage of portable electric lighting should not exceed 36 V, which should be checked with inscriptions on Shields and current collectors.

Make sure that the floor at work, in no case, is in good condition

When installing heavy parts, choose a position that allows you to process it with one or less installation.

Choose the scheme and processing method in advance, take into account the convenience of changing tools and making measurements.

During work:

When moving the tool to the grinding wheels, safety glasses should be worn (if there is no protective shield on the wheel). If there is a protective screen, do not put it aside, but use it for your own safety. Check that the handle is well fixed, insert it into the grinding wheel as far as possible at a distance of 3-4 mm. Do not resist the circle when cutting, but look at it half-turned.

Control the state of blocking the rotating parts of the machines you need to work with.

Do not remove the chips with your hands, but use a wire hook.

All machine tools use 4 to 8 ATM pressurized air. Air flow at this pressure is very dangerous. For this reason, compressed air must be used very carefully so that its flow does not accidentally fall on the face and ears of the person who uses it or works nearby.

The safety of certain workers is the responsibility of their immediate leader. In general, managers are responsible for labor protection and safety at work: enterprises, departments, heads of departments, etc. Responsibility for the implementation of labor protection and security requirements at the enterprise is also divided into areas of control and assigned to employees with appropriate powers. For example, employees of the Energy Service assigned by orders are direct supervisors of the organization of the system of instructions for the protection and safety of labor in the workplace and its high - quality operation-work. Employees themselves must take care of their safety. To stay healthy and continue working, workers need:

know exactly the requirements of safety and labor protection guidelines and always comply with them;

timely transition from training and medical examinations;

Creation and implementation of programs, measures to improve the quality of working conditions;

Organizational and methodological assistance to units in the field of health: assistance in the development of safety and labor protection instructions, maintaining copies of their control, providing instructions to departments and senior employees, magazines, cards, other documents on labor protection, visual aids, rules and standards;

Participation in the examination of workers ' knowledge on the results of training in labor protection conducted at the enterprise;

Help prepare any documents related to labor protection and labor protection: a collective agreement, various contracts, call orders for work on weekends, schedule changes, etc.;

Help list:

Pre-shift, preliminary and annual medical examinations;

special nutrition;

Horse documentation;

Organization of training for employees and managers;

Check your health regularly in sections;

Conduct introductory labor protection and security briefings.

In order to qualitatively control the fulfillment of labor protection and labor security requirements, health professionals at any time:

inspection of machines, equipment, equipment;

Checking documents on labor protection (keeping journals, familiarizing employees with labor protection and safety rules, accounting for work clothes and personal protective equipment, issuing permits, etc.), checking the safety of personal protective equipment and their practical application;

control the use of safe practices and work methods by workers.

In order to successfully carry out the tasks assigned to them, OT specialists cooperate with other services of the enterprise (employees, energetics, mechanics, ambulance point, etc.), as well as with the OT Commission and the trade union authorized by the Labor team on OT issues. Instructions from horse specialists

The labor protection service monitors the safety of all types of work performed at the enterprise. OSH engineers have the right to suspend any work carried out in violation of the requirements of safety and labor protection guidelines. At the same time, they provide instructions, which indicate the nature of violations and indicate the deadlines for their elimination. Ignoring the requirements of these requirements by the persons to whom they are issued causes criminal liability in disciplinary, material and especially severe cases.

The order includes:

the essence of the violation of the requirements of the established rules, safety and labor protection guidelines;

Links to regulatory documents whose requirements are violated;

the period during which violations must be eliminated;

the person is responsible for eliminating identified violations.

The order is drawn up for the head of work and drawn up in 2 copies, one of which is given to him under the signature. If the manager refuses to accept the order, an act is drawn up about it, or the inscription "refused to accept the order" is formalized in the order. If the acceptance of the work order is refused, they still stop, and the identified violations must be eliminated. Inspector requirements may require an unscheduled labor protection and safety briefing to be held.

As soon as the violations are eliminated, the responsible person reports this in writing to the horse service. After the OH and S engineer checks the implementation of the necessary measures and puts the appropriate mark (+ date, signature) in the appropriate order, the work can be continued. Recipes are stored in the horse service. The procedure for storing them in organizational units is established independently. For example, in OT verification journals, you can enter information about the instructions given (the nature of the violations, the deadlines for elimination, the responsible persons).

Fire technical minimum

Heads, specialists and employees of organizations responsible for fire safety are trained to the fire-technical minimum at the level of knowledge about the requirements of regulatory legal acts regulating fire safety, the fire regime, the technological process and the fire hazard of the organization's production, as well as the requirements of methods and actions in the event of a fire. fire prevention is in an organization that allows you to develop practical skills in saving people's lives, health and property in the event of a fire.

Fire-technical minimum training for leaders, specialists and employees of organizations not associated with explosive and Fire Hazardous production is carried out within a month after hiring, and subsequent training at least once every three years after the last reading, as well as for heads, specialists and employees of organizations. with explosive and Fire Hazardous production, once a year.

Employees of organizations with an engineer (technical) qualification in fire safety, as well as employees of the authorized federal executive body for solving problems in the field of fire safety and teachers of educational institutions teaching the subject "fire safety", employees with permanent work experience. the fire safety zone may not be trained in a fire-technical direction for at least five years, within 1 year after entering work (service) to a minimum.

Responsibility for the organization of fire and technical minimum training in the organization is assigned to its head.

Minimum fire safety training is organized as follows:

Out of production

At work

Separation of production and Fire-technical minimum level training. Fire-technical minimum training, separated from production according to specific programs developed and approved in the prescribed manner, includes:

heads and chief specialists of the organization or persons performing their duties.

employees who are responsible for the fire safety of organizations and conduct fire exercises.

Heads of Voluntary Fire Protection primary organizations.

Heads of out-of-town medical institutions for children and adolescents.

Workers who perform gas welding and other hot work.

drivers of fire engines and motor pumps of children's health institutions;

Other categories of workers (citizens) by the decision of the leader.

On-the-job training in Fire-technical training facilities, Ministry of emergency situations

Emergency fire safety requirements test. Regardless of the duration of the previous inspection, an emergency test is carried out on the fire safety requirements of the organization's employees:

In the approval of new or modified regulatory documents containing fire safety requirements (in this case, only knowledge of these regulatory legal acts is checked).

After fires, as well as in the event of violation of the requirements of regulatory documents on fire safety by the employees of the organization;

If there is a break in work for more than a year in this position.

When control measures are carried out by state fire control bodies.

The size and order of the emergency inspection procedure for knowledge of fire safety requirements is determined by the party who began its implementation.

The list of control questions for testing the knowledge of employees of organizations under the jurisdiction of Federal executive bodies is developed by the relevant federal executive bodies taking into account the specifics of production activities and includes a practical part - actions in the event of a fire, the use of preliminary means to prevent a fire.

A list of control questions for other organizations is developed by the heads of the organization (owners) or employees responsible for fire safety.

Control over timely verification of knowledge about the fire safety requirements of employees is carried out by the head of the organization.

Fire safety measures guidelines. The fire safety measures directive is developed on the basis of these regulations, regulatory fire safety documents based on the fire hazard characteristics of buildings, structures, buildings, processes, technological and production equipment.

Allowed number of raw materials, semi-finished products and finished products located in the premises at the same time;

combustible waste and dust collection, order and periodicity of storage of fatty work clothes;

the fact that the axis of the instruments is limited (pressure gauges, thermometers, etc.), deviations can cause a fire or explosion;

Tasks and behavior of employees during a fire, including when calling the fire department, emergency shutdown of technological equipment, extinguishing ventilation and electrical equipment (including during a fire and at the end of the working day), the use of fire equipment and fire automatics, evacuation of flammable substances and material assets, inspection of all premises (units) of the enterprise and its safe state;

the number of people who can be at the enterprise at the same time.

Fire safety measures guidelines list persons responsible for ensuring fire safety, including:

notification to the fire department and notification (notification) of facility management and duty services;

To do this, organize the rescue of people from existing forces and means, including in the provision of first aid to victims;

checking the availability of automatic fire protection systems (warning systems to protect people from fire, fire extinguishing, smoke);

If necessary, the shutdown of electricity (except for Fire Protection Systems), conveyor devices, units, apparatus, the closure of raw, gas, steam and water communications, the state of accident and the closure of ventilation systems in neighboring rooms, etc. development of fire and smoke release buildings;

stopping all work in the building (if the technological process of production permits), except for work related to fire suppression measures;

To exclude all employees who are not engaged in fire suppression from the danger zone;

execution of General fire extinguishing instructions before the arrival of the fire department (taking into account the specifics of the object);

ensuring compliance with the safety requirements of employees involved in fire suppression;

Organization of fire evacuation and extinguishing material assets;
to meet fire units and help them choose the shortest route to approach the fire;
to provide information to fire units involved in firefighting and associated accident-rescue operations about the information needed to keep hazardous (explosive), explosive, highly toxic substances in a place where they can be processed or stored;

when arriving at the fire department, it is necessary to inform the fire extinguisher chief about the design and technological characteristics of the object, the amount of substances, materials, items stored and used in the object and the dangerous properties of the fire and other information necessary for the successful elimination of the fire;

Organization of the involvement of forces and Means for the implementation of activities related to the suppression of fire and the Prevention of its development.

Providing the premises with preliminary fire-fighting equipment. When determining the types and quantities of primary fire extinguishers, the physical-chemical and fire-hazardous properties of combustible substances, their interaction with extinguishers, as well as the area of production facilities, open areas and structures should be taken into account.

Technological equipment is equipped with fire extinguishers in accordance with the requirements of technical conditions (passports) for this unit.

To extinguish fires of different categories, dust extinguishers must have the following costs.

ABCE chang for Class A fires

B, C, E for class fires or ABCE powder

For Class D fires - d powder

The appointment of buildings, buildings and external structures of a certain category for the risk of explosion and fire is carried out in accordance with the following regulatory documents:

Federal Law No. 123-FZ "technical regulation on fire safety requirements" of July 22, 2008.

SP 12.13130.2009" determination of categories of buildings, buildings and outbuildings for explosion and fire hazards " set of rules.

NPB 105-03 fire safety standards"identify categories of buildings, buildings, and outbuildings for explosion and fire hazards".

The choice of fire extinguisher (mobile or manual) is determined by the size of the fire sources. Portable fire extinguishers should be used when possible fire sources are available.

When choosing a fire extinguisher with an appropriate temperature limit for use, the climatic conditions of the operation of buildings and structures are taken into account.

Public buildings and structures on each floor have at least 2 manual fire extinguishers.

For explosion and fire hazards, a Class D room is not equipped with fire extinguishers unless the area of this room exceeds 100 square meters. meter.

If there are several rooms of the same fire hazard category, the total area of which does not exceed the maximum protected area, the placement of fire extinguishers in these rooms is carried out in the following order. The distance from a possible fire source to the location of the fire extinguisher should not exceed:

20 meters-for public buildings and facilities

30 meters-for Class A, B and C rooms for explosion and fire hazards

40 meters-for rooms of Class G for explosion and fire hazard

• 70 meters-for rooms of Class D for explosion and fire hazard

Fire extinguishers sent to recharge from the enterprise are replaced by appropriately charged fire extinguishers.

When protecting buildings with computer technology, telephone exchanges, museums, archives, etc. the peculiarities of the interaction of extinguishers with protected equipment, products and materials should be taken into account. Designated rooms must be equipped with claxon or carbon dioxide fire extinguishers.

Rooms equipped with automatic stationary fire extinguishers are provided with fire extinguishers for 50% of the calculated number of fire extinguishers. Each fire extinguisher installed on the object must have a passport and serial number.

The starting or locking and starting device of the fire extinguisher must be sealed with a disposable seal. The fire extinguisher is sealed by special organizations during the production of the fire extinguisher by the manufacturer or during the regular repair or charging of the fire extinguisher. The following signs apply to a disposable seal:

individual seal number;

the date of charging the fire extinguisher is Month and year.

The head of the organization ensures the availability and suitability of fire extinguishers, the periodicity of their inspection and inspection, as well as the timely reloading of fire extinguishers. Taking into account the presence of fire extinguishers, as well as other primary fire extinguishers, the frequency of inspection and charging is carried out in a special free Journal. In winter (temperatures below + 1 ° C), water-based fire extinguishers should be stored in heated rooms.

Firefighters located on sidewalks and sidewalks should not prevent people from safely evacuating. Fire extinguishers should be placed in places located near the exits of buildings at a height of no more than 1.5 meters.

In industries and warehouses that are not equipped with an internal fire water supply system and automatic fire extinguishers, as well as on the territory of enterprises (organizations) that do not have an external fire water supply system, or buildings (structures), and external technological devices of these enterprises (when fire extinguishes) for the placement of primary fire extinguishers. organizations) more than 100 meters from external fire water supply sources, Fire panels must be equipped.

The required number of fire shields and their type are determined by the category of buildings, buildings (structures) and external technological devices for the risk of explosion and fire in accordance with Appendix 5 of the Government of the Russian Federation Resolution No. 390 of April 25, 2012.

Fire panels are equipped with non-mechanized fire extinguishers and equipment in accordance with annex 6 of the Government of the Russian Federation Resolution No. 390 of April 25, 2012.

To store water installed next to the fire shield, the barrel must have a volume of at least 0.2 cubic meters. equipped with meters and buckets.

The volume of boxes for sand should be 0.5 cubic meters. equipped with meters and shovels. The design of the box should ensure the convenience of sand mining and eliminate precipitation.

Sandboxes, as a rule, are installed with boards in rooms or open areas where burning or burning liquid is spilled.

For explosion and fire hazards, 0.5 cubic meters of sand reserves are provided for Class A, B and C rooms and external technological devices. meters for every 500 square meters. meter protected area, as well as rooms of Class G and D, and external technological devices for the risk of explosion and fire - at least 0.5 cubic meters. meters for every 1000 square meters. meters are protected. To insulate the ignition source, the covers must be at least one meter long and one meter long.

In rooms where flammable and / or fast-burning liquids are used and (or) stored, the dimensions of the paintings must be at least 2 x 1.5 meters. Clothes are stored in waterproof, lockable boxes (boxes, wrappers), which allows you to quickly use these tools during a fire.

It is not allowed to use primary fire extinguishers, non-mechanized fire extinguishers and equipment for domestic and other purposes not related to fire extinguishing.

The enterprise of pharmaceutical production should be located at a distance far enough from the production, which negatively affects the quality of its product.

Construction, reconstruction and repair of buildings of enterprises of pharmaceutical production of the pharmaceutical industry should be carried out in accordance with the provisions of QMQ 3.01.02-00 "safety equipment in construction".

It is necessary to design and build production buildings with the exception of pollination, pollution levels as much as possible and the fall of insects and animals on them.

The entire territory of the enterprise should be kept clean. Effluent tanks designed to expel atmospheric precipitation must be cleaned and repaired regularly according to the approved schedule. The use of roads, passages and areas between buildings, structures and structures for storing materials, they are prohibited from laying equipment or production waste.

Smoking on the territory of the enterprise is allowed only in specially designated places, equipped in accordance with the "standard fire safety regulations at enterprises of industrial pharmaceutical production" SHMQ 2.01.02-04.

In production, production rooms and warehouses should be equipped with automatic fire extinguishers and automatic fire alarm.

The administration of the enterprise is obliged to carry out control over the maintenance, operation and repair of buildings and structures.

Production rooms should have air flow control equipment and an effective air flow intake and air traction ventilation system equipped with temperature, humidity, purification efficiency and pressure change measuring devices in filters.

The productivity of air traction ventilation systems should be 80-90% of the productivity of airflow intake ventilation systems to ensure the delivery (podporini) of air in "clean" rooms.

The air supply systems of antibiotics should be completely isolated from the air systems of the production of medicines for other medical purposes.

In the manufacture of sterile medicines, horizontal or vertical laminar flows can be created using special equipment throughout the room or in certain local zones to protect particularly important plots or operations, depending on the production need.

Production rooms can be equipped with an air flow one-stop storage system if necessary, and this system must ensure the proper purification of air from mechanical particles and microorganisms, automatically coordinate climatic parameters (air temperature, humidity) to create reasonable conditions for the technological process and service personnel.

In production rooms, it is forbidden to combine production effluent with farm-fecal effluent.

Filters are installed on the pipes of the water supply system, depending on the need.

The pipes are made of materials that allow them to be sterilized using steam, they must be installed obliquely so that the liquid flows completely, and there must be no parts in it in which the liquid will remain standing.

Requirements for household and additional rooms, their number, condition and location

In accordance with the requirements of QMQ 2.09.12-98 "administrative and household rooms of enterprises of pharmaceutical production", the rules for the design of enterprises of pharmaceutical production, buildings and structures of the food industry, and the rules for the construction of sanitary and additional rooms shall be established in each pharmaceutical production enterprise.

The design and construction of domestic and additional buildings should be carried out taking into account the need to simultaneously launch them with production facilities.

The composition of special household rooms and devices is determined depending on the groups of the production process.

Household rooms should be placed as close to work as possible.

It is forbidden to organize general sanitary and household rooms for employees of sterile and nosteril production.

Special household rooms should be equipped for employees working on plots in an environment that creates a large degree of pollution of special clothing and the body.

The inclusion of personnel in aseptic rooms is carried out through special household rooms (showers, changing rooms, etc.) — sanpropusknics.

Wardrobes, toilets, washrooms and bathing rooms where home and work clothes are stored should be separate for men and women.

The number of changing rooms, shower sizes, shower sets, foot baths, bet hand washers, consumer water supply devices, toilets and the like should be determined especially taking into account the number of shift handlers that make up the majority.

Tarnovs, channels, traps, pissuars and unitases in toilets and toilets should be cleaned, washed and disinfected regularly. The floors of toilets should be kept dry.

Depending on the nature of the production, 40% of the calculated number of bet hand washers can be placed next to the work areas of the production rooms (on the drum in the toilet).

Each washbasin must be connected to pipes where hot and cold water comes in.

In the washing rooms, electric towels, mirrors, clothes hangers, containers for liquid soap and solid soap hangers should be provided, as well as a hand washer in a chlorine solution based on the account of one device per 40 people in the maximum number of shifts.

Laundry rooms should be provided for at enterprises of pharmaceutical production for washing special clothing. The composition and area of laundry rooms should be determined according to the standards and rules of construction for the design of enterprises of pharmaceutical production of household services to the population.

Wardrobes should be designed to store Street, home and work clothes.

Wardrobes designed for work clothes should be placed separately from street and home clothing wardrobes. Household rooms should be equipped with flow and suction ventilation in accordance with the requirements of QMQ 2.09.12-98 "household and administrative premises of the Enterprise".

Catering points must meet the requirements of sanitary rules established for enterprises of pharmaceutical production of catering.

Requirements for the protection of the surrounding natural environment

Conditions for the formation of wastewater and discharge into water bodies QMQ 2.04-01-98 " drain. Design standards "and QMQ 2.04-03-97" drain. External systems and structures must comply with the requirements of" and be coordinated with the state sanitary supervision authorities, with each individual receipt.

The entire external drain system must be closed. Branches (lotocks) can be installed in open areas designed to exclude precipitation (rain) water and water that serves for washing.

The sewage should be closed for the sewage of contaminated production inside the workshops.

Open rods (lotocks) can be built to allow for floor washing as well as the water generated by washing the apparatus and pipes with clean water.

The leaking systems of production waste in liquid state should be adapted to eliminate the leaking of liquid into the back. The places where these waste passes should be equipped with appropriate ventilation.

Effluent that cannot be cleared of specific contamination is destroyed or discharged into specially designated areas.

The enterprise is obliged to provide regular laboratory control over the efficiency of purification of production and household wastewater

Fire and explosion safety requirements

The development prohibits the use of substances and materials with unexplored fire and explosion hazards and toxic properties in the production process.

Fire and explosion safety should be ensured in the development of the technological process, the introduction of hardware into it, the implementation of control and management, as well as in the selection of anti-accident protection tools.

Control over the state of explosion hazard of technological facilities is established in the prescribed manner.

The categories of Hazard in terms of explosion of buildings and rooms in which technological processes are placed are determined by the project organization separately for each specific case in accordance with TLTM 24-86 "technological design network norms".

It is forbidden to use ethyl and methyl alcohol in one production, in a workshop or device at the same time or alternately in one container and pipes, and in one equipment.

Productions that use methanol and ethyl alcohol as raw materials, auxiliary material or products are usually recommended to be placed in other-other workshops of the enterprise.

In the event that the production process requires the simultaneous application of methanol and ethyl alcohol, it is mandatory to carry out preliminary preparation (heating, rectification, etc.) work on separate technological equipment.

In the implementation of technological processes, conditions must be provided that exclude the possibility of fires, explosions, accidents, poisoning and contamination by environmental production waste (wastewater, ventilation waste and the like).

All production workshops, warehouses of raw materials and finished products, administrative and other auxiliary buildings and structures should be provided with preliminary fire extinguishers.

The ventilation system must be combined with a fire-extinguishing alarm.

Electrical equipment of power and lighting system networks must meet the required standards according to the classification of Regions and the category of buildings and rooms.

In fire-explosion-hazardous Productions, the pressurization of fire-explosion-hazardous liquids and liquefied gases and vacuum discharge should be carried out using inert gases.

Since there is a possibility of dust separation in tablet production, which is dangerous in terms of explosion, the work on the organization of the technological process and the use of equipment must be carried out in the prescribed manner.

In the granule shaping operation, measures must be taken to prevent the formation of explosively hazardous levels of Toose vapors in the event that quick-firing fluids (referred to as Toose in the next place) are applied.

Fire prevention system – it is a set of organizational measures and technical means aimed at eliminating the conditions of a fire.

These activities include the maximum mechanization and automation of technological processes, the use of non-combustible and difficult-burning materials in the production of as much as possible, the separation of Fire-Hazardous Devices from other rooms with non-flammable materials, or the installation of such devices as far as possible, the use of hermetic containers and equipment for flammable substances, the, the correct use of heating equipment is carried out, among others.

Types of burning

The combustion process can be conditionally divided into the following types:

- 1) flash is a moment-long flash of a combustible mixture. In this case, there is no chance that the mixture will be prepared so that the burning will continue.
- 2) The occurrence of burning as a result of heating.
- 3) flare-up-the continuation of burning with a flame.
- 4) spontaneous combustion is the spontaneous combustion of a combustible mixture without heating from the outside, as a result of exothermic reactions that occur within substances mainly in organic matter.
- 5) spontaneous ignition is the continuation of spontaneous combustion with flame.
- 6) explosion-the passage of an extremely fast combustion chemical process with pressure and energy generation. This temperature is referred to as the flame temperature if the flammable substance is provided by the emission of flammable vapors from itself at certain temperatures.

Evacuation routes

When designing a building intended for each industrial enterprise, evacuation routes will be organized that will definitely make it possible to evict people from there in time of fire. Evacuation routes must necessarily be at least 2 for any industrial enterprise. In the event of a fire, it is necessary for workers to leave the room of an industrial enterprise in a certain period of time, marked by the shortest path.

Requirements for workplace safety

Permanent workplaces in pharmaceutical production should be equipped with appropriate furniture (comfortable desk for records, chairs, wardrobe for work and accident

instruments), the necessary individual protective equipment, medical aptechka, a set of production instructions and a fire safety guide.

In workshops, it is impossible to block workplaces, corridors and passages for transport with raw materials, semi-finished and finished products, as well as various homogeneous items.

It is necessary that the windows intended for internal inspection and cleaning of technological equipment are not blocked.

Metal corrosion surface containers must be inspected and tested internally every 12 months.

Shutters must be provided for the connection of water, steam or inert gas networks for washing and air-assisted cleaning of apparatus with explosive hazardous and toxic substances before repair, internal inspection and testing.

There should be no locking device between the container and the storage valve.

Activated activated ignition faucet can be installed between storage devices and stationary containers designed to operate under pressure of toxic, flammable or explosion-hazardous gases, whereby the switch-on faucet must be mounted in a nozzle that connects the container with the two storage devices, and in any case of the tap probe, one or two of the storage devices must be connected to the container.

The total number of storage valves is determined by calculation in the prescribed order.

Storage valves should be placed in places convenient for inspection.

Measures should be taken to ensure that when the storage valves are installed on apparatus (pipes) with a flammable and toxic product, they start in as Little position as possible.

Emissions from the valves installed in the apparatus on the basis of toxic vapors and gases and heavy from the air should be sent to a special closed system, which allows you to return waste products to production. The debris can be thrown into the atmosphere after being decontaminated in a special suction device.

The Storage Plate (membrane) can only be installed before the storage valve, when there is a device between them that allows control of the plate setting.

All storage plates must have a pharmaceutical factory stamp and contain a plate-opening pressure.

It is forbidden to install storage planters, in which there are signs of corrosion, bends, abrasions and other mechanical damage.

In the installation of explosive plates (membranes), it is necessary to take measures to exclude the possibility of separation of harmful and explosion-hazardous gases into the room and the emission of a spark in the event of membrane development, as well as injury from its fragments and parts.

The installation of rupture membranes must be recorded in the appropriate notebook and certified by the signature of the person in charge.

All pressure vessels are required to have sath pointers and storage tubes that do not allow the rods to overflow.

It is forbidden to fill containers in the flow method, which is freely poured with quick-firing liquids.

Special purpose compressors should be used to compress gases.

The installation and use of autoclaves and the design and use of a special room (autoclave) in which the autoclave is being installed are carried out in the manner prescribed by the legislative acts.

Measures to reduce the level of exposure of hazardous and harmful production factors

The equipment of enterprises of pharmaceutical production of finished medicines should be hermetic, resistant to chemical influences and not contaminate raw materials, semi-finished and finished products with oxides, metal salts and other impurities.

The apparatus designed to carry out technological processes in which strong-acting and toxic substances (chlorine, bromine, cyanide acid, cyanide salts, arsenic, etc.) are applied should be placed in boxing, closures or insulated rooms equipped with local pullers and the necessary devices that prevent the spread of harmful substances.

Safety requirements when carrying out repairs

Conditions and procedure for performing repair work

The conditions and procedure for organizing, conducting equipment maintenance and repair work are determined taking into account the specific conditions for the use of equipment.

The equipment maintenance system is based on a set of maintenance and planned-careful repair work.

Maintenance is carried out in the period between each repair according to the requirements of regulatory technical documents on the use and maintenance of equipment by the service provider (machinists, apparatuses, operators, etc.) as well as technical personnel (assistant Masters, locksmiths on duty, electricians).

The volume of maintenance includes:
maintenance in the process of use-wiping, cleaning, regular external inspection, detection of all malfunctions, lubrication, inspection of lubricating and cooling systems of bearings, monitoring the condition of reinforcement details and joints, and checking the wire setting connected to the ground;
performing minor repair work on the equipment — eliminating minor defects, tightening reinforced areas and contacts, replacing preservatives and pads, partially adjusting, determining the general condition of the insulation, etc.

All failures detected in the work of the equipment must be recorded by the user staff in the shift book and eliminated by the user and service personnel in the shortest possible time.

The service personnel attached as responsible for the equipment are required to regularly review the records recorded by the user personnel in the shift book and take measures to eliminate the indicated malfunctions.

The need, period and duration of stopping equipment for maintenance purposes are determined by the enterprise, depending on the nature of the technological process and the possibility of safely conducting work. Maintenance (inspection) of machine equipment can be carried out with or without interruption of equipment, depending on the composition of the work.

It is envisaged to carry out current, medium and capital repairs in the service system, depending on the nature of damage and abrasion of the components of the equipment and the level of workability of repair work.

The main work of the current repair consists in carrying out maintenance operations, replacing quick-absorbing details and knots, repairing futerovks and anti-corrosion coatings, cleaning the insulation trench using compressed air, measuring its resistance, etc.

A sample list of works that must be performed in the current repair of a specific type of equipment is approved by the chief mechanic of the enterprise and is a mandatory application of the repair book.

It is recommended to draw up a defect record for the current repair of complex equipment (compressors, centrifuges, etc.).

Medium repair will consist of a system of repair work, which is carried out with the replacement or restoration of certain parts, nodes and their adjustment, in order to partially restore the resource of the equipment.

Overhaul will consist of a system of repair work carried out with the replacement or restoration of any parts, including the main ones, as well as adjustment, in order to restore the suitability of equipment and fully or almost completely restore their resources.

Deadlines for conducting repair work, appointment of responsible persons, requirements for the qualifications of persons performing repair work

To carry out repair work, the annual plan-schedule of repair of equipment and devices, the monthly plan-schedules of repair of equipment and devices, the monthly plan-careful repair schedules, defect records, cost estimates, work performance schedules, work organization plan, naryad-permission documents and other documents should be drawn up.

Monthly plan-careful repair schedules are made no later than the 25th day of the month preceding the planned date.

The defects record is compiled by the head and mechanic of the device and the device is discussed at the MTX session, after which it is submitted for discussion to the relevant departments for 90 days after overhaul and 30 days before the current repair.

The head of repair work receives the equipment prepared for repair from the head of the workshop or another person appointed by him, having drawn up an act of transfer of equipment to repair.

The equipment that has been overhauled is accepted by the head of the sex or the person appointed by him after the trial and expiration of the period of operation, having drawn up an act of transfer of equipment from overhaul at least three days after the expiration of the period of operation.

The need to separate (fence) the plot under repair and special requirements for the implementation of pre-repair work, ensuring the safe execution of repair work

The repair worker (contractor, repair service) is obliged to hang warning posters in places that will be dangerous when performing repair work, block holes in the wall designed to transfer equipment and materials to the repair zone inside the workshop. In the process of performing work inside the workshops, dug wells and ditches are blocked by the repair worker.

On the territory of the enterprise and in the shops, drawbridges with supports are built to pass through the trenches dug in the places where people pass. Warning signs and signs are installed on the fences, and at night — special lighting devices.

The sex administration is obliged to introduce sex workers to the order (order) that the object will be stopped for repair. Objects with a particularly high risk should be provided with a safe state and appropriate instructions for repairing the object.

In the event of a violation of the rules of safety equipment by the contractor's employees, the sex administration has the right to suspend work and exclude a violation person or the entire brigade from carrying out work.

The organization of training and instruction in the safe conduct of repair work, in the manner prescribed by this organization, is entrusted to the administration of the contractor.

When performing repair work, the contractor is required to ensure that the passages for transport to the workshops and fire taps and the area around and inside the workshops are not blocked by various types of equipment, materials and construction waste.

In the process of repair:

- a) testing of apparatus and pipes without completely eliminating employees from the danger zone and developing special measures;
- b) it is forbidden to carry out work related to fire at the same time, which can cause the output of potentially hazardous or flammable products in terms of explosion (opening equipment, pipes, cleaning them with air, etc.).

All persons participating in the repair must be in special clothing of the specified sample.

The equipment being transferred for repair must be cleaned of technological products, washed, if necessary — neutralized.

In order to exclude the possibility of activating the equipment before repair, the equipment's transmission ties must be in the position that they were removed as much as possible, hardened by gaskets placed under the start-up trays, the electrical circuit that drives the electrovigatels must be disconnected at least two places, as well as the "ignition is prohibited in the launch devices. Posters with the inscription" people are working " should be hung, as well as other circumstances should be marked.

In pipes working under pressure:

- a) disconnecting pipes from equipment assigned to repair;
- b) with the participation of the person responsible for carrying out the repair work, the sliding valves and valves on both sides of the disconnected plot and the drainage and circulation networks by its networks, as well as the sealing of the risers;
- v) sliding caps and valves that disable the part of the network that needs to be repaired are prohibited from "activating". Hanging posters with the inscription" people are working";
- g) depressurization in the off-pipe section;
- d) extinguishing sliding covers and valves should be removed by installing a section or equipment under repair, Stoppers (gaskets), which are recorded in the installation book, not necessarily dense. The plugs should be clearly visible butt and installed with the buttocks facing up.

To ensure the repair work of heavy-duty technological equipment, workshops and plots should be equipped with load-bearing machines and mechanisms with the ability to carry a load of the appropriate weight.

In order to work on loaders and mechanisms, repairmen are placed who have a certificate that they are allowed to work on loader mechanisms and receive special instructions.

Responsibility for violations of labor protection rules

Responsibility for the implementation of these rules in the design, construction, assembly of enterprises of pharmaceutical production pharmaceutical production shall be assigned to organizations that perform the relevant work.

Pharmaceutical production sanitation

Sanitation and hygiene

Production rooms of pharmaceutical enterprises should be kept in accordance with the rules of the following sanitary regime:

the amount of harmful substances in the air in the work zone GOST 12.1.005-2000 SSBT "air in the work zone. Not exceeding the maximum permissible saturation level according to the " general sanitary and hygienic requirements;

the permissible temperature, relative humidity and speed of movement of air in production rooms are determined by the excess heat in the workplaces, the category of work performed according to the degree of weight, taking into account the season of the year;

noise and vibration levels in production rooms GOST 12.1.003-89 SSBT "noise. General safety requirements", Gost 12.1.012-90 SSBT " vibration. No more than the amount set in the" general safety requirements " requirements;

electric light of production, sanitary and household rooms, raw materials and finished product storage rooms QMQ 3.01.05-98 "natural and artificial light. It must meet the"design standards" and provide sufficient light power to create normal working conditions. Also, in clean rooms, lighting devices have a structure that does not give a chance to accumulate dust, and in the event of a fracture, its fragments must be closed so that they do not scatter;

safety requirements to prevent the impact of electric current on a person GOST 12.1.019-86 SSBT "Electrical Safety. General requirements"to meet;

static electricity protection measures GOST 12.1.18-93 SSBT "static electricity. Spark safety. Implementation according to"general requirements";

Labor hygiene in chemical pharmaceutical enterprises

General definition of factors of production that determine the working conditions in the production of drugs

Chemical factor. The tests carried out show that the main incompatible influencing factors in chemical - pharmaceutical enterprises are pollution of the air of the working zone with harmful organic and inorganic substances, pollution of clothing and body skin.

Contamination of the air environment with toxic substances can be observed at all stages of the technological process: in preparatory, basic and final operations, the amount of harmful substances that can be contained in the production Air occurs due to insufficient level or lack of mechanization in the performance of most operations, a violation of technological order. These processes include transportation of drug materials, the introduction and release of substances into apparatus, the use of nogermetic chemicals, and the injection and release of chemical products into apparatus.

The composition of chemicals that pollute the air of the working zone at most enterprises in the production of medicinal preparations is complex in nature, and at the same time is a link with the presence of a large number of chemical ingredients in the form of aerosols, vapors or

gases. The stage of the technological process, depending on the type of medicinal preparation to be obtained, the air of the production rooms can be contaminated with ready-made products in primary, intermediate and chemical synthesis. In such conditions, harmful substances enter the body mainly through the respiratory tract and, to a lesser extent, through the skin of the body and the gastrointestinal tract.

The effect of a harmful substance on the body can be painted in the entire stages of the technological process: the preparation of raw materials is observed directly in the process of obtaining drug preparations, in the final stages. In this, the character and degree of influence of chemical factors on the body of workers is determined by the improvement of technology and chemicals, the receptor of medicinal substances, as well as the construction and planning of rooms and the organization of air exchange in them.

In the case of pollution of the air of production-rooms, a large roll is played by the occasional interruption of the technological process in the first place. The periodic operation scheme of longitudinal processing the implementation of the process is due to the fact that liquids or spill-repellent materials are laid and released several times during the day in apparatus and jichoses, and the material to be processed is transported in different ways. This situation significantly complicates the effective organization of activities to prevent air pollution. At the same time, the organization of the operation of the technological process according to a continuous scheme makes it possible to lose a number of processes and operations, the sources of which are considered polluting the air of the working zone (from semi-factories to apparatus. like packing, release, transportation). In addition, a multi-cocktail and dangerous hand cocktail allows you to create the best conditions for losing hair.

The degree of air pollution by vapors and gases of harmful substances is greatly influenced by the pressure value in the communication networks of the apparatus. From the point of view of hygiene -- the most appropriate cocktail conditions are created under the conditions of synthesis of medicinal preparations under vacuum, since in this case, poisonous substances cannot get out of the gills. Vacuum processes can be observed in the reactor compartment and are widely used in the extraction and examination of medicinal substances.

At the same time, a lot of chemical processes in the synthesis of semi-finished products and ready-made drug preparations are increased and go at high pressures. For example, the solubility of aniline from chlorbenzene goes at a temperature close to 200°C and a pressure of 5.9-9.8 mPa (6.0-100 atm), while the synthesis of Amine up to Phenol goes at a temperature of 35 degrees and a pressure of 19.6 mPa (200 atm). In such processes, ensuring the Hermeticism of the joists is achieved by connecting pipes and apparatus with flanneted compounds and applying fluoroplastic, asbestos-bearing and other rolled materials with a special structure.

Special chronometer observations show that an average of 10-12% of the working hours of apprackers in the production of sulfonamide preparations pass under conditions with high amounts of harmful substances. The highest level of contamination of chemicals is observed in sharoyites, where the Hermeticism of technological processes is disturbed. For example, in the phase of hydrolysis of phenylhydrazinsulfate in the production of amidopyrin, when sampling through a dense lid of the apparatus, it is observed that the concentration of sulfur gas is more than 4 times that of REC.

Dust. Dust pollution of the air of working rooms can be compromised mainly in the preparatory and final y stages of obtaining medicinal substances. At the preparatory stage, the

dust separator is the main source, the storage of raw materials is carried out in the delivery from warehouses to production shops, as well as the processes of grinding, mowing, sieving, transportation, laying them on apparatus. Chunonchi, high concentrations of dust are observed in workplaces at the stage of milling plant raw materials, grinding the initial components of synthetic means. In this case, the degree of pollution of the air of the working zone can be 3-5 times higher than the permissible levels.

At the final stage of obtaining drug preparations, air pollution is observed in the processes of contamination with high levels of dust of ready-made drug preparations, most often in the processes of tableting, dragging, drying, mowing, sifting mixtures, packaging and wrapping ready-made drug products, the concentration of dust can exceed the permissible values several times. In the work of vibrating sieves and especially in the process of manual sieving of products, it is observed that the concentration of dust in the working room air exceeds the permissible values by 5, and more times. For example, during the manual packaging of finished products, the concentration of dust in the air in the respiratory zone of workers can be 100mg / m³ or more

It is known that the nature of dust exposure to the body and the degree of conspicuous biological changes are largely determined by the dispersion of dust. The dust of certain drug preparations will be made up of powders 85-98% less than 5 µm in size. This creates conditions for large amounts of drug dust to enter the body through the respiratory tract and digestive organs (with saliva).

Microclimate. At the enterprises of the chemical and pharmaceutical industry, the microclimate of the production rooms must comply with the requirements of the installed CK-245-7i. However, the investigations carried out show that heated surfaces in apparatus and communication heat networks under insufficiently insulated conditions have a concomitant effect on the body of workers by chemical factors with a warming microclimate. The high temperature of the air fan can be mainly around apparatus (crystallizers, solutions, hydrolyzers), which go in drying sections and at high temperatures, and fall out with thermal separation. For example, in the hot season of the year, the air temperature in these plots will be 34-38°C and higher at a relative humidity of 40-60%. If we consider the conditions of the hot climate of Uzbekistan, this indicator can be 45-50°C

Thus, a warming microclimate in some workplaces at enterprises of the chemical and pharmaceutical industry can serve as an additional factor deepening the influence of chemical factors.

Noise. The source of the noise associated with the production of medicinal preparations on the aircraft is a very wide range of technological apparatus. They include compressors, vacuum-filters, drum dryers, centrifuges, product crushing and milling tools, vibrating sieves, vacuum-pumps, etc. can be entered. In some cases, the noise level exceeds the permissible levels. For example, in workplaces around centrifuges, noise parameters are more than 5 dB above permissible values, 5-6 dB around vacuum pumps, 14-17 dB next to compressors, The Machine section is considered the most inappropriate plots, and the accumulation level of high-frequency noise in these places is often more than 20-25 dB above permissible values. It should be said that even at the permissible level, production noise can deepen the effects of chemicals.

Wellness activities for cocktail conditions. The fight against air pollution of the production rooms should be aimed primarily at improving technological processes and chemical processes

in obtaining medicinal preparations. In this case, it will be necessary to carry out activities such as replacing harmful substances entering the drug receptor with less harmful ones, transferring open technological processes to a closed type, transferring high-pressure processes to low-pressure processes, mechanizing work processes, isolating heat from aggregates. The creation of New-new technical means makes it possible to improve the conditions of air conditioning and cocktails in the chemical-pharmaceutical industry in general, envisages the transition to continuous technologies with ensured Hermeticism, and creates conditions for the control and control of aggregates and mechanisms through distance.

Industrial automation is a huge asset in the fight against professional losses, allowing you to reduce the number of workers to a minimum and reduce them to be near technological joists. In doing so, automation of technological processes and their application-based management create conditions for creating interdependence of production aggregates by playing a large roll in the niche, independently performing the specified processes and coordinating its technological sequence when it is necessary.

However, even in conditions where the most modern technological processes are put into practice, it is impossible to completely get rid of the separation of gases, vapors, dust, heat and moisture in certain quantities into the air of the ham working zone. Therefore, the rational ventilation of rooms in order to counteract professional damage, along with the improvement of technological processes and Quixotes, has a great preparedness. In order to achieve high-efficiency ventilation of the air of production rooms, it is important to correctly plan the complex of rooms, make up the inner surfaces of the rooms and fences, and in this case use materials that do not absorb harmful chemicals from the Uzi; In the direct removal of harmful substances from their places of separation, it is advisable to install maxillary ventilation devices that correspond to the nature of the properties of the quixotic ones being used and the work to be performed.

For example, it will be necessary to fix the nutch-filters with zonts on which the curtains hang, to install the sampled faucets in pana places in the form of air-releasing cabinets. It is necessary to install zonty air suction cups with periodically opening lids of reactors and slightly protruding sleeves on the upper side of other jixozes. Large amounts of harmful substances can be released into the room air in sampling, opening the lids of the apparatus, releasing components from the reactors and other operations, so the use of personal protective equipment is required when performing such operations.

Between noise control measures, it will be necessary to pay great attention to improving the technological process, correctly planning production rooms, using noise-absorbing building materials (penoplast, felt, fatty fiber plates). From this, it is necessary to control the timely conduct of preventive examinations of apparatus and systems, in which the sources of the distribution of noise are calculated. In certain cases, it is recommended that workers make good use of personal protective equipment (angifones) in conditions where there is no possibility of lowering noise levels to permissible values.

Treatment and prophylactic measures for the protection of the health of workers receive the organization and conduct of preliminary and periodic medical examinations in their composition. In addition, it is important to adhere to the established order of Labor and Recreation, organize rational nutrition, practice physical education and sports.

Labor hygiene in the production of synthetic medicinal substances

Enterprises for the production of synthetic medicinal preparations carry out the release of several hundred types of various remedies, and their raw materials are attached to six groups:

Inorganic medicinal substances (bromine, iodine, potassium permanganate preparations).

Medicinal compounds in the aliphatic series (alcohols, simple esters, aldehydes, aldehyde acids, carbonic acids, aliphatic amines, amino acids and so on).

Medicinal compounds in the alicyclic series (terpenoids, vitamins - A, K, D, R, E, hormones, substances that replace missing serum).

Medicinal compounds in the aromatic series (phenols and their derivatives, aromatic carbonic acids and their derivatives, sulfanilamide preparations, aromatic sulfonic acid derivatives).

5. Organic compounds of elementoorganic medicinal substances (margarine, surma, bismuth, Mercury, phosphorus substances, x-ray contrast tools).

6. Heterocyclic and medicinal compounds (five- to six-membered heterocyclic compounds with one or two atoms).

The primary raw material of synthetic medicinal products is stone coal, oil and other substances, the products of extraction and processing are obtained, and their number is several hundred. These are organic and inorganic chemicals in various forms, being in liquid, solid and gaseous deposits. They are subjected to complex technological processing, mainly aromatic, to a lesser extent heterocyclic and aliphatic organic semi-products are obtained. Among the main ones are aromatic amines and nitroaromatics of various forms, phenols and naphthols, their sulfonic acids and haloid derivatives.

As auxiliary raw materials in the production of synthetic drug preparations, most inorganic acids (sulfate, nitrate, hydrochloric acid, oleum), organic acids and their anhydride (vinegar, Acetic, acetic anhydride), alkalis (sodium alkali, water with ammonia), salts (sodium, potassium, magnesium and so on) most metals and their oxides, sulfur, alcohols, esters, aldehydes, ketones are used.

Very, the technological scheme in obtaining a lot of synthetic preparations has a different character. For example, the preparation of sulfonamide, germane, narcotic and many other preparations consists of several stages (10 or more). In this case, this enterprise goes with the use of organic and inorganic compounds in very large quantities, characterized by a high degree of saturation with various devices and devices, type of water distribution network, gas, electricity, sewage and other communication systems.

The process of obtaining drugs consists of conducting chemical reactions, filtering operations, drying, grinding, mixing, sieving, weighing, packing and packing into containers.

The most characteristic reactions in drug synthesis are nitroxylation, sulfonation, methylation, ethylation, chlorination, and amination. The raw materials of these reactions are in their structure) apparatus, more precisely in reactors, which, by the nature of the work performed, are called aminators, nitrators, sulfurators, chlorators.

The initial processes in the synthesis of medicinal preparations are made up of a lot of preparation, operations, and the quality of raw materials brought from enterprises in the related field does not meet the requirements for the synthesis of drugs and established in large part. In such cases, primary raw materials are carried out in primary cleaning, such as washing, extraction, rectification, grinding, milling, sieving, re-crystallization. The primary connection of workers with harmful products begins with the time of obtaining raw materials from warehouses under the pharmaceutical plant and workshops and putting them in the apparatus.

In fact, the process of producing synthetic substances begins with the receipt of one or another semi-product, from which medicinal substances are synthesized through various possible reactions in the subsequent stages.

Primary components that have been pre-processed are placed in reactors. The application of products to the apparatus is carried out in most cases by pumps, air or steam pressure, load transmitters using its own flow or vakkum. Transportation of ingredients in preparatory workshops is carried out using lentasmion transporters, elevators, schnecks, as well as hydraulic and pneumatic systems. For these purposes, the workshops have independent pumping stations of the nodes, at which compressor, vacuum or centrifugal pumps are placed. In accordance with the technological regulation, most components are lowered into the apparatus heated or boiling. Aggressive, fire- and explosion-hazardous products may be involved in the reactions. This requires the use of the most improved technologies in its place. These technologies require measurement-control, recording instruments, high-quality communication and fixation and application with fittings. In the process, workers must strictly adhere to the rules of Technical Safety and cocktail hygiene.

At this stage in obtaining synthetic substances, the most common operations are such as sampling semi-finished products and ready-made substances through the open lids of the apparatus, controlling the acid-base resistance of the reactions that occur, and measuring the level of liquids. Despite the fact that these operations are carried out within short periods (3-5 minutes), they remain a source of the release of large amounts of harmful substances into the air of the working zone. For example, a large amount of sulfur gas, which is in excess of REK at the time of sampling during the hydrolysis step in taking amidopyrine, is released. In the Vakkum method, air muxite contamination will not be as high in the case of sampling points through hardware shutters or special sampling faucets.

Processes associated with the transportation of a reaction mixture from one apparatus to another require great attention and caution. As a rule, for the fact that most of the processes of certain reactions, departures and the synthesis of products are performed under great pressure, the release of toxic substances into the working air vent can be observed when the Hermeticism of the smokers is violated. Obtaining a lot of synthetic medicinal substances is associated with the filtration process. As the observations show, when performing these processes in filter-presses, nutch-filters, due to the fact that the open filtering area in the containers is significantly larger, nitrogen oxides, ammonia, farmaldehyde in large quantities can be discharged into the air of the working zone. Cocktail hygiene is most appropriate when serving drum filters, automatic filter-press, drum vacuum filters.

When synthesizing medicinal preparations, operations on the separation and extraction of the finished product from the reaction mass are carried out in extractor-apparatus, rectifying devices, crystallizers, various centrifuges. At this stage of the production of medicinal preparations, Organic Solutions of various types are widely used benzene, dichloroethane, toluene, chloroform, trilchloroethane and B.q. On this plot of production, workers can come into contact with harmful products in emergency situations, when the Hermeticism of smokers is violated, when a hand cocktail is used.

At the final stages of obtaining medicinal substances, drying, grinding, sieving, packaging of products is carried out. These processes should be carried out under such conditions that the dust, vapors or gases of medicinal products do not separate from the air of production at all.

Activities to improve cocktail conditions. Among the main health-improving activities in enterprises producing synthetic medicinal products, it is possible to include the widespread use of technological process improvement, automation and mechanization. In addition, the replacement of periodic technological processes with technologies that work seamlessly, the control of technological jixozes by distance are considered autonomous wellness activities. Preventive wellness measures, the planning of the type of production rooms in the system and the correct placement of technological facilities in these rooms in accordance with the operating procedure, the widespread use of air-permitting and local ventilation devices, standardization of starting products, personal protective equipment, etc.q. muxim has Ahamat.

The role of treatment-preventive measures and, first of all, preliminary and periodic medical examinations in the fight against professional damage in the production of drug drugs is high. The organization of rational nutrition of workers, the introduction of a scientifically based and recreational procedure, explanations on the safety of Labor and equipment, and production sanitation have a special purpose.

Labor hygiene in the production of antibiotics

One of the important tasks in providing Axolini with the necessary medicines is to further expand the development of antibiotics, which are widely used for the purpose of preventing and treating diseases. To date, more than 40 types of antibiotics and more than 100 forms of drugs have been produced in medical korchrnas.

Their total comparative weight is 18-20% within the industry - products related to medicine.

Antibiotics are substances that are developed in the process of treacherous activity of microorganisms, plants and animals of the upper stage and have the property of bactericidal or bacteriostatic action. To date, around 500 antibiotics have been produced globally that are related to the class of chemical compounds in various HIL. The antibacterial properties of antibiotics became the basis for their widespread use in medicine, in particular in the therapy of infectious diseases and inflammatory processes and the practice of their prevention.

In addition to the use of antibiotics in medical practice, Ham is widely used in the food and dairy-meat industries. They are added to their food in order to quickly increase the weight of animals and birds, so and so.

The technological process in obtaining antibiotics consists, accordingly, of several stages that are carried out in succession in quixoses: (a)maturing planting material and biosynthesizing (fermenting) antibiotics; (B) primary processing of cultural liquids; (v) filtration; (g) separation and chemical purification (extraction, ionalmashinization method, deposition method); (d) preparation of ready-made drug forms; (e)packaging and placement in containers. Primary technological processes are based on the cultivation of planting material in flasks and fermenters (produtsent). The grown production is a produtsent strain, which is transferred to special apparatus-inculcators in order to enrich it further. The process of growing molds, bacteria in inclusions is carried out under strictly defined conditions, which are provided by heating and cooling systems, air supply, special grips for mixing the mass being grown and enriched. After that, the producent is transferred to the fermentation process. Fermentation is said to be the cultivation (maturation) of the Deb-producent and the maximum antibiotic dressing. Antibiotics are synthesized in the body of microorganisms or secreted in the process of biosynthesis in the cultured fluid. The main solution for the fermentation process is fermenters. Their yield can be varied, even up to 100,000 liters. Fermenters are concentrated in

heating and cooling systems, giving a sterilized air mixture, a mixer, as well as mechanisms for the introduction and release of edible mucite and cultured liquid. This barrel of the technological process is described by the Hermeticism of the grips used. This practically eliminates the possibility of contamination of air mucite with substances used for biosynthesis of antibiotics, as well as biomass generated by the final stage of the fermentation process. The combination of antibiotics with a large number of substances that are present in the cultured bone to form insoluble braicmasci. In order to increase the concentration, as well as to ensure the full immersion of impurities in it, the liquid is sanded with hydrochloric acid until the pH is 1.5-2.0. The treated cultural fluid is filtered (filtered) until a tinic filtrate called a "native solution" is obtained to make it free of mycelium and precipitated ballast substances. The treated filtrate liquid flotation is carried out in rom filter - presses of the Open Series, resulting in the dissolution of the native solution. Syringes when manually applying products to filter presses can come into contact with a cultured liquid that contains antibiotics. The next step in obtaining antibiotics is separation and chemical purification. At this stage, the concentration and purification of an antibiotic solution is carried out to such an extent that it is possible to obtain a ready-made drug from it. The amount of antibiotics in a Nativ solution is very low, so it is a very complex and laborious process - to extract it cleanly, clean it and bring it into the form of a ready-made medicine. For example, to get 1 kg of antibiotics, you will need to process about 600 liters of cultured fluid. In antibiotic extraction and chemical purification, one of the following methods can be used: 1) extraction method with the use of different solutions; 2) deposition method; 3) ion replacement method. In the biosynthesis of antibiotics, the extraction and ion exchange method has wide application. In recent years, Ham has been used to obtain other types of drug preparations from the ion exchange method in antibiotic separation and purification. The main advantage of this method is that there is absolutely no way to use toxic and explosion-hazardous solutions in this: The method is also useful from the economic side, since its technology is simple and expensive, the price does not require jixos and raw materials. The extraction of antibiotics from a sodium solution is carried out in extractor - separators, the main drawback of which is the manual injection of the product into the extractors, as a result of which the air of this sex can be contaminated with solutions. For example, in the production of tetracycline and oxytetracycline, air mucitis with the substance isooctanol can be contaminated. In addition to solutions to air muxit, oleic acid, sodium alkali, chauvulic acid, butyl and ethyl alcohols, butylacetate and b, due to the poor improvement of the chemicals used in the separation and chemical cleaning of antibiotics.q may fall. The ion sorption method is such that the sodium solution is transmitted to ion-Exchange columns containing sulfocationite SBS-3 using centrifugal pumps. As a result of Ion exchange, the antibiotic is sorbed into ionites, which is then desorbed in an ammonia-borate buffer solution.

This method has a number of advantages over the method of deposition and extraction. When working with sinks, it does not require manual labor, which puts an end to the possible contact of workers with concentrated solutions and sinks and antibiotic residues in place of 3. In addition, this method does not use poisonous Organic Solutions.

The pasty product obtained in the process of chemical cleaning is then dried and sieved. The drying process in the production of antibiotics plays a very muxim roll, since its correct Organization determines the quality of the product produced. Thermostable antibiotics, which are obtained in crystal clear and have a certain moisture content, are usually dried in vacuum

drying cabinets. Antibiotics obtained in the form of water concentrates after chemical cleaning are sent for drying in evaporative-drying aggregates and vacuum-sublimated dryers. The use of manual labor in placing and releasing products into cabinets in the drying department is the main disadvantage of the technological process in this department. This indicates that the performance of operations, as well as the mixing and drying of the powdery drug mass, control of the working order, can keep workers in contact with antibiotic dust. Insufficient hermetic closure of drying cabinets contributes to the release of certain toxic substances into the air of production rooms, and the residual concentrations of these substances can be contained in the composition of antibiotics. For example, a methanol residue, tetracycline - isooctyl alcohol, chlorohydrate tetracycline, and oxytetracycline - P - butanol and hydrochloric acid residue can be found in ready-made chlorotetracycline. Sterilized dried antibiotics are packaged in sterilized glass jars (vials). Dosing dry antibiotics in vials, clogging, sealing and cooking are performed in vending machines. In some cases, a semi-automatic "technologist" can be used for this purpose. In this case, only the filling of vials with antibiotics is automated. All other operations are performed manually, therefore, under such conditions, the air of the production rooms can be contaminated with the dust of antibiotics. In the case of packaging several types of antibiotics at once, workers may experience the combined effects of these products. For drinking purposes, antibiotics are excreted in the form of tablets or dragees, the process of taking antibiotics is as follows: the raw components that are part of the antibiotic – fillers (sugar Tolga, calcium stearate, talc) are placed in a blender, mixed and moistened with a mixture of granulated sugar, gelatin, hydrochloric acid and ethyl alcohol. Then the resulting mass is transferred to the granule and directed to drying. Drying is usually done in calorific dryers. After the pellets are dried, the talc, calcium stearate and starch mixture are treated with an interpretation to increase the desiccation property, then cipsulated and deposited in convalutions in Rotary pill machines, described from a hygienic point of view by the fragmentation of the pill-making process, insufficient Hermeticism and an abundance of manual operations. For these reasons, antibiotic dust can practically get into the air of the working zone at all stages of the pillaging operation.

Lecture 6. Qualification of the ventilation system. Heating, air conditioning and lighting system in pharmaceutical production.

Plan

- 1 qualification of the ventilation system.
2. Heating system in pharmaceutical production.
3. Air conditioning system in pharmaceutical production.
4. Lighting system in pharmaceutical production.

Key words and phrases: technique and fire safety. Pharmaceutical manufacturing sanitation. Control maiori-application of technical documentation

The allotted time is 2 hours. Views of ventilation and its device

Ventilation in production is a system of necessary devices to release excess heat, moisture, dust, harmful gases and vapors from rooms and create a microclimate, in accordance with the requirements of the state standard.

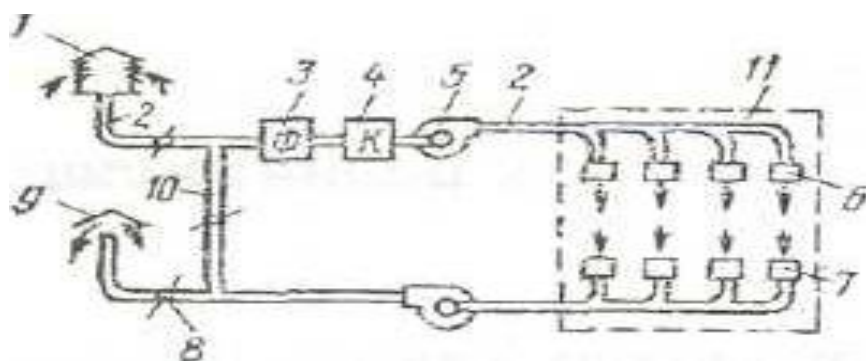
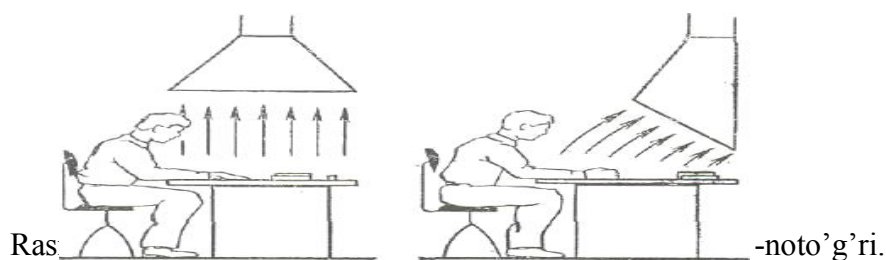


Figure 1.1. Mechanical air inlet and outlet blowers.

1-Air receiver; 2-air transmitters; 3-filter; 4-calorifier; 5-centrifugal blower; 6-air inlet holes into the room; 7-air outlet holes; 8-adjusting valve; 9-air outlet device; 10-transmission device that provides air circulation; 11-room.

The exchange of air in the rooms is carried out through the windows and pipes for this purpose in a natural way, at the expense of the difference in the temperature and pressure of the indoor and outdoor air. Such ventilation is called natural ventilation or aeration. Blowers can transfer air to the room and release air from the room, or do both of this at the same time. Blowers are divided into general and local blowers, depending on the place of use.



Generalizing

while the blower replaces the air in the entire room, the local blower replaces the air in certain areas (figure 1.2). The efficiency of the blower will depend on the capacity of the ventilation device and compliance with certain rules for the organization of Air replacement.

The air being released from the room must be taken directly from the place where the lesions are being separated or from the contaminated zone. In doing so, it is necessary to prevent the flow of dirty air being released from the room from passing through the zone where people breathe, or through the zone where people are more frequent. The dirty air that is discharged out of the room should be released in the direction where the wind flow is good

Air exchange detection. The design of ventilation begins with the detection of air exchange in rooms or workplaces. This takes into account the climatic zone, the season of the year, excess heat in the air environment, humidity, gases, dust, etc.

If several harmful substances are separated from the room in one direction at a time, the total ventilation calculation is carried out by generalizing the necessary air volumes to lower each substance to a safe concentration.

If several harmful substances are being separated from the room in each direction at the same time, the air exchange is calculated separately for each of them, and then the maximum value of the calculations performed above is accepted when calculating ventilation.

In rooms with a Normal microclimate and in rooms where there are no harmful substances or the amount of harmful substances in the air is within the permissible norm, air exchange is determined by multiplying the number of workers by the amount of air per pi worker, which corresponds to the norm by W_m .

YA'ni

$$W = n_i W_m \quad \text{m}^3/\text{soat} \quad (1.1.)$$

Air exchange to release damage in the form of gas and dust from the room W_{gch}

$$W_{gch} = V_{gch} / (V_{xx} - V_{xk}) \quad (1.2.)$$

here V_{gch} -the amount of harmful substance excreted from the room, mg / hour;

V_{xx} -the permissible amount of harmful substances in the room air, mg/m³; V_{xk} -the amount of harmful substance in the air entering the room, mg/m³.

V_b of harmful vapors and injectors that are excreted in the paintwork. land quantity (g / hour)

$$B_{b, \text{yer}} = 0,01 S m_{\text{yer}} q_c, \quad (1.3.)$$

Where S is the area of the surface on which the object is painted, m²; m_{yer} is the contribution of volatile peanuts in the paint, %; Q_c -1 m² is the varnish on the surface on which it is painted, the consumption of paint materials ($Q_c = 60 - 90$ g/m² on spraying or $q_c = 100 - 180$ g/m² on dyeing with,

The amount of VDV (uglyerod oxide, nitrogen and aldehyde oxides) of harmful substances released into the air when operating internal combustion engines (kg / h).

$$V_{dv} = (A_1 + B_1 V_{dv}) q_x t / 6000, \quad (1.4.)$$

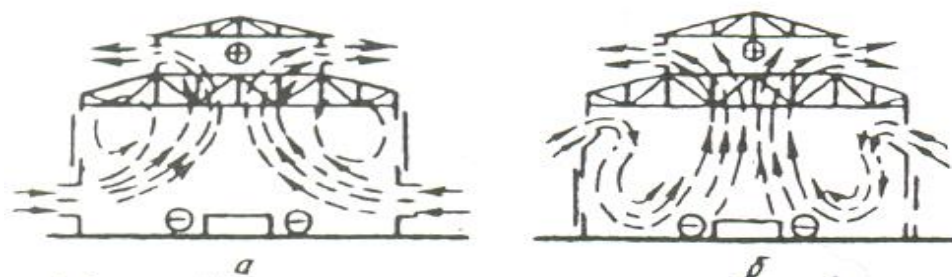
where A_1 and B_1 are equal coefficients: $A_1=9$, $B_1=12$ for carburetor engines; $A_1=160$, $B_1=13.5$ for diesel engines; V_{dv} -working volume of engine cylinders, l; q_x -volumetric contribution of harmful substances in exhaust gases (for carburetor engines-uglyerod oxide – 4...6 %, uglyerod oxide for diesel engines 0.05...0.07 %, nitrous oxide 0.007...0.009 %, aldehyde oxide is taken 0.035...0.050%); T -engine run time. Ayrim qishloq xo'jalik ishlab chiqarish xonalarida, masalan temirchilik xonasida, oziqa sexlarida, issiqxonalarida va shunga o'xshashlarda ortiqcha issiqlik ajralishi kuzatiladi.

Ortiqcha issiqlikni chiqarish uchun havo almashinuvi W_i (m³/soat)

$$W_i = 3,6Q_{opt}/C \quad (1.5.)$$

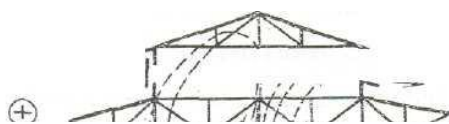
where Q_{opt} is the total amount of excess heat separated from the sources in the room, Vt ; S is the heat capacity of dry air (approximately equal to 1 j/kg of calloria); ρ_{vn} is the density of air entering the room kg/m³, t_{vv} is the room temperature in accordance with the state standard, °C; t_{vn} is the

Natural ventilation. In accordance with sanitary norms, all rooms should be designed natural ventilation. The natural movement of air in the room occurs according to the difference in air densities and due to the difference in internal air pressure with external air (4.3.- image).



1.3.- fig. Air exchange scheme, which is carried out at the expense of air density.

Tabiiy shamollatish xonalarning chiqarish kanallari, shaxtalari va darchalari orqali amalga oshiriladi. Bular o'z navbatida, xonadan katta hajmdagi havoni chiqarish va unga kiritishni mexanik shamollatkichlarsiz amalga oshiradi va bundan tashqari u mexanik shamollatish sistemasidan arzonidir. Tabiiy shamollatish issiq sexlardan ortiqcha issiqlikni chiqarishning eng yaxshi vositasi hisoblanadi.



Rasm 1.4. Shamol yon tomondan bo'lganda bino ayerasiyasi.

This is divided into types according to the disadvantage of ventilation, the strength and direction of the wind, the nature of the operation of natural air exchange devices. Such a ventilation system is called organized if devices are installed on ventilation devices that adjust the amount of air flow direction.

Deflectors are used in order to increase the tensile strength of the air. It is installed at the top of the ventilation ducts. As a result of the passage of air flow through the deflector, thinning is formed in the air ducts, and under the influence of this, the speed of air in the channel increases.

The diameter of the deflector is defined as:

$$D = 0,0188 \sqrt{W_d / v_d} \quad (1.6.)$$

where W_d is the working productivity of the deflector, m³ / s; v_d - the speed of air in the deflector, m / s. In accounting cases, $v_d = (0.2-0.4) \times v$ can be assumed. Where v is the airspeed, m/s. The performance of natural air exchange devices depends on how correctly they are used. Therefore,

when the elements of natural air exchange devices are installed, they must be tested. To do this, the channels and holes in which the air exchange is envisaged are opened, and their surface is determined. An anemometer is installed in the middle of the airway, measuring the speed of the air. The performance of the ventilation device is found based on the results obtained as follows:

$$W_T = 3600 v_{an.x} S_{XT}, \quad (1.7.)$$

here $v_{an.X}$ is the speed of air according to the anemometer display, m/s; S_{XT} is the total surface area of the air passage holes, m².

The total duration of testing should be 1.5...2.0 hours in the stationary technological process in the workshop. Air humidity is determined using psychrometers installed in the hole. Since the humidity of the air entering the room from a homogeneous hole is homogeneous, it is measured with one psychrometer, while the humidity of the air leaving the room is measured with several psychrometers.

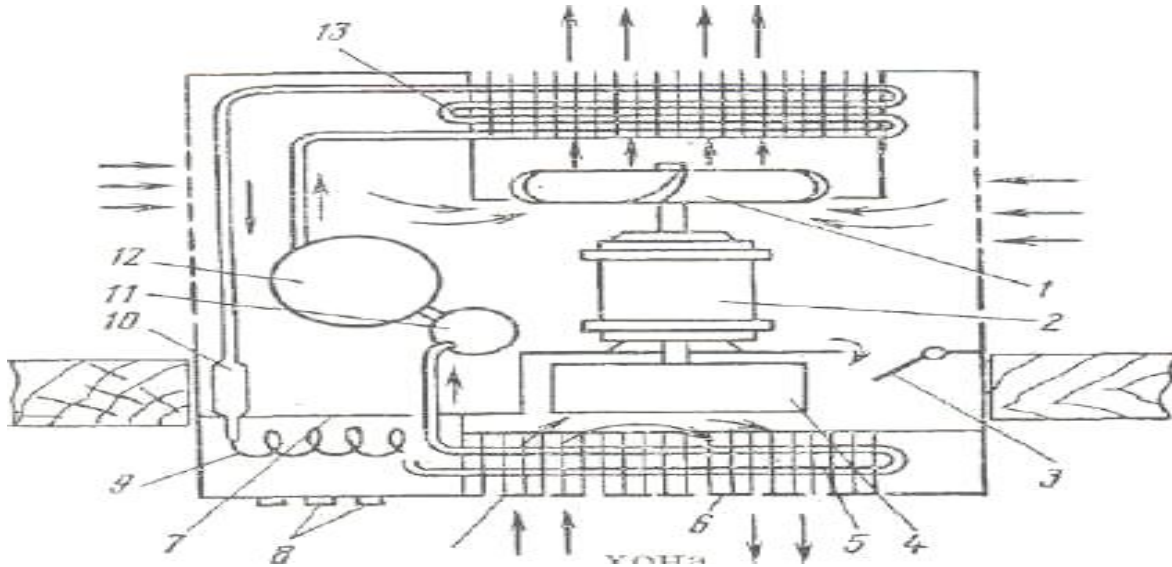
The mass of air entering and leaving the room G_X (kg/hour) is determined based on the result of the checks as follows:

$$G_x = W_1 \times \rho_x, \quad (1.8.)$$

where ρ_x is the density of air entering or being released into a room.

Mechanical ventilation equipment. In mechanical ventilation systems, the movement of air from one place to another is carried out using centrifugal and axial blowers or ejectors (4.6.- image). In the centrifugal blower, the working wheel with a shovel will be located in the shell-shaped cojoux, and the axial blower will be located in the cylindrical cojoux. Centrifugal blowers low pressure (up to 1000 Pa), medium (1000 to 3000 Pa) and high pressure (3000 to 15000 Pa)

The air entering the room is heated using a calorifier. And for air cooling, two types of air relief coolers are used: shallow and contact. Surface coolers are structurally similar to calorifiers, and are served by cold water, ammonia, or freons as Cold Carriers, with air-contact cooling done by passing air through the wet cavity of the irrigation chamber.



1.7.- fig. The principle scheme of the capacitor BK-1500.1-axis blower. 2-electric motor of the blower. 3-zaslonka. 4-centrifugal blower. 5-evaporator.6-air filter.Hurdle 7. 8-Control Remote. 9-capillary tube. 10-drying filter.Expander 11.12-rotary compressor.Capacitor 13.

Air conditioning. Simple ventilation system

An air conditioning device is important in the ventilation system. To do this, air is passed through a special dust holder and filter. The common use of a dust catcher is a cyclone (8.-image). Industrial fabric, paper, oil electric and ultrasonic filters are produced. The oil filter filtering element is a metal mesh dipped in oil.

Blowers cannot provide all the parameters of the air at once in the zones where workers work. Only conductors can perform these tasks. They can automatically adjust the temperature, humidity, air excitability and purity of its release and ionization. In incomplete convolution, a fraction of the numbered processes are performed, and in complete convolution, all are performed.

The conditioning system is divided into central (serving several rooms) and local (providing a microclimate in one room) types.

In addition to condensationers, which provide a normal microclimate for humans, there are also condensationers, which are used to increase the shelf life of various agricultural products and for another purpose in ensuring the turunity and cleanliness of technological processes.

In order to ensure the microclimate in home and administrative rooms, household condensationers such as BK-1500 and BK-2500 are produced (Figure 8).

The BK-1500 conduit is designed for rooms with an area of 25 m², and the BK-2500 for rooms with an area of 35 m². These capacitors perform the following functions: cool and dust the air, automatically maintain the air temperature, reduce air humidity, change the direction and speed of movement of air flow, and in addition, in the ventilation mode, the manufacturer can replace air with the external environment.

Heating, air conditioning and lighting in pharmaceutical production

The purpose of the topic is to provide students with information about heating, air conditioning and lighting in pharmaceutical manufacturing enterprises and the formation of primary skills.

Heating in production. Views of the heating system

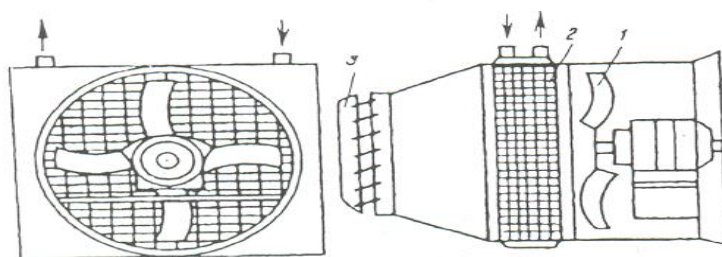
Heating is intended to maintain air temperature to ensure normal operating conditions in the working zone. Heating takes place in local and Central views. In production conditions, local heating is used in the cabins of moving machines and when heating rooms with a total area of no more than 500 m², located far from the main production building. In the rest of the cases, central heating is used.

Water, steam and air are used as heat sources in heating. Water and par are piped to heating devices installed in rooms by heating in special boilers. The hot air transmitted to the rooms is heated in calorifiers in large quantities, and water, vapors, are heated by electricity. Accordingly, heating is divided into water, steam, air and combined heating. When heating with water or steam, radiators or ribbed pipes are used as heating devices.

The heating system with air is divided into central and local types. The central system of heating with air will be equipped with driving equipment. In such heating systems, calorifiers are installed outside the heated rooms. If heating of a certain zone in the room is required, then heating units with local air are installed (4.7.- image).

From the point of view of labor protection, it is necessary that heating systems ensure the air temperature of production buildings and workplaces to be homogeneous throughout the heating season, be safe for fire and explosion, and be associated with ventilation systems and convenient in use.

In order to carry out the main and remont-restoration work, heating must be carried out in any buildings and structures where people work long, time or constantly (more than 2 hours).



4.8.- fig. Scheme of heating unit with Air: 1-blower; 2-water radiator: 3-iron closers.

The temperature of water in heating systems with low pressure water is 85 at the time of access to heating devices...95°C, and when kayaking from them it is around 65-70°C.

The heating system with high-pressure water will be made up of a closed system that creates a mechanical circulation of water. High-pressure heating systems in heating equipment reach temperatures of 120-135°C.

Steam heating systems are also in turn low-pressure (up to 70 kPa) and high-pressure (up to 70 k Pa).

In heating systems with air, cold air is transferred to the awnings of calorifiers using absorbent blowers, and at the time of passing between high-temperature awnings, the heated air is directed into the room.

Heat supply of chemical pharmaceutical production enterprises.

Most of the enterprises operating in the chemical-pharmaceutical and biotechnology sector are supplied with heat and electricity using thermal power centers, some enterprises have their own private heating centers or boilers.

Thermal power centers are steam turbine power stations where, together, heat or electricity is generated and transferred to networks. The purpose of generating heat and electrical energy together is to transfer the heat of steam treated in the turbine to the heat grid. This prevents the loss of heat in the energy supply system to the environment in the process, and the fuel consumption is 25...Reduces to 30%.

Heat supply of enterprises is carried out in a centralized way using thermal power centers. It also takes large investments and a long time to build thermal power centers (for example 5 or 6 years). Also, the trunk heat networks quickly fail, and in them 20% of energy is lost, and in electrical networks up to 17% of energy is lost.

Heat Supply Systems.

Heat supply systems are described as follows: by working capacity, by the source of heat and by the type of heat carrier.

Heat supply systems are divided into maximum and central heat supply systems according to their working capacity.

Local heating devices with heating devices designed for industrial production - an example of the type of local systems of the Heat Supply System. This method is not designed to transport heat over long distances. As advantages of the domestic heat supply system, it can be said that in such a process, without dependence on thermal power centers, the product can be heated to different homogeneous high temperatures.

As disadvantages, the following can be said: when setting up and fixing this device, a large amount of material costs is spent, the coefficient of use of fuel heat is small (20...60%), can pollute the environment, has excessive large costs for repair and adjustment.

In a centralized Heat Supply System, the heat from which the common sources of use are calculated is transported from electrical centers or district heat centers, to heat production enterprises. This system consists of: a steam turbine device (generating electrical energy and transferring heat with Steam) or heat generators that generate steam and water of the desired parameter; heat networks equipped with auxiliary devices that provide heat transport (steam and water); heat receivers.

Auxiliary heating devices or boilers are built only where the central heat supply system is not satisfactory.

The larger the source of the Heat Supply System, the greater the useful coefficient of work, and the greater the consumption costs of the heat network.

The heat in the Heat Supply System is divided into water and steam heat carriers, depending on the appearance of the carrier.

Water is used in residential buildings and apartments, and water and Steam are used in industrial enterprises. Water has been used as the sole heat carrier in recent years.

The advantages of water in its use as a heat carrier are: long-distance (50...60 km) can be transported; can be controlled centrally in conveying heat to ist'emolchi, central heat supply is able to maintain heated steam condensate in the electrical system, it is easy to connect heat to the trunk networks being transferred to ist'emolers, and finally, water heat networks are long and reliable operation.

As for the disadvantages of water: the fact that the heat with a temperature of more than 2000C cannot be used as a carrier, and the huge energy consumption in conveying to the consumer is the expense.

Advantages of steam: steam can be used directly in technological devices, there will be no energy consumption costs for transportation, it is possible to quickly heat steam networks, the surface of heating devices will be small.

As a disadvantage of steam, the following can be said: a large amount of heat is lost from the steam networks to the environment, heat delivery to the IST'emolchi will be limited (can be transported up to 10 km), due to corrosion of pipelines, steam systems will serve for a low time, condensate pollution and leakage can occur, it is difficult to collect. Thus, the use of single heat carriers Heat Supply simplifies the system, excessive consumption reduces costs, ensures high-quality and inexpensive use of equipment.

Water and steam grid systems can be implemented through single-pipe, double-pipe and multi-pipe systems. In a single-pipe system, the hot water being transmitted to the IST'emolchi does not return to the station. In this case, hot water is spent first on heating apartments and enterprises, and then on providing hot water. In a network in such a system, it is ensured that the water temperature is heated to 1800C and above to reduce excess costs.

If it is necessary to provide heat to long-distance objects, one-pipe systems are used when the cost of installing a pipe that returns heat to the station and the fuel consumption of pumps in the networks is large.

The two-pipe system ensures that the water returned from the IST'emolers returns to the Heat center, with reduced costs for fuel and for water preparation, since the quality of the circulating hot water will be at a high level.

Heat consumers.

Chemistry is considered to apply to the field of Pharmacy and biotechnology to the following processes:

1. Water and Steam are both heat carriers and reagents at the same time.
2. The heat dissipation process is a process with a small temperature (130...1500C).
3. The main parameter of heat carriers is the temperature required to optimally carry out technological processes and the creation of a microclimate in the workshop of the enterprise.
4. The expenditure of heat for technological processes depends on climatic factors (that is, on the temperature of the outside air).
5. In enterprises, the reuse of secondary energoresurs that are being generated in the form of heat, covering the costs that will be spent on Heat Supply with this recycled heat.
6. The parameters of the use of heat in various homogeneous production enterprises differ from each other.

Heat can be used for the following purposes:

1. Heating enterprises, ensuring air exchange, cooling the air, providing hot water (in this case, the temperature of hot water can be from 600C to 700c), in residential buildings, the

temperature of the outer surface of heating radiators should not exceed 800C, and in manufacturing enterprises this temperature should not exceed 1000C.

2. Thermal technology devices and devices (reactors, heaters, evaporators, rectification columns, dryers, etc.). In these devices 0,3...0.8 MPa ($t < 1800s$) of pressurized water vapor and water (at temperatures up to $t = 1500C$) are applied. In biotechnology, water vapor is mainly used with a pressure of 0.3 MPa and a saturation temperature of 132.90 C.

Power-operated technological devices (presses, grinders, steam pumps, turbochargers). This direction is not commonly used in biotechnology.

The process of providing enterprises with heat is among the processes that work in the season. All other processes are considered processes carried out throughout the year.

In the summer season, the decrease in heat loss is due to the fact that the use of heat by enterprises is reduced, the amount of heat that can be spent on heating raw materials, intermediate products and the air of drying devices is relatively reduced. But on the other hand, there are difficulties in the operation of cooling and freezing systems, and excess energy is used for these cooling systems.

Heat dissipation modes.

The heat dissipation regime of an enterprise can be seen from the time dependence drawing of heat expenditure. The drawing of spending a day of heat depends on the type of technological process, duration of work, volume of production and other indicators. To obtain accurate results, calculations based on the technologist are carried out or formed by using a device.

In the absence of this data, the comparative consumption of heat (in steam, hot water, in Cold Carriers) is used for technological purposes. The specific heat consumption indicator depends on the modern adaptation of the technological process, and over time, the technological system is modified in addition to the year. Heat carriers and their parameters also change. Therefore, the specific heat consumption is used in the approximate estimate of heat consumption and the determination of heat consumption for technological processes in the calculations of desirability.

Heat spent for production purposes $Q_{i.ch.}$ and the amount of product produced is expressed in terms of the dependence of P by the following equation:

$$Q_{i.ch.} = Q + qP$$

Here,

Q is the heat consumption that does not depend on the amount of product being produced, q is the consumption of the specific heat to produce a single product.

The graph of the expenditure of heat for a day of the enterprise in the process of two-shift work is shown in the figure below.

In the scheme presented in the picture, it is described that heat is spent during the A -week, b -month and v -year.

The indicator of the uneven distribution of heat consumption is the "hour of the number of uses of the maximum heat load" and is determined by the amount of heat consumed:

$$\tau_{\max} = \frac{Q_{yil}}{Q_{\max}}$$

Here, Q_{yil} is the total consumption of one year of heat, Q_{max} is the maximum amount of heat per hour.

Typically, technological devices in the biotechnology industry run an average of 8,000 hours per year, while the maximum number of uses for heat loading is 5,500...5,700 hours.

Heat carriers and their parameters control methods.

Steam-turbine power centers in industrial enterprises transmit heat using steam and hot water. The parameters of the heat carriers being transferred do not always satisfy the consumer. Devices that control the desired pressure and temperature of the heat carrier are called heat preparation devices.

To increase the steam pressure and temperature, devices with steam-flow compressors are used. Reduction coolers are used to reduce steam pressure.

To reduce the temperature of the water, elevators are used, which appear to be water-flowing, where high-parameter water absorbs cold water (which is usually reused under the influence of heat). As a result, at the exit from the elevator, the water will have the necessary parameters.

In some systems, water can also be cooled by atmospheric air, a process carried out in gradirnya devices, with water being treated from top to bottom and air from bottom to top.

Central heating points of the enterprise.

A manufacturing enterprise is usually connected to one central Heat point if it is made up of different hil workshops, and they are located in different hil territories of the enterprise.

Central heat points are established in steam turbine power centers or districts to control incoming heat, control the parameters of heat carriers and ensure the delivery of heat in the furnace to an individual workshop in the enterprise.

In the picture below, the central heating point of the enterprise is placed. Steam 1 enters the territory of the enterprise through pipelines. The consumption of steam is measured by the consumerator 2. The distribution of steam to a different homogeneous system is carried out through Collector 3. This collector is mounted with devices that measure the pressure and temperature of the Steam.

If all systems at the enterprise will need reduced pressure steam, a reduction coolant is installed before the collector, and a protective Valve is installed in the Collector.

According to the order of the local Heat Supply Systems, reduction valves 4 and water heaters 5 are installed on the streams radiating from the Collector. 7 water is transmitted through the pipes using pump 8.

Hot water is transmitted to the IST'emolchi through the pipes. The condensate coming out through the Steam road and collector comes to the condensate collector through the exhaust pipes, as well as through the water heater and through the pipes of the maximum heat supply systems, through the condensate transmitter, and from there through the condensate road with the help of a pump, heat is transferred to electrical centers or district heat points. The speed at which the pump is transmitted is controlled using a sath controller, the condensate consumption is determined by a water meter. If the pressure in the condensate collector is greater than the pressure in the condensate transmitter, the condensate can be transmitted without the help of a pump.

Heat dissipation devices.

Heat sinters must meet the following requirements:

- must be provided with devices that control and measure temperature, pressure and consumption,
- must have protective valves,
- must be provided with condensate and air conditioning units and sample separators,
- must be provided with devices that reduce temperature and pressure if necessary.

Devices and equipment must have the following documents :

- passport,
- drawings,
- execution schemes of apparatus and pipelines,
- instructions for use and repair,
- rights and obligations of employees using the device.

The heating, ventilation and air conditioning system in production buildings must be designed in accordance with the current building standards and regulations according to the requirements of the instructions for the sizing and construction of industrial enterprises, as well as this document.

Production rooms work effectively. the vent flow controller, flow creator and absorber must have a ventilation system, instruments to measure temperature, humidity, filtration efficiency and pressure changes in the filter, and an OOP - test (hermetic and leakage testing).

The effectiveness of the flow supply system in ventilation and air conditioning should be determined in the operating zone, taking into account the adopted scheme for organizing the exchange of air, resulting from the conditions for ensuring the required parameters of the air supply.

The blower device of the blower ventilation is installed on the roof, as far as possible, to the clean place of the blower, taking into account the direction of the wind. The airflow, which is fed to rooms belonging to the B and C levels of cleanliness, is cleaned in three stages.

The air flow supplied to rooms belonging to the D - level of cleanliness can be cleaned in two stages.

The ventilation air preparation system must ensure the cleanliness of the air in the " clean " rooms in accordance with the schedule and a positive change in pressure compared to the surrounding rooms with a much lower level of cleanliness. In neighboring rooms where the level of cleanliness is different, the pressure change should be 10-15 Pa, as a rule.

Filter chambers and internal and external surfaces of ventilation devices in " clean " rooms must have a coating that allows them to be treated with a disinfectant solution. With the help of air pollution control devices, it is necessary to regularly assess the effectiveness of the work of filters. The replacement or hermetization of filtering equipment means that the replacement period has come when the air flow resistance has doubled compared to the normative indicator, as indicated by the instruments. Increased resistance indicates a decrease in filter efficiency or its damage.

The air supply system for the production rooms of penicillin antibiotics must be fully isolated from the air system in the production rooms of other medicines in medical need.

The generating capacity of the suction ventilation system must be equal to 80-90% of the generating capacity of the discharge ventilation system so that it does not completely absorb the air in the "clean" rooms.

The sucking air in the production rooms is passed through an elegant filter in order to prevent poisoning of the environment.

In the production of sterile drugs, depending on the need, in order to protect the most responsible plot or operations, it is possible to create a horizontal or vertical laminar flow all over the room or in a separate small zone, using special devices.

In a "clean" plot or "clean" room, where vertical laminar flow is created, a flow-giving ventilation filter should be placed inside, and a suction ventilation hole should be placed on the floor or at the bottom of the wall. In "clean" rooms or "clean" plots with horizontal laminar flow, flow-giving filters and suction ventilation holes are placed along opposite walls.

"Clean" belts must meet the following requirements:

- the guide flow, cover and surface of the panel should be made of smooth and durable material;
- pre-cleaning filters must be made of material that can be used once or cleaned thoroughly and used again;
- final filtration, pre-tested and hermetized, is carried out through elegant filters;
- laminar flow rate should be around $0.45 \text{ m} / \text{s} \pm 20\%$;

The work of sterile air laminar flow devices should be constantly monitored in accordance with the relevant instructions and the inspection schedule.

At the required points, the production rooms can be equipped with a air conditioning system that provides airflow, and it must provide

- clean the air from microorganisms to the appropriate extent;
- automatic control of climatic parameters (temperature and relative humidity of the basin) on the way to creating the most favorable conditions for the operation of technological processes and personnel;
- to have high aerodynamic stability to maintain optimal air distribution and other parameters in the building and its individual rooms;
- elimination of the appearance of static electricity and associated dust accumulation;
- low noise during Operation,
- construction using material that does not resist disinfectants and does not emit dust, as well as anti-rust (corrosion) coatings.

Each building must have a system for supplying compressed air, if necessary, nitrogen, as well as a technological system for distributing them to all the necessary rooms.

The absence of impurities or oil vapors in the air being supplied from non-lubricated compressors is darcor.

Air and nitrogen in the pipes are dehydrated in order to prevent the vapors from condensing.

Lighting

The power supply and electric lighting network of production buildings is designed on the basis of the rules of construction standards and other regulatory documents in force.

All production household and sanitary rooms and storage rooms, especially those with eye control, must have a lighting network with sufficient capacity to create good working conditions.

Lighting devices in " clean " rooms must meet the following requirements:

- structure dust-free and convenient to assemble;
- the top must be closed so that the pieces are not scattered around when broken.

Sanitation

Production rooms must be kept clean and in the appropriate order in accordance with the rules of sanitary order. It is not allowed to grow flowers, accumulate ahlat, the appearance of insects. The fact that each enterprise has a program for conducting sanitary events, which sets out the following::

- list of rooms and equipment to be assembled and processed, style and their periodicity;
- list of inventory, material, washers and disinfectants used in room Assembly and equipment processing;
- list of employees and managers charged with assembling rooms, performing equipment processing.

From these instructions, the relevant personnel are constantly kept in an alert and are included in the program for training and professional development of personnel.

Washers and disinfectants used in the assembly of rooms and in the processing of equipment it is necessary to allocate a room for storing inventory and materials. To prevent the appearance of microorganisms in a stable form, it is necessary to replace disinfectants. Disinfectant solutions should be sterile. In order to prevent the growth of microorganisms, the prepared solutions must be briefly yellowed in pre-washed containers. It is forbidden to pour freshly prepared solutions into partially filled containers.

The amount of mechanical particles and microorganisms in the air in the production rooms and the level of microbial contamination of the equipment according to the appropriate instructions should be regularly monitored.

Lighting in production. Types of lighting and the basic requirements for them

Lighting in production is an important hygienic indicator of Labor, an integral part of its scientific organization and a culture of production. Through light, we communicate informations about the form of the quality of external factors through our eyes to our brain. Through light, we can easily perceive objects in size, color. We can work qualitatively and efficiently without getting tired for a long time if the light is in demand. It is possible to safely carry out processes in production under the influence of light at the required level. Normal light has a positive effect on the mental state of the handlers. Lighting is natural (through the diffusion of its rays in space directly using the sun) and artificial (carried out using electric lamps).

The main technical dimensions of lighting. Light is the visible radiation of the electromagnetic spectrum. Its main characteristic is the wavelength and the frequency of oscillations calculated so that they are in the following relationship.

$$\lambda = s/\nu, \quad (2.1.)$$

Where s is the speed at which light is emitted.

The sensitivity of the eye is different in all sections of the visible spectrum. At the limit of the green spectrum, the wavelength is highest at =554 nm.

The main light-technical sizes used in assessing the quality of lighting include light strength, illumination, return coefficient, brightness of light, luminance pulsation coefficient, luminance unevenness coefficient, etc. The magnitude that evaluates the spatial density of the light stream is called Light. Light force I (KD) it is said D to the angle at which the light flux DF is propagating relative to the body.

$$I = df/d\omega, \quad (2.2.)$$

The light Force returning from the 1/600000 m² area of the platinum surface was taken as its unit and named kandela (KD).

The light flux is measured in df Lumen (LM). It characterizes the light power of radiation and is evaluated on the perception of light in our eyes.

Luminance E is said to be the DF density of the light flux on the surface. The luminance is measured in Lux (LK) and is calculated by the following formula.

$$E = df/ds, \quad (2.3.)$$

where ds is the surface area where the light stream falls, m².

If the light power I, the lighting source is known as illumination at a given point on the illuminated surface

$$E = I \cos \alpha / L^2, \quad (2.4.)$$

determined by the formula. Here is the angle between the center of the illuminated surface and the line connecting the lighting source. L is the distance from the surface point where the illumination is calculated to the lighting source.

The quality of lighting will depend on the size of the surface to be illuminated and its properties. The ability of the illuminated surface to return, absorb and transfer light flow, the return coefficient s is estimated by the absorption coefficient s and the transfer coefficient s (9.1.- table). These coefficients are determined by the following formulas:

$$\alpha_s = F \alpha / f; \quad (2.5.)$$

$$\beta_s = F \beta / F; \quad (2.6.)$$

$$\gamma_s = F \gamma / F; \quad (2.7.)$$

where f is the flux of light falling on the illuminated surface, lm; F_α, F_β, and F_γ is the flux of light returning, absorbing, and passing from one side to the other, LM, respectively from the illuminated surface.

The main characteristic of the illuminated surface is its ability to repel light.

2.1.- table

Coefficients of light return, absorption and transfer of certain colored surfaces and materials

Color of the surface or material	α_s	β_s	γ_s
Black	0,005	0,995	-
White	0,80	0,20	-
Grey	0,35	0,65	-

Black-malla	0,15	0,85	-
Blue	0,10	0,90	-
Oynarang	0,85	0,15	-
Dyeraza window	0,08	0,02	0,90

The unit of brightness is nit (Nt). The brightness of latticized surfaces in a given direction YA (Nt) is calculated by:

$$YA = dI_{\alpha} / dS \cos \alpha \quad (2.8.)$$

where dI-directional radiated dS is the light force of the surface.

The human eye has the ability to adapt light to its different manifestations. But the sharp difference in brightness on the surface of objects with the surrounding primary color leads to an increase in the sensitivity of the eye to them. The presence of sharp shadows in the working zones disrupts the degree of adaptability of the eye to changes in brightness and leads to increased eye fatigue. This increases the likelihood of injury to workers. The main color is understood as the overall color that directly catches the eye of the interior surface of the room. The primary color is characterized by its ability to repel the flow of light, and it is considered light when $s > 0.4$ and dark when $s < 0.2$.

In order for the brightness to be evenly distributed over the field of view, it is recommended to paint the ceiling and walls of the room in bright salad, light-yellow, light-green and similar colors. The production equipment should be painted light-green color, the movable part should be painted light-yellow, and the open mechanisms should be painted light-red color.

An important characteristic of lighting is the difference in brightness on objects with the main color.

$$K_o = YA_r - YA_o / YA_r, \quad (2.9.)$$

where YA_r and YA_o are the primary color and the brightness of the object without matching.

The difference in colors with the base color is many when $K_o > 0.5$, medium when $K_o = 0.2-0.5$, low when $K_o < 0.2$.

The pulsation coefficient of illumination is estimated by the relative vibration depth at the time of change in the flow of light when operating K_{yop} gas-based lamps in alternating current.

$$K_{yop} = \frac{E_{\max} - E_{\min}}{2E_{yp}} 100\%, \quad (2.10.)$$

where K_{vp} is the luminance pulsation coefficient (10...20 %); $E_{\max}$ and $E_{\min}$ are the maximum and minimum luminance during light oscillation, lk; E_{ur} is the mean value of luminance during light oscillation.

The quality of the working surface lighting will also depend on the plane of its lighting, and the coefficient of unevenness will be assessed by the K_{no} .

$$K_{no} = E_{min} / E_{max} \quad (2.11.)$$

In order for lighting at work to satisfy hygienic requirements, the unevenness coefficient of lighting should not be less than $K_{no} 0.3$ lk.

Artificial lighting and basic requirements for it. Artificial lighting is in general (local lighting, which provides lighting directly from the workplace, enters into general lighting) and combined views. It is not allowed to use only local lighting inside the building.

Depending on the location of the equipment, the lighting can be evenly distributed or designed to illuminate a certain area, taking into account the location of the workplace. Artificial lighting can be both working and emergency. Working lighting is used in all cases in order to ensure normal operation, in addition to this, they are used to illuminate the passage of people, traffic (when natural lighting is not enough).

Emergency lighting is used when the main lighting is suddenly extinguished in cases of explosion, fire, people poisoning, dangerous injuries, prolonged interruption of technological processes and other unforeseen events.

Evacuation lighting 0.5 lk is installed in places where more than 50 people work, and in the passages of production buildings, where the release of people from the room is associated with the risk of injury, when working lighting suddenly turns off.

To facilitate the normalization of lighting in the workplace, all work is divided into discharges that take into account their accuracy. The lighting norms established when the objects of differentiation are located at a distance of no more than 0.5 m from the operating eye are presented below in jadlval.

So to each discharge of the visual work, the angular size of the object of differentiation is corresponding to the degree of.

$$\alpha_{ul} = \alpha_o / L, \quad (2.12.)$$

where O is the largest dimension of the object of differentiation; L is the distance to the working eye of the object of differentiation.

Vision is also negatively affected by light pulsation. The pulsation coefficient of illumination when lighting rooms with gas discharge lamps operating in alternating current with a frequency of 50 Gs should not exceed the values presented in the table below.

2.2.- table

Discharge and indicators of vision-based work

Characteristic of visual performance by degree of accuracy	The razryads of vision works	Minimum size of the object of differentiation, mm	Angular size of difference objects α

Highest accuracy	I	0,15 dan kam	$0,3 \times 10^{-3}$ dan kam
Very high accuracy	II	0,15...0,30	$0,3 \times 10^{-3} \dots 0,6 \times 10^{-3}$
High precision	III	0,30...0,50	$0,6 \times 10^{-3} \dots 1,0 \times 10^{-3}$
Mean accuracy	IV	0,50...1,0	$1,0 \times 10^{-3} \dots 2 \times 10^{-3}$
Low accuracy	V	1,0...5,0	$2 \times 10^{-3} \dots 10 \times 10^{-3}$
Rough accuracy	VI	5,0 dan ko'p	10×10^{-3} dan ko'p

The next important factor determining the demand for lighting is the differentiation of colors other than the main one in the object and the main color characteristic.

2.3.- table

The permissible value of the pulsation coefficient K_{yop} in lighting

Lighting system	Visual performance discharge		
	I, II	III	IV...VIIIa
General lighting	10	15	20
Combined lighting	20	20	20
Common local	10	15	20

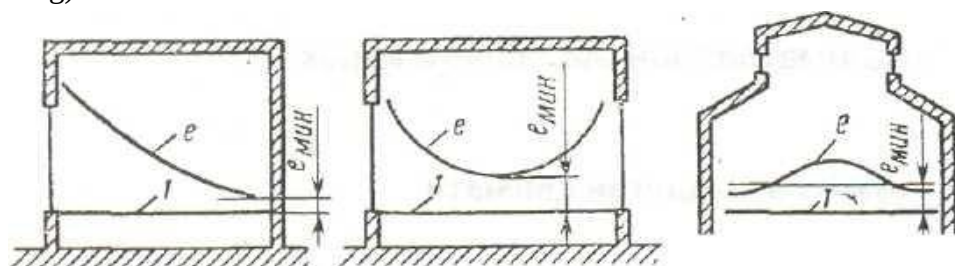
The highest luminance is 5000 lk single-discharge (highest precision) works while the minimum luminance is 74 lk is set for IV discharge works which require periodic general control of the production process.

Since many of the vision work performed in agriculture are works that require moderate, low and very little accuracy, moderate lighting is prescribed to these production rooms. For example, in a mechanical shop, it was recommended that the total lighting be 300 lk, in piggeries-50-75 lk, etc. In works performed outside the building, the illumination of working surfaces is set to be from 2 to 50 lk, depending on the discharge of vision work.

Natural lighting and basic requirements for it. Natural lighting of rooms can be achieved by direct sunlight falling on them, light diffusing into the sky, and the return of light from different sources on Earth. The recorded lighting views together form the average level of natural lighting and characterize the light climate in this place, and it is assessed by the light climate coefficient M .

Natural lighting is designed for rooms where people will be constant. Artificial lighting is used to fill its disadvantage if natural lighting is insufficient under the condition of the viewing works.

Natural lighting of rooms is carried out through side lighting holes, side lighting windows, lighting holes above, lighting flashlights above, side and upper holes, combined lighting (2.1.- fig).



a

b

v

2.1. image. Scheme of distribution of the coefficient of natural illumination by the trim of the room. a-one-way side lighting; b-two - way side lighting; v-lighting from above, 1-flat working level.

Since the level of natural lighting can change for a short time, it is normalized by the coefficient of natural illumination, and not by the illumination of the workplace.

The natural luminance coefficient e is defined as.

$$e = \frac{E_{uv}}{E_{mau}} 100\% , \quad (2.13.)$$

here the E_{uv} is the natural illumination of some inner node of the room, lk ; E_{mau} is the natural illumination of the interior at the same time, external horizontal illumination, lk .

Natural lighting is considered good if the e is 80% e_n when lighting from the side and 60% e_n when lighting from the top. The unevenness is not less than 0.5 in the case of discharge I and II, and not less than 0.33 in the case of discharge III and IV.

If the lighting of the production is designed and carried out correctly, the processors will be less tired, better in mood, better cocktail safety conditions, higher cocktail productivity and quality of products.

The lighting of the production will have quantitative and qualitative indicators. Quantitative indicators include the flow of light, the degree of illumination, the clarity of the surface, the coefficient of light return.

The flow of light is said to be F , the power of the energy of light. This power is assessed by the fact that the human eye perceives light. Lumen (lm) kabul kilingan as a unit of light flow:

$$F = J /$$

All light sources emit light stream unevenly in space. Therefore, the concept of the density of the light stream in space - the power of light J -was introduced for quantitative evaluation. The light force consists of the ratio of the light current to the angle F of the material in which it propagates:

$$J = F / \omega$$

The power of light is measured in kandel (kd). A light flux equal to 1 lm within a material angle equal to 1 Steradian is characteristic of a light force equal to 1 Candel (1 kd). The Fusion charor is made of platinum with a pressure of 20,46,650 K and a pressure of 101,325 Pa, with a surface area of 1/600,000 m² the light flux emitted from the light diffuser is taken to be a unit of light flux equal to 1 lm.

Luminance YE represents the surface density of the light stream and is measured in Lux (lk):

$$E = F \cdot S$$

Where S is the surface of the illuminated surface, m². If the surface density of the luminous flux is 1 lm/m², the surface luminosity is 1 lk.

The clarity of the surface L (kd/m²) is equal to the ratio of its projection in the plane perpendicular to the direction of the surface force radiating in the direction under consideration:

$$L=J/S \cdot \cos \alpha$$

The main quality indicators of lighting the production of the operating conditions of the eye include the background, the difference of the object from the background (contrast), visibility, attenuation indicator, luminance pulsation coefficient.

The background defines the sliding property of the surface that is resting on the object being dimmed. Yorkin is a good kuradi of autumn in the background (e.g. >0.4); when e.g. = 0.2-0.4, the background is a urtacha, and when e.g. > 0.2, the background is a tuk.

The difference (contrast) of the object from the background K is expressed through the difference in the clarity of the two adjacent light fields, in particular, the object that is dimming with Lf and the difference in the middle of the lobe:

$$K = \frac{L_{\phi} - L_{o\phi}}{L_{\phi}}$$

In the clarity of the background with the object, the object is visible in the background only if the fark is bulged. The fark is large when K>0.5, medium when K = 0.2-0.5, and small when K<0.2.

Visibility V is an indicator that determines how well an object or light field is being observed by autumn. Visibility is determined by the number of farces in relative units:

$$V=K/K_1,$$

Here: K is the fark in the conditions of the Karala autumn work, K1 is the smallest fark that the autumn arang can distinguish.

Whitening indicator R is the norm of lightening the autumn whitening effect of the lighting kurilma, as a result of this effect, the curving function of autumn is disrupted (whitening):

$$P=Z-1 \cdot 1000$$

Where: Z=V1 / V2 is the fall attenuation coefficient-Kn, determined from this formula:

$$K_n = \frac{E_{\kappa am} - E_{\kappa u2}}{2E_{yp}} \cdot 100$$

Here are: Yekat, Yekich, yeur-the largest, smallest and urdacha wear of the illumination in one period of change, lk.

One of the main factors in increasing cocktail productivity of workers in the textile industry is the illumination of workplaces. Properly organized kiling lighting ensures that the cocktail conditions are in meior. It has only been found that job productivity has increased by more than 5% due to improved lighting.

It is known that a person receives 90% of information through fakat autumn. This means that the rational organization of illumination at the enterprise is the reason why the health of a person and the activity of the central nervous system is in meior. Unfortunate accidents can occur when the illumination is insufficient or if it is not rationally positioned, as a result of the inability to perceive dangerous parts of the machine. Meiori illumination leads to an increase in cocktail productivity and good quality of products.

Types of lighting, systems and their classification.

The lighting of the workplaces is carried out mainly according to the scheme in the well:

Types and systems of lighting in production.

As you know, the source of natural light is the groom. An artificial light source, on the other hand, is an electrical energy blur, which is carried out through flue lamps and fluorescent lamps. Natural light is illuminated from the side of the building (from the windows), from the upper (in which the light is through the sheds or Zenith flashlights) and from the combined, that is, from the Upper, through the windows on the sides.

It is necessary to give aloofness to the fact that the sex is illuminated by natural light, which is good and useful to a person on the day of the day.

In enterprises, artificial lighting typical of textile enterprises is used when the sizes of work two, three shifts or workshops are large, since in such large workshops it is impossible to provide sufficient and uniform lighting in the case of natural light with a booty sex.

Artificial light is common (in the case of Bovine sex), While maxillary light is applied in the fakat workplace, mixed or common light with maxillary light together. It should be noted that in the case of the maxillary light alloy, the single uzi Hecht maxal does not apply.

If homogeneous light-emitting lamps are evenly mounted on the sex base, this is called Equal-taxed total light. This is called General localized lighting if the light flux to the installation of the lamps is integrated into the kuprok workplaces or the necessary sections of the head.

The working light on the function of the artificial light node - that is, the light necessary for the normal course of the technological process at the enterprise, is bulged into the light and special light used during accident accidents.

The light used for accident accidents is used to evacuate workers and, in some cases, continue work on muxim plots. These are such that when a work light is flying, an explosion, fire, accidents can occur, and the technological process can fail in the long term. Lighting in such cases (i.e. accident mode) should not be less than 5% of the parameters of the working light, and at the same time not less than 2 lk in the workshops and rooms, and 1 lk in the arrangement.

Lighting intended for the evacuation of workers is obliged to be at least 0.5 lk in the rooms, and not less than 0.2 lk in the organization (especially on stairs and sidewalks). For this, flue lamps and fluorescent lamps can be used. The light system used for accident accidents must be supplied from the source at Aloxi.

A special type of Light includes light used in the irradiation maxad. This light is erythematous radiation, that is, irradiation of workers with ultraviolet rays in a special room - photariums or through labyrinth corridors. This is especially necessary for sex workers who are now widely used, whose phakat is illuminated by artificial light. As you know, during the working day of porridge, they do not spoil the grooming, and the autonomy of ultraviolet rays in organisms increases. Another type of irradiation, bactericidal irradiation, is used in water and air sterilizing maxad.

Requirements for production lighting.

In order for lighting in production conditions not to harm the health of workers, it is required that it be evenly distributed in the raw parts of the room during operation, which does not strain the eyes. The light should be inconspicuous, so to speak, until the beginning, the light beam should not fall directly into autumn. The spectral composition of light should be chosen in such a way that, as a result, a person correctly perceives the colors of the objects around him. There

should be sharply distinguishable shades in the workplaces, and the illumination of the surrounding muxit with the workplaces should not make much difference. Because, as a result of the fact that a person often changes his eye from one condition to another, the accommodation of the eye is impaired, and the complete state of the organs of vision occurs.

The main requirements for production lighting are as follows::

- lighting device it is necessary to ensure that the spectral composition of the light is close to that of sunlight;
- the type and accuracy of the work to be performed should be sufficient in the level of illumination and comply with hygiene requirements;
- it is necessary that there are no properly falling and returning lights in the working region;
- in accordance with the criteria, emergency lighting must be installed in the production rooms;
- hazardous jobs should be covered at a high level;
- it is necessary that the lighting device is dangerous and does not have harmful factors, namely noise, damage from electric current, heat leakage and sources of fire leakage;
- control-measuring instruments, safety alarm should be reliably and continuously illuminated.

Lecture 7. Clean rooms in pharmaceutical production, their classification and requirements for them.

Plan

- 1 clean rooms in pharmaceutical production.
2. Classification of clean rooms in pharmaceutical production
3. Requirements for clean rooms in pharmaceutical production.

Base words and phrases: Clean rooms in pharmaceutical production, their classification and requirements for them.

Allocated time - 2 hours.

Clean rooms – the concentration of aerosol particles in their air and the amount of microorganisms is to some extent a holding chamber (a solid, liquid or multiphase object or microorganism with dimensions of 0.005-118 to 100 μm).When classifying clean rooms, particles ranging in size from 0.1 to 5 μm are examined. For normal rooms, air purity is estimated by the mass concentration of pollution in the air.

For clean rooms-the volume of air is estimated by the amount of particles per unit volume, in which particles with dimensions equal to or greater than a certain size are considered. 1 M3 the number of particles of a certain size in the air determines the class of cleanliness of the room.

Class A. Local zones for technological operations requiring the most minimal risk of contamination (filling, closing, opening ampoules and vials,mixing zones under aseptic conditions). The conditions of the A Class provide for a working position with laminar air flow. Laminar air flow systems in place of work should ensure uniform speed (0.45+0.09) m/s (EU GMP norms).

Class B. Environment for the zone of Class A, in the case of preparation and filling under aseptic conditions.

Classes C and D. Clean zones for conducting technological operations that allow a higher risk of contamination in the production of a sterile product.

Examples of technological processes in different purity classes

Examples of zones of technological processes for a product purity class performed under sterilized aseptic conditions in a primary wrapper is a product packaged in a primary wrapper that requires no risk of contamination. Preparation and packaging under aseptic

conditions C preparation of solutions that require minimal risk of contamination. Wrap the product in a primary wrapper. Preparation of sterilizing filtering solutions D preparation of solutions and subsequent preparation of the primary packaging for packaging. Work with the primary wrapper after washing

Blowing / filling / hermetizing technological processes

held in automatic mode. Process passing one continuous technological cycle

calculated for, in which a primary packaging is formed from thermoplastic granules, which is then filled and hermetized. Fertile laminar air

equipment for blowing/filling /hermetizing technology, which is used for production in aseptic conditions of the operating zone of the A purity class with flow, can be installed in rooms of the C purity class of the environment, provided that clothes for a/b classes are used. In the equipped state, the purity of the environment must correspond to the norms both in terms of the amount of particles inside, in terms of the amount of viable microorganisms, and in the working state – only in terms of the amount of viable microorganisms.

Sterile product in primary packaging. Preparation of primary raw materials, primary packaging and preparation of the product should be carried out in the clean zone of the D purity class. This is necessary to ensure a low level of contamination with particles and microorganisms. With microbial contamination forming a special risk for the finished product (the product will be a good nutrient medium for the growth of microorganisms, or a sufficiently long period will pass before its sterilization, or the technological process is carried out mainly in open containers), preparation should be carried out in the zone of the C purity class. Packaging the product in the primary packaging before final sterilization should be carried out in the zone of S purity class. When there is a high risk of contamination of the product from the environment (primary packaging filling passes slowly or the mouth of the primary packaging is wide or the filled primary wraps remain open for a few seconds before hermetization) packaging wrapping should be carried out in a cleanliness class zone and in the environment of the C cleanliness class.

Preparation of ointments, creams, suspensions and emulsions and packaging before final sterilization is carried out in zones of the C purity class.

Sterilizing filtering product. Preparation of primary raw materials for processing and preparation of solutions should be carried out in the zone of the C purity class. If additional measures excluding contamination (filtering to closed capacitatesarr) are provided, they can be carried out in the zone of the D purity class. After sterilizing filtration, it is required to process the product under aseptic conditions and pack it in the primary packaging; in this case, the quality of the air in the place of work should correspond to the purity Class A, and in the environment-to the purity Class V.

Product produced under aseptic conditions. From washing the primary wrapper, kaeyin u D should be in a clean zone with an environment that is not inferior to the purity class. Treatment of sterile starting raw materials and primary packaging should be carried out in the working zone of the A purity class, in the B purity class of its environment, if subsequent sterilization or sterilizing filtration is not foreseen. Then the preparation of solutions that must undergo sterilizing filtration is carried out in the environment of the C purity class. If sterilizing filtration of solutions is not foreseen, the processing of the starting raw materials and products should be carried out in the zone of the A purity class, in the B purity class. Technological operations on the preparation and packaging of the product under aseptic conditions should be carried out in the environment corresponding to the place of work in the A purity class and the B purity class. With a final non-closed product, such as a liophilic dried product, the transmission (transport) of primary wraps must be carried out until the end of the compaction process or in hermetic transmission devices, which are in the environment of the B purity Class A purity class zone or in the environment of the B purity class.

Preparation of sterile ointments, creams, suspensions and emulsions and packing when the preparation is carried out at open capacities and the subsequent sterilizing filtration is not foreseen, B should be carried out in the zone of the cleaning Class A, which is in the environment of the cleaning class.

Production of aerosols for inhalation, packing them in hermetic aerosol wraps is performed in a closed system. The clean components (cylinders and valves) of the product or primary winding must be supplied with the Zone filtered air, which is exposed to the environment, and at least comply with the requirements for the environment of Class D. The zone must be accessed through air switches.

Principles of building clean rooms

Basic principles of building clean rooms conditionally divided into:

- determination of the type of air flow in the room;
- formation of air flows;
- the necessary balance of air exchange and the multiplicity of air exchange supply;
- application of multi-stage air filtration and related filters;
- ensure the difference in the necessary pressures;
- control of air parameters;
- the use of effective project-design solutions, appropriate materials and equipment.

Air currents. The correct Organization of air flows is one of the determining factors that determine the productivity of clean rooms. Air flow should take away from the room all particles that are separated from people, equipment and materials. In this case, there should be no stagnation zones in the room where air exchange is not good.

There are two types of air flows:

- unidirectional (laminar) flow (air travels in one direction, with parallel flows passing at the same speed in the cross-section);
- unidirectional flow (turbulent).

The laminar flow of air meets the highest requirements of air purity, but providing the room with such flow requires a large expenditure of air.

In aseptic production, the air flow rate is $0.45 \text{ m/s} \pm 20\%$ for unidirectional flow zones. This will be equivalent to the air consumption of 1820 m³ per hour per room area of 1 m².

The value of the air circulation system is proportional to the air consumption.

When designing clean rooms, it is necessary to reduce air consumption to a minimum due to the following:

- only these ensure a high level of protection of the necessary technological process stages;
- reducing the zone with unidirectional airflow to the absolute minimum;
- reducing the rate of unidirectional air flow to a minimum, taking into account factors affecting the stability of flow movement and heat flows upstream of heat sources;
- limiting critical zones with laminar airflow from the environment where a lower level of cleanliness is possible using intermediate walls or plastic curtains;
- the use of turbulent flows.

When designing, the following should be taken into account:

- sequence of operations;
- movement of flows of raw materials and auxiliary substances;
- planning solutions;
- equipment location;
- and requirements for cleanliness.

The need to apply unidirectional airflow to provide rooms of cleanliness Class A, B, and for rooms of purity Class C and less – unidirectional airflow was determined during the experiment and confirmed by practice.

Unidirectional airflow can be vertical or horizontal.

With a vertical flow of air, clean rooms are more often applied, it goes from filters on the ceiling to pull-out holes on the floor or walls.

Balance and multiplicity of air exchange. Air exchange balance.

Air preparation systems for clean rooms (ventilation and air conditioning system) are built using air recirculation, that is, the air coming into the room consists of the external air that has undergone the necessary preparation and the air being recirculated, taken from the clean room and undergoing repeated cleaning.

One of the most important principles of building clean rooms is compliance with the balance of air exchange, that is, the proportion of external air coming to a clean room should be sufficient to ensure the loss of air in the circulation system, the desired level of static pressure in a clean room and the fulfillment of hygienic standards. Without this condition, dirty air from the environment enters the clean room.

Air exchange carrality. The magnitude of air exchange is determined by the number of cycles of air exchange per hour in a room, and this is an important indicator of clean rooms of Class A, B, C and D.

Prior to 1997, the European Union recommended that the minimum air exchange threshold for GMP Zones B, C and D be at least 20 cycles/hour.

In the new application of the European Union on the production of sterile drugs to GMP, it is stated that the multiplicity of air exchange for Zones B, C and D should be determined, taking into account the size of the room, equipment and personnel in it, and it cannot be less than 20.

Differential pressures. In rooms that are cleaner, there should be more air pressure to prevent impurities from entering from the external environment. An exception to this are clean rooms in which work with hazardous substances is carried out. For them, a negative differentiation of pressures will be necessary, that is, the pressure of air in the working zone should be lower than in the environment.

The difference in pressure between classified and unclassified zones must be maintained at least 15 Pa; the difference in pressures between the classified zone and the less class adjacent zones is maintained at least 10 Pa.

Air preparation system for clean rooms. Air conditioning systems for clean rooms are built in three stages:

- first stage-coarse cleaning filters;
- second stage-fine cleaning filters;
- the third stage is the final cleaning filters.

Coarse cleaning filters

5 μm large-sized fiber and large, which comes into the circulation system

designed to remove particles. Air purification productivity in these filters is 90%. Thanks to the installation of coarse cleaning filters, it is possible to protect and extend the service life (about nine times) of fine and final cleaning filters, which are very expensive. The cost of coarse cleaning filters is relatively high, so during the service life of fine and final cleaning filters they are replaced several times.

Fine cleaning filters after coarse cleaning filters in the air tubes, it is installed to remove particles with a size of 5-1 μm from the air flow.

The final air purification filters capture particles (aerosols, microorganisms) with dimensions measured by a tenth and a hundredth of the μm from the flow of air coming directly into the clean room.

Currently, fiber filters are used to purify the flowing air, at the base of their application lies the use of a large group of non-woven filtering materials.

The development of technology for the production of various textiles of the non-woven type made it possible to obtain machine-made fiber layers in the form of mats with the desired uniformity and strength. Fiber layers can have different structures: from a dense structure (paper, cardboard) to a slightly connected structure (cotton, vatin).

In terms of constructive execution, fiber filters are divided into three groups: **cellular, roll and panel filters**.

Cellular fiber filters it will be flat, pocket and pleated. Flat filters are filled with porous fiber material 25-50 mm thick (7.3.a-figure).

In twist filters, the filtering materials are planked with folds that allow the filtering surface to be increased.

Roll fiber filters it will be both flat and twisted (7.3. B, V pictures).

The Material is made from viscose antimicrobial fiber, which contains up to 2-4% antibacterial drug – catamine-in the structure of the polymer. This filtering material can be used repeatedly.

The productivity of cleaning the air with filters from these materials is from 80% to 90%.

Air **gentle cleaning** for **pocket** and **tiled** type filters are applied. Bag type filters use non-woven material from chemical fibers as a filtering material. These filters are used in the temperature range from minus 30 to plus 900c. The frames of the filters are made of multi-layer plywood or galvanized steel. In rooms requiring air purification from particles up to 0.1 μm in size, there was a high efficiency of purification: HEPA-type (high-efficiency special air filter) and ULPA-type (extremely high air filtration) filters are used. The guaranteed productivity of HEPA-filters filtering for particles with dimensions of 0.3 μm is 99.97%, that is, the passage of particles through this filter does not exceed 0.01-0.03%, the productivity of filtering particles with dimensions of 0.1 μm with an ULPA - filter is 99.999 %. As a filtering material consisting of a filter material, which is folded in a rigid frame with "folded folds" of the filter, glued filtering paper with a hydrophobic coating is used from glued Fiberglass, Glass Submicron fibers. Hermetics are used to eliminate the outflow of air through the frame of the filter, as well as through the joints between the filters themselves.

Planning clean rooms. A clean room is an expensive residential structure, the value of which increases as the level of cleanliness increases. When designing, it should be taken into account that the area of a clean room or its cleanest zones will be minimal. It is advisable that the cleanest zones repeat the operating zones of equipment-equipment according to their shape. Striving to minimize the area of a clean room should not lead to such a congestion that employees are forced to break the requirements of cleanliness and touch equipment and walls.

Instead of a large clean room, it will be wise to create several clean zones with cleanliness classes, which are determined by the indicators of its purpose. Equipment-equipment should be placed in the clean zone only in such a way that its technologically connected part with the clean zone, for example, the loading and extraction device, and equipment maintenance should be carried out from the outer zone. When designing a clean room, placing jobs and equipment, it is necessary to consider the type of transfer of a technological process in which employees move as little as possible. When developing planning solutions of clean rooms and clean zones, it is important to take into account air flows, correctly place equipment, production furniture, structures of workplaces, etc. In a clean room, the main source of pollution will be workers, which, with their movement and heat separation, will disrupt the structure of air flows. For this reason, it is necessary to place the zones most sensitive to pollution away from the directions of movement of workers, entrances and exits.

In a clean upper-class room, the outer wall should not be used as its single wall. This can lead to heat loss, imbalance of air exchange, condensation of moisture in Windows, sun exposure, etc. Therefore, the scheme "room in the room" will be the preferred solution, in which a cleaner room will be located from it in one clean room. Figure 7.5 shows a possible spatial scheme of elements of clean rooms. Clean rooms can also be built on a modular principle, so they will be well adapted to rescheduling. The main element of the room is equipment on the ceiling. The ceiling is performed in the form of standard-sized slots, on which the necessary modules are installed :

- filter-blower,
- lighting,
- drawer, berk, etc.

Auxiliary rooms (service, cleaning supplies storage, material preparation, waste disposal zones, toilets, food eating rooms, etc.), personnel movement and material movement directions are placed to exclude intersecting pollution and prevent particles from falling into zones that are more clean than less-cleanliness zones. So the application of desolation devices allows you to exclude unnecessary access or exit from a clean room for the transfer of information.

In sterile zones and upper-class zones, it is necessary to use a phone with a dial without a disc or with a button. Let the phone construction handle it

needed. Open pipes and cables create favorable conditions for pollution collection and make it difficult for cleaning and disinfection to be carried out, so in clean rooms they must be brought to a minimum.

Planning maintenance zones, control remotes,

it is necessary to consider the location of communications and pipes outside clean rooms or in less clean rooms. To view activities from the outside inside a clean room, it is necessary to consider the number of arched windows during Normal use (in addition to emergency situations), the entry and exit of employees, materials, the movement of products and waste must be carried out through air ducts that can be performed in a separate hona form or in the form of a transmission chamber (for materials, etc.). The air hose ensures that the pressure differential is constant when moving from one room to another and protects the clean room from contamination. Additional cleaning of personnel may be envisaged in the gateway (using air blowing or using a protective ("adhesive") coating of the floor, which receives impurities from the billets).

Changing rooms. Changing rooms are performed as air switches and serve to prepare employees to enter and exit a clean room. In them, the clothes provided for by the instruction are worn, the hand is washed, and so on, the equipment will depend on the class of the room it will take. At this time, the changing room is usually divided into three zones:

- the entrance zone to the room, where clothes that are not placed in a clean room and personal

things are removed and stored, hand washed and dried, etc.k.;

- transition zone, in which clothes are worn for a clean room; in this zone, a transverse seat is usually installed, which serves as a physical and psychological barrier when changing clothes;

- exit zone, here is the final check before entering the clean room transferred, special sterile gloves are worn in sterile production.

The blocking structures of the clean room and its elements must ensure the fulfillment of the basic cleaning requirements:

- ensuring Hermeticism;
- non-separation of impurities;
- there should be no protruding parts, sharp corners, hard-to-reach places to clean, no grooves, boots, etc.;

- have a smooth surface;
- does not form the illusion of light on surfaces, paints in eye-catching colors;
- durable and long service;
- be editable-resistant surfaces, moisture-resistant and resistant to mold formation;
- to be resistant to the effects of washing, disinfection and other substances;
- ensure ease of Use and maintenance;
- Assembly in the room, as needed
- ease of disassembly and rescheduling

must provide.

Walls. Blocking structures for rooms of cleanliness Class A, B and C

glass metal is applied as it complies with the requirements of cleanliness and re

allows planning to be possible. Therefore, it is often also used in the construction of clean rooms of the Lower Class D, whereas for them it is enough to use the usual stone and concrete structures with improved finishes. The cheapest and most common solution is steel panels with several layers of coating, in which the outer surface is covered with epoxy, powder or other paint. Stainless steel panels, which are more expensive, are used in productions with an aggressive environment. In clean rooms, it is not necessary to use wooden items, wooden details, wooden furniture, etc. Wood is a source of polluting particles, creating favorable conditions for the survival and reproduction of microorganisms.

Windows. Window sill areas should be thoroughly hermetized. It is advisable to apply double windows in the place of a "metal-mirror" niche, providing a flat, non-haughty wall surface, so that the use of curtains inside a clean room is not allowed. If you need a blinds or curtains, they can be motagged between the windows inside the window. There should be no under-window boards on the windows.

It is advisable to give them a downward slope towards the room in order to reduce the accumulation of impurities in the area where there are under-window boards and to facilitate cleaning. The window structure should not allow the opportunity to open it.

Doors. In a clean room, there should be a minimum number of doors. Sliding-open doors do not apply in clean rooms, since they will have difficult-to-clean areas where dust accumulates. It is advisable to equip the doors with their mandatory opening devices, as well as with signs or symbols.

Most. The most important requirements for the ceiling are Hermeticism and strength. It should ensure the protection of the clean room from impurities that are in the surface area of the ceiling and provide reliable, hermetic and convenient fastening of air diffusers, lamps, fire sprinkler systems, etc.

it should exclude exposure to air flow and ensure the convenience of replacing and servicing them in clean room conditions. The " ceiling - walls " should be envisaged to round out the seams.

Three types of ceilings are used:

- cassette, it is mounted on a raster structure made of aluminum profile, which is fastened with special arrows on the ceiling of the building; the ceiling itself is made of galvanized sheet steel 1 mm thick with a powder coating;
- panel, in which penopolyurethane filled panels were used, in contrast to the cassette ceiling;
- light ceiling, it is built on such a principle as a cassette ceiling, but thin sheets and steel galvanized profiles are.

Floors. The floors should be smooth, without pits and pores, but not slip, easy to wash and disinfect, resistant to edirice, resistant to the action of aggressive substances accidentally spilled or scattered, have the necessary antistatic or, if this is determined by the conditions of use, electrical conduction properties, do not distinguish impurities themselves. The most

common types of coatings for floors are vinyl (linoleum, etc.) and epoxy coating. For classes C and D, as well as ceramic (tile) and other types of coating are used.

Pipes. Pipes and fittings are adapted to efficient cleaning, it is convenient to reach as much as possible, in different pits and reach for cleaning

it should not be located in difficult places. It is necessary to hermetize their passages through the wall. Fittings, valves, etc. should be outside the clean room.

Lighting. The electrical equipment structure should take into account the requirements of clean rooms, not create conditions for the accumulation of impurities, be convenient for cleaning. It is advisable to place the lamps "evenly" with the ceiling or give them a shape that does not disturb the air flow. This can be done by placing the luminaires over the mesh distributor of air, or at the expense of the shape. The storage tanks, power supply distribution boxes should be located outside the clean room. In laboratory research and production, autonomous laminar devices are used when small volume clean local zones are needed—these devices can provide Class B air purity in the work zone. Depending on the purpose of the Laminar device, various modifications of them are released. Autonomous devices will have different purposes (protect the product from the environment, protect the environment and personnel from the product, and at the same time protect the product from the environment and the environment and personnel from the product).

Due to the high speed of the arrival of air in the room (through the air tubes in the wall and/or ceiling) and its expulsion (through the exhaust holes next to the floor), the air conditioning system causes limited productivity in operation. As a result, a high turbulent flow is created in the room with intensive intervention of air layers. The filtered air coming into the room mixes with the existing impurities and dilutes it. As a result, cleaning the air from impurities that occur in the process of human activity is not achieved. In this, excess pressure is created, which only excludes the arrival of polluted air through slits, windows and doors. Therefore, in recent times, devices with laminar (layered) flow of purified sterile air (boxing, cabinets, etc.) are widely used in chemopharmaceutical and biotechnological enterprises, the amount of air pollution can be reduced to 1 particle at 1 dm³. In devices that provide Laminar flow, air travels with parallel layers at the same speed, approximately equal to 0.5 M/s. Initial and highly productive bacterial

the air passing through the filters is sterile and displaces all suspended particles from space limited by the walls through the open side. In the operating zone of the Laminar device, a small excess pressure is created, which excludes the fall of contaminated air from the room. In order for the device to work efficiently and extend its service life, it will be better to place a laminar cabinet in a separate small clean room, which is provided with air filtered from the beginning. Air flow to the Laminar device can come in a horizontal or vertical direction.

When conducting sterility tests, it is recommended to use a device with a horizontal laminar air flow, since under these conditions it will be less possible to transfer microorganisms with air from the hand of the handler or from the equipment used to the sterile environment. The main disadvantage of horizontal laminar air flow devices is the possibility of transferring suspended particles in the air to the room and working personnel. In these cases, it is recommended to use a laminar cabinet with a vertical recirculation flow of air. The flow of air absorbed into the cabinet creates an air curtain that reduces the aerosol from the Cabinet to the minimum coming into the room. At this time, filtered air protects objects to be processed in the work chamber from possible contamination.

To carry out work with toxic, especially cytotoxic and infectious materials specially designed laminar stations are used.

The outer body of the Laminar cabinet is made of enamel-coated metal, and the workpieces (table and inner surface) are made of stainless steel. The front wall of the work chamber is made of a transparent but ultraviolet-proof material (such as polycarbonate or

polished glass). For air circulation, a centrifugal fan is used, in which a certain speed of operation is set. Air is transmitted to the working chamber through a HEPA filter, which is hermetically installed on a special frame, which effectively captures particles in the air.

Since the microflora present in the air is usually in hanging particles, their removal leads to the fact that the air is cleared of both microbial contaminants and hanging particles. Fluorescent and ultraviolet lights are installed in the work Chamber. The Laminar cabinet is also equipped with an air flow rate meter and a performance clock counter.

Portable clean zones where the air flow is laminar are performed in the form of portable modules, the dimensions and number of sections of which are selected depending on the task set, the dimensions and shape of the equipment. They will be flexible and allow easy implementation of job rescheduling in a cleanliness class. In the chemical-pharmaceutical and biotechnology industry, flexible curtain devices are used to create clean zones of Class A, modular cabins are used that correspond to the size and shape of equipment-equipment (figure 7.19). They are also performed from separate modular components, which reduces the cost of building clean rooms. To carry out the technological process, the cabin can be accessed through switches.

In the chemical-pharmaceutical and biotechnology industry, the third generation of clean rooms is currently being introduced. Previously, the protection scheme for pollution control followed all rooms and worked according to the principle of horizontal or vertical flow of air. But, since these systems of clean rooms require very large capital and current costs, the second generation rooms have appeared. The use of sterile cabins and clean working zones made it possible to greatly reduce areas with Class A conditions, resulting in a decrease in the rate of circulating air flow. In both cases, clean rooms are formed in the building independently of the air conditioning system.

If clean room devices are included in air conditioning systems, air filtration and distribution functions are allocated, further savings in capital input and current costs can be achieved.

It should be borne in mind that air conditioning devices for air conditioning and for clean rooms will occupy a large space, and pharmaceutical preparations will have a relatively short life cycle. This leads to frequent rescheduling and changes in the intended nature of certain production zones. For this reason, air preparation and distribution systems must be simple and easily rebuilt. In order to achieve the optimal ratio of costs and results, as early as the design stage, it should be considered to divide the production area into zones with different requirements for air purity, to determine the volumes and shape of rooms with air purity of Class A.

For this purpose, isolating or barrier technologies are used, the essence of which is the physical isolation of work zones from the surrounding area due to the use of a hermetic insulator, which reduces the volume of the sterile room to the volume of the zone requiring sterility. This technology is widely used in the production of sterile preparations. In the production of solutions for injections in ampoules, only for such steps as sterilizing the process and delivering empty sterile ampoules, filling ampoules with a solution for injection and soldering them, the volume of air protected by laminar sterile flow

it is possible to limit.

At the last moment, a number of foreign firms are developing new equipment-equipment specially designed to work together with insulators. Such

the external environment that surrounds the insulators can be of the D purity class and even lower.

Another consequence of the reduced air requirements around the insulator is that operators can wear normal laboratory clothing instead of the uncomfortable and expensive clothing to work in clean Class A and Class B rooms.

Lecture 8. Requirements for employees in pharmaceutical production.

Plan

- 1 requirements for employees
- 2 Actions in clean rooms
- 3The Organization of instruction, training and verification of their knowledge
- 4th team and individual protective equipment

Base words and phrases: Requirements for employees, actions in clean rooms provide guidance to Employees, Organization of training and verification of their knowledge, collective and individual protective equipment of employees

Allocated time - 2 hours.

Requirements for employees in pharmaceutical production

Control of the health of employees at enterprises of pharmaceutical production order "on improvement of the system of preliminary and periodic medical examination in the employment of employees in the Republic of Uzbekistan"(June 23, 2000, registration number 937 — Bulletin of regulatory documents, 2000., No. 12).

Requirements for employees

At the time of hiring an employee, it is advisable to introduce a special section into the employment contract and establish in it the obligations and responsibilities of the employee for personal hygiene. For example, in rooms with a cleanliness class of 5, workers are obliged to come to work without makeup, do not drink alcohol before the working day, do not smoke in the territory of the enterprise and for two hours before coming to work. The last requirement is that the concentration of particulate matter in the air that the chestnuts exhale with their breath is very high, a concentration that decreases very slowly after the end of smoking. These particles are often small in size and are not caught in the mask. Sometimes the question arises: Do you need to take a bath before entering a clean room? Practice shows that there is no need to take a shower at work if a person has washed to work. In addition, bathing in warm or hot water under the shower leads to the opening of skin pores, the separation of sweat and microorganisms. Without it, microorganisms do not protrude on the surface of the skin coating. There is no strict information about the need to take a shower before direct work. At the same time, in individual cases, it may be required to take a shower after work. Shower nets can be meant for accident situations. It is necessary to take a shower (not a bath) at home every day, after all it is considered more effective than a bath.

Persons placed in clean rooms: compliance with personal hygiene requirements; compliance with the rules of behavior in clean rooms; lack of contraindications to work in clean rooms for Health; Study in a training course before being put to work and subsequent regular retraining; strict adherence to all instructions and work regulations. An important factor is the positive attitude of employees to maintaining cleanliness, their order, order, tendency to strictly follow the rules, reliability. The readiness of employees to record and analyze the mistakes and shortcomings of themselves and others, to inform about all violations in the work provides the basis for the analysis and implementation of risks in the technological process, and allows maintaining the established level of cleanliness. But it is their implementation that creates certain difficulties for individual individuals. At the same time, cleanliness and unconditional adherence to the routine are mandatory conditions for effective work, and it is also impossible to get closer to a clean room without fulfilling them!

The body surface area averages 1.75 sq.m. The outer skin coating is renewed in a few days, when a person allocates several hundreds and millions of particles with a size of 0.5 μm in each reality. The total mass of the separating particles per day is 10 g. A separate danger is posed by microorganisms. Three conditions are necessary for their reproduction: heat, moisture and nutrient medium. In most parts of the body, these conditions exist in harmony, these are, first of all, the head, hairpins, nose, mouth, ears, nails and the space around them, the places where a person hides under clothes. Particular attention should be paid to the cleanliness of such places.

Anyone entering a clean room: thoroughly infects their hands before entering the room, wash hands up to the wrist before entering sterile zones; wash hands after leaving the hostel; do not wipe their nose with their hand; keep the oral cavity tidy and clean their teeth regularly; should dress neatly. When an employee leaves the house, he learns what he was doing the day before (working as a field, fixing a car, caring for pets, sports games, etc.k.) must remember and organize itself.

Make-up utensils and ornaments

Makeup tools (dream for eyelashes, upa, lipstick, nail polish, rumyana, etc.k.) provides a favorable environment for the proliferation of microorganisms. Expensive jewelry decorations tend to have many places where impurities accumulate, so they are required to be removed before entering a clean room. The following useful rule should not be forgotten: not to bring items into a clean room that are not needed for work or to ensure the activities of employees.

Hand washing

Proper hand transmission and handling are an important component of preparing employees to enter a clean room. At the same time, when working, a person grabs various surfaces with his hands. Hands should be infected every time you enter a clean room. There are various hand washing schemes: before changing clothes and/or before entering a clean room. In most cases, the hands are washed before changing clothes. For clean rooms and sterile Productions belonging to high purity classes, this is a strict rule. Otherwise, moisture can get on clean clothing, especially on its sleeve.

Hand washing scheme: solving rings and other decorations. Holing the hand before soapy. Soap the entire surface of the skin of the hands (bactericidal soap). It is advisable to use liquid soap with a dosing agent that does not form drops. Hard soap leaves a damp mark and flows. The surface of the hand is rubbed and washed, special attention is paid to the nails, the zones around them, between the fingers, the parts of the skin that are under the ring. Lint-free brushes made of plastic can be used. When using brushes, it is necessary not to damage the skin. The hands are rinsed under a stream of water until the foam of dirt and soap is completely gone. Hands are dried with a hairdryer or disposable vors are used non-separating towels. In cases of special responsibility, Nera filters can be used to dry the hands. It is not allowed to wipe the hands with ordinary towels of general use. If a towel wrap is used, the hands are wiped only with a clean part of them that no one has touched. Further actions (changing clothes, entering a clean room) are performed only with dry hands. There are additional rules for sterile production: the hands are washed up to the wrist; the hands are treated with disinfectants, which must be kept for 1.2-2 minutes after application to the hand, at which time the wrists must stand so above the wrists that no liquid flows to the critical surfaces (fingers). Special gloves can be used to change clothes so that the hands do not touch sterile clothing. These gloves are removed after changing clothes and sterile gloves are worn to work or working gloves are worn over them. Every clean room should have a hand washing guide. In sterile production, it is advisable to use rakovinas with a rounded bottom to prevent moisture from accumulating.

Actions in clean rooms

It is necessary to establish control over compliance with the rules established by employees. In this case, it should be remembered that there is nothing worthwhile for clean rooms. It is the small ones that pose the greatest danger. The main criterion that determines the rules of behavior is to avoid anything that can contaminate a clean room.

How to move in a clean room? It is necessary not to rush, not to act sharply. This is determined by two reasons: when moving quickly, the separation of particles from a person accelerates; rapid movements disrupt the movement of air currents and lead to the spread of impurities. Unnecessary actions should be excluded at all. It is only necessary to perform the actions prescribed by the regulation. Some people have a habit of shaving, rubbing hands, face and other body parts, repeating gestures a lot. Such actions are not allowed. People who cannot get rid of harmful habits should not be included in clean rooms. In the clean zone, it is forbidden to eat, drink liquids, smoke, read newspapers and magazines. Respectively, the room will receive food products (including drinks), chewing gum, medicines, matches, lighters, cigarettes, papers and other utensils not provided for in the technological process, printing products, etc. Import of S are prohibited.

The wristwatch is a source of pollution. It is necessary to remove the clock before entering a clean room. It is impossible to speak out loud in a clean room. Loud speech and screams sharply increase the intensity of the separation of impurities from the mouth. Bending over the workplace, leaning on walls and equipment, moving items from place to place or pressing them on the body is prohibited. It is necessary to observe special caution when working in unidirectional airflow. It should be remembered that if the hand or other body part falls between the filter and the work zone, the working zone will definitely get dirty. Impurities separate from the person's mouth, nose, wherever he is looking. Therefore, when there is a need to contact the operator, it is necessary to approach him so close that he is forced to turn and look, so that when talking, the particles that separate from the mouth separate from the working zone to the other side. If the need to hit the aksa or cough occurs, it is necessary to turn from the side of the working zone, cover the mouth with gloved hands, and then replace the glove. If hitting or coughing the accent continues to repeat, it is necessary to leave a clean room and inform the management about it.

It is necessary not to leave items that are not necessary for work in a clean room. Any failures in the work of equipment and any deviations from the requirements established in the instructions should be reported to the head.

Health status

The criteria for assessing the state of health are quite simple: Individuals with acute and chronic diseases are not allowed to clean rooms. In the first gal, this applies to acute respiratory diseases. Coughing, hitting the buttocks, runny nose and tears have a negative effect on the level of cleanliness. It is also worth counting diseases such as conjunctivitis and other eye diseases; diseases of the upper respiratory tract; skin diseases, including herpes, boils, seborrhea (Thrush). Some people sweat a lot, which also makes it worthwhile to work in clean rooms. Injuries also lead to the separation of impurities.

Organization of work on the provision of instructions to employees, training and verification of their knowledge

All employees of enterprises of pharmaceutical production, including their heads, must study in accordance with the established procedure for their profession and types of work, receive instructions, check their knowledge and undergo re-certification.

Testing the knowledge of labor protection of workers, managers, engineering and technical personnel directly related to the organization and performance of work in production

should be carried out in accordance with the "Model regulations on the organization of studies in labor protection and testing of knowledge"(August 14, 1996, registration number 272).

In jobs with harmful working conditions, employees are given free milk or other equivalent food products in accordance with the established norms. When working in extremely harmful working conditions, therapeutic and preventive meals are provided free of charge in accordance with the established norms. The rules and conditions for the free provision of milk or other equivalent food, as well as therapeutic and preventive nutrition, in the manner prescribed by the government, in order to prevent the harmful effects of harmful production factors on the human body, it is necessary to prepare an employee for work in harmful conditions or to exclude or protect against the presence of harmful If one or the other of them is not possible, it is necessary to limit the level (concentration) of harmful factors or the time of their impact on workers, that is, to organize the appropriate work routine in order to protect workers from harmful production factors, mainly medical preventive and organizational measures are used. It is up to the employer to provide sanitary and preventive services to employees of the organization in accordance with labor protection requirements. For these purposes, the organization is equipped with sanitary facilities, dining rooms, medical service rooms, working hours and mental relaxation in accordance with the established norms; sanitary posts are equipped with a number of medicines and ambulance equipment, devices (devices) are installed in hot stores and to provide workers with gas brine. validated.



In order to prevent people (patients prone to allergic diseases, suffering from them) who are prohibited from working in harmful conditions for medical reasons, E) workers who work in

hard work and in harmful and (or) dangerous working conditions, as well as in transport-related work, undergo mandatory preliminary work at the expense of the employer. work) and periodic (for those under the age of 21 - annual) medical examinations (examinations) to determine the suitability of these workers for the performance of assigned work and the Prevention of occupational diseases. In accordance with medical recommendations, these workers undergo an emergency medical examination (examination).



Harmful and (or) dangerous factors of production and the work on which preliminary and periodic medical examinations (examinations) are carried out and the procedure for their conduct is determined by regulatory documents approved in the manner prescribed by the government. If necessary, additional conditions and guidelines for medical examinations (examinations) may be included in some organizations by decision of local authorities. Workers who carry out certain types of activities, including work related to high-risk sources (exposed to harmful substances and harmful production factors), as well as working in high-risk conditions, undergo mandatory psychiatric examinations at least once every five years in the manner prescribed by the government. In the necessary cases, vaccination is used-various vaccinations are carried out in the body of an employee to increase immunity to diseases.

Medical and preventive measures include tightening the body, physiotherapeutic procedures, industrial Gymnastics, the organization of preventive nutrition, healthy rest and compliance with the rules of personal hygiene.

In harmful and (or) dangerous working conditions, as well as in special temperature conditions or in cases related to pollution, employees are given certified personal protective equipment that wash and clean. The norms for the issuance of these funds are approved in the manner established by the government. The employer is obliged to ensure the purchase at his own expense, delivery to workers in accordance with the established norms, storage, washing, cleaning, drying, disinfection, disinfection and provision of special clothes, special shoes and other personal protective equipment.

Team and individual protective equipment of employees

GOST 12.4.011-89 and OST 64-7-473-83 SSBT "individual protective equipment in the production of finished medicines in order to reduce or eliminate the impact of harmful production factors on employees of basic production and auxiliary services at enterprises of all pharmaceutical production in the field of pharmaceutical production. Classification. In accordance with the "field of application", collective and individual protective equipment should be used.

Team protection tools include:

means of normalizing the air environment of production rooms and workplaces (ventilation and air purification, heating, maintaining air temperature, humidity in the same norm, etc.);

tools for normalizing the lighting of production rooms and workplaces (lighting devices, lighting places, light protection devices, etc.);

means of protection against noise, vibration, electric shock, static electricity, high-level temperature of the equipment surface;

means of protection against the influence of mechanical and chemical factors.

Employees of pharmaceutical production should be provided with individual protective equipment in accordance with the "standard standards for free issuance of special clothing, special shoes and other individual protective equipment for employees of pharmaceutical production enterprises" (September 24, 2008, registration number 1861 — collection of legislation of the Republic of Uzbekistan, 2008, Number 39, article 402).

Individual protective equipment is divided into the following groups:

custom clothing;

custom shoes;

special headgear;

protective equipment of the respiratory organs;

hand protection tools;

protective equipment for the head;

face protection tools;

hearing organ protection tools;

eye protection tools.

In the production of ready-made medicines, individual protective equipment should not be a source of harmful and dangerous production factors and should not cause product contamination.

The administration of the enterprise is obliged to provide employees with the necessary individual protective equipment in accordance with the established norms, keep an account of the provision of individual protective equipment, ensuring compliance with the deadlines for their use and the necessary conditions for storage, washing, cleaning and repair.

Measures to prevent employees from coming into direct contact with starting materials, semi-finished products, finished products and production waste that has a detrimental effect on employees

The processes of drying and sample selection should exclude the possibility of contamination by hazardous substances in terms of explosion-fire and, if necessary, be equipped with local towing equipment.

For toxic, quick-firing and aggressive liquids, the measurement of the levels in the capacitive apparatus should be carried out only with the help of satholders, which exclude the need to open the lid of the apparatus.

The gaskets of fast-firing liquids and liquefied flammable gases in apparatus and containers should be safe in terms of fire.

It is not allowed to apply measuring windows to measure the level of toxic, toxic and fast-firing liquids. As an exception, subject to the presence of caps that are protected from mechanical damage and automatically seal the connecting pipes, as well as a red stripe indicating a sufficient level of fluid, measuring windows can be used in machines and containers with an excess pressure of at most 8.5 kgs/cm². In this case, the measuring windows must be protected by an appropriate metal flange.

Requirements for ensuring the protection of employees from the influence of hazardous and harmful production factors

The organization of technological processes and production equipment should exclude the possibility of workers in contact with harmful and aggressive substances that affect the maintenance of equipment and carry out production operations.

Lecture 9. Production, storage, transportation and acceptance of material and raw materials in pharmaceutical production. Requirements for the warehouse.

Plan

1. Production of material and raw materials in pharmaceutical production.
2. Storage, transportation and reception of material and raw materials in pharmaceutical production.
3. Warehouse requirements.

Base words and phrases: Material, raw materials, storage, transportation, reception, warehouse in pharmaceutical production.

Allocated time - 2 hours.

Its analytical passport must be attached to the raw materials coming into production.

Raw materials and auxiliary materials are put into production in accordance with the requirements of scientific and technical documentation after the conclusion of the technical and quality control departments has been obtained and laboratory tests have been carried out.

In the process of producing medicines, the work on the preparation of raw materials (obtaining from dishes and wraps) should be carried out in a separate room in order to prevent them from being damaged by germs.

It is forbidden to take raw materials, auxiliary substances and finished products manually, these products must be taken with the help of shovels and ladles.

The raw material must be accompanied by its toxicological and fire description.

Raw materials should be stored in warehouses in the primary packaging of the plant.

In order to prevent accidents, raw materials that have fallen into technological processing must be cleaned of all types of impurities.

Requirements for methods of storage and transportation of starting materials, semi-finished products, finished products and production waste

Raw materials and materials used are stored in general factory warehouses and transferred to the workshop in an amount that provides a reserve of one to two days.

It is advisable to design the storage rooms in the newly designed ampoule workshops with the aim of being able to store glass drots, glass ampoules, cartonage items and other supplies of materials used in such production directly next to the workshop.

Raw materials and auxiliary materials should be placed in such a way as to ensure the possibility of their free convergence to each other.

Quick-firing liquids with a fire extraction temperature of 450c and below should be stored in reservoirs.

Quick-firing and flammable liquids should be stored in metal containers. In some cases, clean and corrosion-causing liquids (alcohols, esters, acids) can be stored in glass containers, in closed bottles with a capacity of up to 80 liters in obreshets with compacting material.

It is forbidden to store strong-acting toxic substances in one room that can interact.

When installing reservoirs for acids and other aggressive liquids and performing their repair work, the need to ensure safety and comfort should be taken into account.

Storage of the finished product should be carried out in rooms where medicines ensure the preservation of the idol.

If necessary, the period of periodic inspection of the stored product, the requirements of the placement method and special requirements for the storage of toxic and strongly affecting, fast fire, explosion-proof hazardous products and products with a limited shelf life should be established.

It is forbidden to store poisons in sexual warehouses.

Strong-acting toxic substances should be stored in special warehouses under the supervision of responsible persons.

The outer surfaces of their rooms in the warehouse should be comfortable for cleaning and disinfection.

Storage rooms should be simple enough, properly lit, equipped in such a way as to ensure a dry, clean and orderly arrangement of stored materials, and provided with a sufficient amount of stellages, cabinets and shovels.

The warehouse must be equipped with a guard alarm. Strangers are prohibited from entering the warehouse.

All starting medicines, auxiliary substances and packaging materials must meet the established standards and specifications.

Acids and alkalis should be stored in a hermetically sealed container, in a separate room equipped with flow ventilation.

Food raw materials (sugar, starch, flour, etc.) should be stored in industrial packaging, separately according to the name, in insulated, dry and ventilated rooms from other rooms of the warehouse.

For the transportation of starting medicines, auxiliary substances and packaging materials, Special Transportation is necessary, which must be kept in cleanliness. The use of attracted or passenger transport is not allowed.

In the process of Transportation, starting medicines, auxiliary substances and packaging materials should be stored in a pana place or protected from sunlight, atmospheric precipitation and dust using a special coating.

It is necessary to equip and maintain warehouse rooms designed for the storage of semi-finished and finished products according to the anti-fire and sanitary standards of the design of enterprises of industrial pharmaceutical production.

In the rooms of reception, storage, issuance and preparation of raw materials, a working area should be allocated, which is designed for the traction of medicinal substances and is equipped with air traction ventilation.

To ensure the repair work of heavy technological equipment, workshops and plots should be equipped with load-bearing machines and mechanisms with the ability to carry a load of the appropriate weight.

To work in loaders and mechanisms, repairmen are put in charge, who have a certificate that they are allowed to work in loader mechanisms and receive special instructions.

When carrying out displacement work of various types of cargo, the following are prohibited:

- a) work on faulty lifting machines and mechanisms;
- b) the use of load-bearing devices and containers that are not branded, faulty and inconsistent in weight and nature of the load being carried;
- c) use of building beams, columns and other structures to strengthen load-bearing mechanisms and devices without written permission issued by the chief mechanic or his deputy;
- g) violation of the rules for the use of lifting machines and mechanisms, as well as the rules introduced at the enterprise.

When lifting loads with a weight of more than 50 kg higher than 1.5 m, the application or durability of load-bearing equipment with the ability to carry loads of the appropriate weight should be checked on the basis of calculations and the installation of chimneys and balconies on which automatically brake tals of the required weight are hung.

Vents with a height of more than 4 M are required to be in inventory accounting.

Storage belts are required when it is necessary to carry out short-term work on a hill above 1.5 m in height without installing planks or fences.

Stairs applied for repair work must be resistant, reliable and meet the following requirements:

- the length of the staircase should not be higher than 5 m;
- zina steps should be installed on the grooves of the sides;
- the length of the ladders should ensure that it is possible to work while standing on a ledge at a distance of at least 1 m from its upper end;
- the lower end of the ladder should have a sharp metal nail in order to prevent it from slipping;
- in cases where it is necessary to hold something or get it out of place, it is necessary to use a ladder that opens into two sides, in which the upper area of this ladder must be surrounded by supports at least 1 m high by three;
- two side-opening ladders must have devices that do not allow opening during Operation;
- the place where the ladder is installed on the transport or on the plot where people walk should be blocked or guarded;

suspended metal ladders with a height of more than 5 m should be blocked with metal Dugas with vertical ties and securely fastened to structures or equipment or held by a person providing security from below;

in the permanent areas used in the repair process, there should be a tarred iron bed, a continuous sidewall of 150 mm from the bottom and supports with a height of at least 1 m.

When using a ladder that can be placed on the wall and opened on two sides:

work on the two highest steps of the ladder;

two working exits on one side of a ladder that opens onto a retractable ladder or two sides;

two or more people rise or fall at the same time;

installation of the ladder in front of rotating shafts, pulleys and other moving parts of the transmission;

it is forbidden to stand or work under the stairs.

Naryad-permission for the repair of pipes and mechanisms of height must be formalized.

Repair work should be provided with the necessary plumbing equipment prepared according to safety requirements.

Warehouse requirements

Equipment used to store substances in warehouses

Warehouse areas. they must have a wide enough capacity to ensure the orderly storage of materials and products of various categories: raw materials and packaging materials, intermediate, unpacked and finished products, as well as quarantine, allowed for release, non-ferrous (brak), returned or recalled preparations.

Warehouse areas should be designed or adapted to provide better storage (GSP) conditions. In particular, they should be clean and dry, and the required temperature should be ensured in them. If special storage conditions (for example, temperature, humidity) are required, then they must be provided, checked and controlled.

Protection of materials and products from the influence of weather conditions should be ensured in the reception and shipment zone areas. Reception areas should be designed and equipped so that the products being taken are able to be cleaned, before placing the loaded Combs in the warehouse.

If quarantine is provided with the storage of products only in separate areas, then such areas must be clearly labeled, and access to it is allowed only to the authorized employee. Any quarantine system that applies to a separate God instead of being quarantined should provide security equivalent to it.

To select samples of raw materials, it is usually necessary to have a separate territory. If the selection of the sample is carried out in the storage area, contamination or collision should be carried out in a removable manner of contamination.

There should be areas with defects (braces), separately allocated for the storage of materials or products that have been returned or harvested back.

It is necessary to store strong-acting raw materials or strong-acting products in safe and protected areas.

Since packaging materials are considered critical for the quality of medicines, special attention should be paid to the safe and guaranteed storage of these materials.

Buildings and equipment

1. Necessary measures must be taken to prevent unauthorized persons from entering the storage space.
2. Storage areas should be large enough to allow orderly storage of materials of different categories.
3. Reception and dispatch areas must be protected from weather influences.
4. Quarantine places should be clearly defined and only authorized employees should be allowed to enter them.
5. There must be a separate area for sampling with the appropriate control conditions.
6. There must be a separately allocated area for the storage of rejected, expired, withdrawn, returned products.
7. Very active and radioactive materials, harmful, hazardous materials, fire and Explosives must be stored in specially designated places equipped with appropriate additional safety and safety tools.
8. Drugs, Psychotropic Substances and precursors should be stored in accordance with international conventions and national legislation of the Republic of Uzbekistan.
9. Lighting the premises for storing products should ensure that all operations are carried out accurately and safely.
10. Materials and medicinal items must be stored in conditions that ensure that their quality is maintained.
11. The principle of shelf life should be applied first, from the standard Özdst 2763: 2018 to Section 4.

Equipment:

- the equipment must be suitable and sufficient to ensure the correct preservation of medicinal products;
- measuring instruments designed for monitoring must be checked in the prescribed manner;

Storage conditions:

- the conditions for storing medicinal products must meet the requirements specified on the drug label.

Monitoring storage conditions-monitoring temperature data and, if necessary, relative humidity.

The temperature map should display the same temperature regime in all storage areas; it is recommended that the temperature sensor be placed in areas with a high probability of temperature changes.

Reception and issuance of medicines and medical items in the warehouse

The reception of medicines and medical items in the warehouse is carried out by the reception Department of the warehouse. When carrying out loading and unloading work, Protection of medicines and medical items from precipitation-hairpins, direct effects of sunlight, high or low temperatures should be provided.

The places of reception and storage of medicines and medical items must be separated from each other.

In case of detection of poor-quality, counterfeit, unregistered medicines and medical items, illegal copies of medicines registered in the Republic of Uzbekistan, as well as

medicines and medical items in circulation, facts confirming their harmful effects on human health, they must be removed from circulation in the prescribed manner and an act is drawn up and disposed of in the manner prescribed by the Cabinet of Ministers of the Republic of Uzbekistan. In doing so, they must be kept on the basis of identification or an act in a specially isolated place separate from other medicines and medical items until they are disposed of in the prescribed manner.

Medicines and medical items returned to the warehouse must be identified and stored in a separate place until a decision is made on them in the prescribed manner.

In cases where it does not comply with the requirements of regulatory documents and other documents in the field of technical regulation, according to the results of analyzes, medicines and medical items returned to the warehouse can be transferred to the main storage room.

According to the results of the analysis, medicines and medical items returned to the warehouse are formalized on the basis of the act and disposed of in the prescribed manner in cases where they do not comply with the requirements of regulatory documents and other documents in the field of technical regulation.

Organization of storage of medicines and medical items

In the warehouse, all medicines and medical items should be placed in stelages and diaphers. It is not allowed to place medicines and medical items on the floor without diaphers. Diaphers are placed in a row on the floor or several floors on the stelages, taking into account the height of the stelages.

The storage rooms for medicines and medical items and the equipment, equipment in them should be kept in a clean state.

Manufacturers and wholesale realization organizations should take appropriate measures to prevent the breakdown of medicines and medical products (spills, splashes, fractures), damage by microorganisms and contamination of drug crossovers.

In the warehouse, it is required to create conditions that are kept from insects, rodents and other types of animals and provide them with the means used against them. It is forbidden to use powerful influencing agents in this.

The storage of medicines and medical items can be systematized as follows:

by pharmacological group;

by methods of application.

The labeling of all medicines and medical items on the wrappers must be laid out and placed with an outward focus.

In manufacturers and wholesale realization organizations, the accounting of drugs is carried out in electronic or paper form by expiration dates.

Medicines should be stored in warehouses separately, depending on their physicochemical nature, subject to temperature, humidity and light regimes under conditions specified by manufacturers.

Temperature and humidity in the warehouse should be recorded in a special electronic program every day or in a journal whose pages are numbered, sewn and sealed (business entities are not required to confirm with a seal).

Medicines that require light protection should be stored in a dark room or in black-painted cabinets with tightly closed doors, or in crates with a tightly closed lid.

When storing thermolabile drugs, they must be branded or adhere to the temperature regime indicated in the instructions for use.

Medicinal plant raw materials (pre-dried) should be stored in dry rooms, closed (glass, metal, wood) containers, where air circulates well.

The following requirements are imposed on the storage of medical items consisting of binding materials:

binding materials are stored in rooms that are dry, air circulates well, protected from dust and rodents. Unsterilized materials are allowed to be stored in unheated rooms. It is allowed to store sterile materials in a room where the temperature level does not change rapidly so that they do not affect the quality of the packaging at temperature changes;

when storing sterilized binding materials in a warehouse, it is necessary to plan them according to the production times.

Requirements for the storage of medical items consisting of rubber items:

the room should be protected from sunlight. Light should only be artificial, electric;

boxes and cabinets with items should be placed no less than 1 meter from the central heating battery, as well as no less than 5 meters from the Ovens.

Storage of medicinal raw material products. The place (warehouses) allocated for the storage of raw material products of a medicinal plant must first of all be able to ensure the appearance of the product and the preservation of the biological active substances that affect it. When storing medicinal plant products, it should be taken into account that external unfavorable factors negatively affect the raw material product. In this case, attention is paid to the temperature and relative humidity of the air (exceeding the norm), as well as the direct effect of sunlight on the raw material product. Relative humidity is the main and dangerous factor when storing raw materials. Because, in rooms with high humidity or poor wind circulation (low), raw materials absorb moisture at the expense of the relative humidity of the air, and as a result, the humidity of the raw materials increases. As a result of this, the fermentation process begins in the plants, and the plant raw materials heat up, and the influencing substances break down. Favorable conditions for the development of microorganisms are created and moldy. Then, the process of mold (fungus) passes into the cells of the raw materials and spoils the color, taste, smell and chemical composition of the raw materials, and finally the quality. Raw materials come into disrepair for use in the pharmaceutical industry. In addition to these, the medicinal plant raw materials that are soaked provide the basis for the development of various zarakunanda. Therefore, in warehouses where medicinal plant raw materials are stored, the relative humidity of the basin is recommended to be up to 13%. Places (warehouses) that store medicinal plant raw materials can be temporary and permanent. For temporary storage, ordinary sheds, barns, dry land piles and building under-roof areas are intended. Heavy and voluminous medicinal plant hom objects (e.g., shimmer, andiz, gulkhairi and other plant roots and rhizomes) can also be kept in swarms on open ground in places where the product was prepared until shipment.

For permanent storage, special improvised warehouses are allocated. Permanent places where medicinal plant raw materials are stored-usually dry, clean, air should circulate well, have the required level of light and temperature. A permanent warehouse building (site) may be

concrete - brick and timber-planked, with a frame. If various cracks have formed in the premises of the warehouse, then they are first watered and leveled, and then whitewashed with lime. Because, existing cracks in the building

Provides the basis for the development of pests. In order to prevent this, the buildings are first plastered and whitewashed. If light falls directly on the warehouse windows, then the windows are whitewashed, protective curtains are installed and hidden from sunlight. Because, as a result of light falling from unprotected windows, the color and quality indicators of raw materials are impaired.

At the same time, it is necessary to constantly pay attention to the temperature of the storage facilities and the relative humidity level. Increased air temperature and relative humidity levels in warehouses lead to the development of warehouse pests. The high air temperature in warehouses leads to the fact that the raw material dries out above normal and volatile aromatic compounds in it fly away. For the storage of medicinal plant raw materials, it is advisable to have a storage facility 10-12°C.

The raw materials are stored in storage rooms in a packed state and placed in individually marked rastali areas. Fixed rastal areas in Aloxi are made of wooden boards. The height of the Rastas (saddles, counters, polkas) is 4m. it is required to be up to 1.5 m wide, the distance to the wall is 25 cm, the cross-span of the seats is 50 cm, and the height from the ground (floor) is not less than 15-20 cm. The installation of warehouse stalls (counters, Polkas) On the basis of such requirements ensures unhindered wind circulation not only from the side surrounds, but also from the bottom.

The medicinal plant is placed and stored raw material products in warehouses in groups based on their properties.

A label (Birch) is hung over each medicinal product. The label will contain the name of the product, when, where, who prepared it, when it was brought to the warehouse.

1) toxic raw materials are stored in rooms where a special lock is installed under a separate list of products - (a).

2) Strong impact etochi plant products (e.g. bellodona, angishvonagul, Begonia, bangidevona, etc.) are also kept separately--(B) in rooms where special locks are installed under the list.

3) fragrant raw materials, essential oil preservatives (e.g. mint leaf, asarun root, basil, etc.) are stored separately, separated from odorless plants. This is because odors from both spicy and fragrant plants can settle on odorless plant Homs. In order to prevent fragrant and quickly ground flowers (such as chamomile, linden blossom, etc.) from crumbling and spreading their smell, it is advisable to store them in crates with paper bedding and well-hidden.

4) hygroscopic products should be stored in iron containers with a well - closed mouth and a paper bed or in bottles with a closed mouth after complete drying of raw materials that absorb moisture from the open air.

Raw materials that are rich in reserve nutrients and have the property of rapid spoilage (e.g., tetanus root, dye-borne Root) are required to be stored in bags in well-windy areas and often inspected. It is recommended to store whole fruits - Apes, raspberries, strawberries, etc.,

usually placed in bags where the right wind blows. As a result of such storage of raw materials, they are damaged by fewer pests. If raw materials are stored in closed iron containers, damage to them will quickly occur. In warehouses where medicinal plant hom objects are stored, it is always required to adhere to cleanliness. That is, after the performance of certain intended work, it will be necessary to clean it from waste, remove dust from the wipes and rasts, and sometimes remove raw materials from the medicinal plant that has fallen out of the residue. Such cleaning work should be carried out daily. Spider nests in deer, geese and various places not only damage the cleanliness of the storerooms, but are also considered a positive environment for the development of barn zarakunanda (fungi and rodents).

Lecture 10. Preparation, storage and distribution of water in pharmaceutical production

Plan

1. Preparation of water in pharmaceutical production.
2. Storage of water in pharmaceutical production.
- 3 distribution of water in pharmaceutical production.

Base words and phrases: Water used for pharmaceutical purposes, purified water, water for injection.

Allocated time - 2 hours.

Water used for pharmaceutical purposes. Water used for pharmaceutical purposes is one of the main elements that ensure the safety of the drug. Its quality is regulated by the pharmacopoeia article (FS) included in the state Pharmacopoeia: FS 42-2619-97 "purified water" and FS 42-2620-97 "water for Injection".

Purified water is used for the following purposes:

production of injectable drugs;

- receiver bug ;
- sanitation;
- washing dishes (except for finishing);
- in laboratory practice, etc.

In the production of purified water is a source of water for injection according to FS 42-2619-97, purified water can be obtained by distillation, ion exchange, reverse osmosis, a combination of these methods or by another method. Purified water must meet the requirements of ionic, organic, chemical, microbiological purity.

Water for injection is used for the preparation of sterile medicines and for rinsing packaging materials, since purified water is obtained from drinking water, which is natural water, so it must be freed from Essential impurities.

Natural water can contain various homogeneous mixtures:

- mechanical particles (insoluble inorganic or organic mixtures);
- dissolved substances (inorganic salts, calcium, magnesium, sodium, chlorine ions, sulfuric acid, carbonic acid ions, etc.);
- dissolved chemically inactive gases (oxygen, nitrogen);
- dissolved chemically active gases (carbon dioxide, ammonia);
- microorganisms (visible, mold, algae, cysts, etc.);

- bacterial endotoxins (lipopolysaccharides of the cell wall of Gram-negative microorganisms);
- organic substances (organic substances polluting natural organic substances - industrial waste, fertilizers, pesticides, etc.);
- colloids (iron $\text{Fe}_2\text{O}_3 \cdot \text{N}_2\text{O}$, Silicon $\text{SiO}_2 \cdot \text{xyN}_2\text{O}$, form complex compounds with organic matter);
- residual disinfectants (chlorine, hypochlorous acid, hypochlorite ion, chloramines, etc.).

Preparation of purified water

The choice of a technological scheme for obtaining purified water depends on the following.

- quality of source (supplied) water;
- choosing the last stage of obtaining water;

Requirements for Pharmacopoeia water;

- requirements for the quality of Water presented at certain stages (for example, distillation, reverse osmosis);
- Pre-treatment steps designed to remove mixtures normalized by the manufacturer of structural documents or pharmaceutical products.

Preliminary preparation is a set of operations aimed at obtaining quality water, which is necessary for the final stage of obtaining purified water.

Extraction is the final stage that provides water intake that meets regulatory requirements.

Filtering. Filtration technology plays an important role in water treatment systems. There is a wide range of filtering devices for different homogeneous applications. The effectiveness of T particle screening varies greatly, from coarse filters (granular anthracite, quartz, sand - multilayer or sand filters) to membrane filters to remove the smallest particles. Devices and system configurations vary depending on the type of filter medium and the location used in the process.

Modern filtering systems are devices with three or five cycle operating modes, automatic (using a programmable controller) and manual control.

In the three-cycle mode of operation of the filtering device, the following are provided: to obtain purified water, back and direct washing of the filter medium. This mode is used in installations with fillings that do not require regeneration (multilayer filters, Birm-based iron quenching filters, activated carbon filters).

The five-cycle mode of operation includes: extraction of treated water, backwashing, regeneration / slow washing, fast washing, and filling of the salt tank. This mode is used for filtering stations, in which it is necessary to update the filter environment (manganese zeolite-based deferration filters, emollient filters).

The use of multilayer filters is one of the early stages of pre-cleaning water. Their use is recommended for water turbidity and high content of mechanical, colloidal particles. The compounds of the filter medium vary depending on the quality of the source water, but are most often manifested by a reserve layer in the form of hydroanthracite, granite, quartz and gravel.

When using multi-layer filters, it is necessary to ensure a minimum water filtration rate of 5-10 m/H and a high reverse rate of 35-40 m/h. Based on this, the correct selection of the pump is an important criterion to ensure the filtration and return speed.

Iron purification filters based on the environment of the Birm and manganese zeolite filter are used to remove iron and manganese impurities present in the water. In addition, hydrogen sulfide dissolved in water is removed using manganese zeolite. As a result of chemical catalytic oxidation processes on the surface of the filter medium, molten iron and manganese are converted to an insoluble form (hydroxide) and removed from the filter in the form of flocculation sediment by backwashing Birm when the filter medium is used, the presence of oxygen dissolved in the concentration is 15% higher dissolved iron concentration. Manganese loses its catalytic properties due to the use of tseolite, so it must be periodically (or continuously) regenerated with a solution of potassium permanganate. In high concentrations of iron and manganese in water, water aeration systems should be used first.

One of the filters widely used in pharmaceutical practice are activated carbon filters, which adsorb and release low molecular weight organic matter and chlorine from water. They are used to improve organoleptic properties (water discoloration, taste improvement, etc.), to protect stainless steel surfaces, rubber objects, membranes that come into contact with them.

Water softening. Softening is a special case of ion exchange. Water softeners remove cations such as magnesium and calcium, i.e. Softening can significantly reduce the ion content before using water to purify into ion exchangers and reverse osmosis membranes. In most cases, automatic softening columns filled with cation exchange resins are used, in which the hardness salt cations are exchanged for sodium cations. When necessary, in pharmaceutical enterprises, continuous (during the day) production of softened water, duplex devices are used, ion-exchange resins are regenerated, which are carried out in turn.

With a decrease in the ability to exchange resins, its automatic restoration is carried out by periodic manual or with a solution of sodium chloride.

Ion exchange. One of the effective ways to remove anions and cations from water. This is one of the most important steps in cleaning, which is used both before treatment and to obtain purified water.

Ion exchange is based on the use of ion exchangers - cross - linked polymers of varying degrees of cross-linking, gel micro or macropore structures covalently bonded to ionogenic groups-the separation of these groups in water or solutions gives the ion pair-a portable counter-agent that exchanges ions and ions embedded in the polymer. a charge of a homogeneous name (cations or anions) is obtained from the solution.

There are two types of Ion exchange apparatus, usually columnar:

- with a separate layer of Cation exchanger and anion exchanger;
- with a mixed layer.

The first type consists of two columns in a row, the first is filled with a cation exchanger along the treated water, and the second with an anion exchanger. The second type of apparatus consists of a single column filled with a mixture of these ion-exchange resins. The cation exchanger is regenerated with anion exchanger containing 5% hydrochloric acid, 4% sodium hydroxide. The advantages of Ion Exchange are low cost of capital, simplicity and lack of fundamental limitations to achieve high performance.

In the process of regeneration, a large amount of strongly acidic and strongly alkaline washes are formed, which must be neutralized before falling into the wastewater system. Ion exchange systems require pre-cleaning from insoluble solid particles, chemically active reagents in the water stream (chlorine) to prevent resin contamination and deterioration of its quality.

Reverse osmosis. Reverse osmosis is the process by which a solvent (water) passes through a semipermeable membrane under the influence of external pressure from solution. In this case, the excess working pressure of the saline solution is much greater than that of osmotic. The driving force of the reverse osmosis is the pressure difference. In order to obtain water in the reverse osmosis method, it is necessary to "force" molecules that propagate in the opposite direction through the semiconductor membrane, creating an excess pressure higher than the osmotic pressure, that is, from the highly mineralized water, it is necessary to enter the unit of clean water and increase its volume.

Reverse osmosis provides the best level of filtration. The reverse osmosis membrane acts as a barrier for all soluble salts, inorganic molecules, organic molecules with a molecular weight of more than 100, as well as microorganisms and pyrogenic substances. After the stage of excess osmosis, the content of dissolved substances averages up to 1-9%, organic substances up to 5%, there are no colloidal particles, microorganisms, pyrogens. The water formed as a result of reverse osmosis contains a minimum amount of organic carbon.

Among the advantages of reverse osmosis, it should be noted its simplicity and independence from the salinity of the source water, low energy consumption and significantly lower maintenance and maintenance costs. The system is easily washed, disinfected and cleaned, does not require the use of strong chemicals and their neutralization.

When performing an osmotic process, a certain problem is the choice of membranes. It should be based on water treatment requirements, operating conditions and characteristics, recovery conditions, safety, water sources supplied to the system.

Reverse osmosis is usually used in pharmaceutical water systems in the following cases.

- to reduce the consumption of acid and alkali necessary for regeneration before ion exchange plants;
- obtaining purified water;
- as a preparatory stage before distillation to obtain water for injection;
- as the last stage of obtaining water for injection (two-stage osmosis).

Storage and distribution of treated water

The main task in the design of the system for storing and distributing purified water is to ensure the constant movement of water in the pipes, the absence of stagnant zones that contribute to the growth of microorganisms and the formation of biofilms on the surfaces. Modern storage and distribution systems refer to a recirculation system that flows in one direction and has the ability to completely extract water from the pipe.

Important parameters when storing and distributing treated water include:

- temperature;
- movement of water and its speed;
- pressure;
- pipeline materials and storage containers.

Distribution and storage of purified water according to GMP regulations should be carried out at temperatures that prevent the proliferation of microorganisms - above 800 C or below 150 C. Systems that use cold water must be equipped with UB systems to lower the level of microorganisms in the water.

The movement of water inside the pipe should be turbulent at a speed of 1.5 to 3 m/s. In hydrodynamics, the degree of turbulence in a fluid flow is described by the Reynolds number (Re).

One of the main problems is the correct choice of materials for storing and distributing purified water. The material of the structures should not worsen the quality of water and meet the requirements and conditions of pharmaceutical production. Purified water according to the requirements of FS 42-26 (9-97 "purified water" and GMP rules) is stored in closed containers with a very smooth surface, which does not change the properties of water and protects it from foreign particles and microbiological contaminants. Above 0.8 Ra) and should be protected from bacteria, dust with a reliable filter. The storage tank must be optimally selected to ensure that the water circulates through the circulation system 1 to 5 times an hour, if necessary, the water in the tank must be completely drained. In the case of any place, the container must be installed vertically, and the height of the container should be equal to 2 diameters.

Main materials used:

- Polymer materials such as PP and PVDF (polypropylene, polyvinylidene fluoride), etc., are often used in the design of cold distribution schemes of purified water;
- stainless steel 316 L, surface no more than 0.8 Ra.

Distillation method and preparation of water for injection.

Water requirement for injection

The main difference between the requirements of Pharmacopoeia (Russia, USA, Europe) for the preparation of water for injection is as follows:

* According to the European Pharmacopoeia, distillation is a mandatory way to prepare water for injection;

Us pharmacopoeia and FS 42-2620-97 (Russia) allow distillation and reverse osmosis.

Distillation. There are three types of distillation processes:

- single column,
- * thermocompression,
- multi-column.

Single column distillation has long been used and is widely used. Its significant drawback is its simple design and high energy consumption, despite the low cost of distilleries.

The essence of the distillation of thermocompression is as follows. Forced compression of steam by the compressor leads to an increase in steam pressure and its temperature. The increased amount of heat (enthalpy) of steam is used to heat water and convert it into steam. The disadvantages of this method are the ingress of foreign particles into clean water, high noise levels and the need for constant maintenance.

The best combination of different homogeneous properties is multi - column distillation, in which the energy of heated water is fully and efficiently used Steris / Fin-Aqua concern is the world leader in the production of multi-column distillations. In 1971, Finn-Aqua was the first to use the principle of multi-distillation to inject water.

Checking water from a sanitary point of view

When checking water from the point of view of sanitation, attention is paid to:

- A). Organoleptic and physical properties of water;
- B). Chemical composition of water;
- V). Bacteriological indicators of water quality;
- G). Presence of radioactive compounds in water;

Organoleptic and physical properties of water. Water with good organoleptic properties is highly valued. This is a natural state of course, such water is characterized by a clear, colorless, odorless, clean, thirst-quenching.

Chemical composition of water. Water sources are contaminated with chemicals due to the untreated discharge of wastewater into bodies of water in industrial sectors. Hygienists have developed an acceptable amount of lead, margimush, zinc, copper and other substances in water, the amount of which is also specified in the drinking water quality standard. The continued contamination of open water sources with the remains of all kinds of pesticides and fertilizers also changes the flora and fauna activities in the soil and waters. Especially in this regard, pesticides resistant to external environmental influences are dangerous.

Bacteriological indicators of water quality. From an epidemiological point of view of water, checking whether there are pathogenic microorganisms from a hygienic assessment is a complex and long-lasting work. Indirect bacteriological indicators are used in this. The less water is contaminated with saprophytic microbes, the less epidemiologically hazardous it is. The presence of an intestinal wand in the water means that the water is contaminated with feces. This means that such water can also contain pathogenic microorganisms.

The presence of saprophyte microflora in water is a sign of pollution, the level of which is expressed by the concept of "microbial number".

"Microbial number" is said to be-1.0 ml of the number of microbes in the water being examined. To do this, 1.0 ml of the water being examined for meat peptone Agar is planted and left for 37 0C 24 hours in a thermostat. In time, the number of microbes that are considered a microbial colony is determined. The number of germs indicates that the water is contaminated with common germs.

The quality of the water is determined by the number of colonies. The colony content in non – polluted, well – equipped artesian wells reaches 10-30, in the water of an uncontaminated mine well – 300-400, in slightly clean, open water sources – 1000-1500, in the water of a vodoprovod, where good antimicrobial measures are taken.

Again, in a bacteriological assessment of water, it is determined whether it has an intestinal wand. Whether the intestinal wand is present in the water is represented by the size of the coli-titre or coli-index.

Coli-titr deb-one intestinal wand holder is said to have the least amount of water. The lower the coli titer, the more contaminated the water is with the intestinal wand in the human population. Coli-index deb-is said to be the number of intestinal sticks in 1.0 liters of water. Studies show that if the coli-index is reduced to three after water neutralization (in which the colititr is higher than 300 ml), then the pathogens of pathogenic microbes, leptospirosis and tularemia, which belong to the group of typhoid, paratyphs, completely die. The quality of tap water is expressed in standard indicators developed on the basis of the above estimates. The number of

saprophytic bacteria in 1.0 ml of water should be at most 100B, the coli-titer should not be less than 300 ml or the coli-index should not be higher than 3.

PURIFIED WATER

Agua purificata

H₂O

M.m. 18,02

In nature, water is abundant, including Sea, Lake, kuduq, spring and mineral waters. Water makes up 3/4 of the Earth's surface. Natural water, dissolved in its composition, contains various mineral salts, organic compounds, gases (oxygen, carbonate anhydride, ammonia, etc. q.) saves. Even the most pure considered rainwater will have various gases, dust and microorganisms added from the air.

In the preparation of various solutions in pharmacies, as a solvent, only Agua purificata, a water purified by driving from drinking water in special apparatus (aquadistillators), is used.

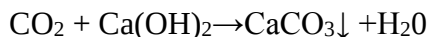
Purified water is a colorless, odorless and tasteless liquid with a RN value of 5.0-6.8 while its density is 1,000 g/cm³ at 4°C.

The expelled water cannot be called completely clean either. It can store Foreign inclusions, although it contains very small amounts of it. They can pass through the air in a state of dust, through a metal fan apparatus, along with its vapors in the process of driving a metal ion or water, into the receiving container as volatile substances, gases. In the state Pharmacopoeia, great importance is attached to the quality control of purified water. One of the requirements for the quality of water, the environment in it should be at the level of the rN value indicated above, that is, there should be no excess acid and alkaline environment in the water. It is recommended to be determined by the Potentiometric method of the state Pharmacopoeia. (DF XI edition, Book 2, p. 113).

At the request of the pharmacopoeia, purified water should not contain substances with reversible properties, nitrite and nitrate salts, carbon dioxide.

When determining whether there are substances with reversible properties, the pink color should not fade in the solution even when boiling it for 10 minutes, adding a solution of sulfuric acid and potassium permanganate to the water obtained in a certain volume. Otherwise it means that water contains repellent compounds.

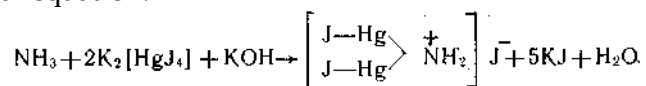
In order to find out if there is carbon dioxide as a foreign additive in purified water, it is shaken by adding a solution of calcium hydroxide in an amount equal to a certain volume. The mixture should remain crispy, without blurring for an hour. Its turbidity indicates that the water contains a carbonate anhydride:



A solution of diphenylamine in concentrated sulfuric acid, which is widely used in pharmaceutical analysis, is used to determine whether there are nitrite and nitrate compounds from foreign compounds in purified water. Under its influence, the verifiable water should remain colorless. Conversely, the fact that water stains the air color indicates the presence of nitrite or nitrate foreign compounds in it.

At the request of the state Pharmacopoeia, purified water should not exceed the content of ammonia from foreign compounds, as well as chlorine, sulfate, heavy metal, calcium ions, in any of them in specially prepared ethalonic (standard) solutions. This is determined by simple reactions involving each of the usual additions. For example, ammonia is detected using the Nessler reagent. The yellow coloring of water under the influence of the Nessler reagent indicates the presence of ammonia or an ammonium ion in it. Its state Pharmacopoeia is compared to a solution of étalon to find out if it is in the permissible amount. The reaction

between ammonia and the Nessler reagent can be expressed according to the following chemical equation:



It is also detected by dipping a chlorine ion in silver chloride, a sulfate ion in barium sulfate, and a calcium ion in oxalate salt.

The remaining residue after complete evaporation of 100 ml of purified water should not exceed 0.001%. When the water content is clean, it will evaporate completely without leaving any residue. With this, it becomes known whether purified water contains various mineral substances.

When preparing solutions for injection, *Agua proinjectionibus*, a specially prepared water that meets the DF requirement, is used. It is prepared in pharmacies on the basis of a manual approved by the Ministry of Health.

The state Pharmacopoeia recommends a thorough examination of the presence of pyrogenic substances and mechanical compounds in addition to water purified as a foreign substance in the composition of water used for injection. Pyrogenic substances are microorganisms trapped in the composition of water and various products caused by their decomposition. If solutions prepared in water stored by pyrogenic substances are used in injection, the temperature of the human body can rise and other diseases can arise. Overexposure of pyrogenic substances in water also causes deaths. The pyrogenicity of water is examined in rabbits according to the biological method listed in DF. This is a 0.9% isotonic solution of sodium chloride prepared in 10 ml of the water being examined, in relation to the ear vein of rabbits of a certain weight, each kilogram of body weight, allocated for a special experiment. The temperature of the rabbits under experiment should not exceed 0.6°C in relation to their initial temperature up to the experiment, even when measured every hour, a total of three times.

Purified water is kept in full, in containers with a sealed mouth and no change in its composition. Every freshly driven and stored water for a day is necessarily subject to quality control.

Water prepared for injection can be stored at temperatures from 5°C to 10°C or 80°C to 90°C, with a mouth in berk jars for up to 24 hours.

Lecture 11. Buildings and equipment for the production of sterile drugs. Cleaning equipment.

Plan

1. Buildings for the production of sterile drugs.
2. Equipment for the production of sterile drugs.
- 3 cleaning equipment.

Base words and phrases: Buildings and equipment for the production of sterile drugs. Cleaning equipment.

Allocated time - 2 hours.

General requirements for equipment

Equipment used in pharmaceutical production GOST 12.2.003-91 " production equipment. General security requirements" and are required to meet other network documentation requirements.

In order to control the production and quality of medicines, it is necessary to build and place the equipment used to prepare them for use, with the goal of making use and service work as easy as possible.

Equipment and control-the Type, Dimensions and descriptions of measuring instruments should be in accordance with the technological processes being carried out.

The placed equipment should not block natural light and air access to the room through the window from the outside.

Control and measuring instruments must be installed to monitor the continuation of the technological process, ensuring that their serviced parts are illuminated.

The scales and measuring instruments used to prepare medicines and control their quality must be calibrated and examined in generally accepted methods on a periodic basis.

In the production, packaging, storage and transportation of the product, its quality control work, it is advisable to use computer technology.

The equipment in the workshop must be installed with the possibility of freely approaching them. When installing equipment, it is necessary not to leave difficult and uncomfortable places for cleaning, since such places can be a source of waste and dust accumulation.

The following requirements are imposed on the construction of the equipment:

a) it is necessary that the starting raw materials, semi-product or finished product contact surfaces of the equipment are made of a smooth and non-toxic, corrosion-resistant material that is resistant to treatment with disinfectants;

b) all parts of equipment that come into contact with production products must be removable and detachable to make them easier to wash, work with disinfectants or sterilize;

c) in order to prevent contamination of finished products and their quality from changing in a negative way, the equipment should not be contaminated with the materials used for their use (for example, lubricants;

g) all transmission devices (transporters, valuable transmissions, transmission privods) must be closed or blocked;

d) bunkers, containers and other similar equipment must be closed;

e) tables for cleaning, washing and disinfection of all technological dishes, apparatus and other equipment on a periodic basis should be drawn up and they should indicate washers and disinfectants. The tables are developed by the head of the workshop and approved by the chief engineer of the enterprise.

According to the schedule approved by the chief engineer of the enterprise in accordance with the current technological equipment, repair system and legislative acts of the installed equipment for proper use, it is necessary to carry out preventive examination of equipment and take all measures for their repair.

Preparation of the equipment for work should be carried out according to the instructions for working with disinfectants or sterilizing it.

The quality of the equipment's readiness for operation should be monitored according to the established procedure when the equipment is treated with disinfectants or after its working parts have been sterilized.

The equipment used for the production of a single type of medicinal product must be cleaned in a way that does not allow different categories of the product to mix.

The equipment used for the production of several names of medicines must be diligently cleaned from the contents of the washing water, until the medicinal substances contained in the prepared medicine are completely eliminated.

Before producing the next designation of medicines, the equipment must be washed, treated with disinfectants or sterilized according to the specified requirements.

The equipment used for the production of antibiotics is not used for the production of other medicines in order to prevent opposite (reverse) contamination.

Safety conditions when placing production equipment

The equipment should be placed with the following goals in mind:

- optimizing the flow of primary raw materials, materials, reducing the need for employees to move from one place to another as much as possible;

- eliminate the possibility of their contamination during the production of medicines;

- eliminate the risk that different products will get mixed up or that production stages will not take place;

- facilitate the washing, operation, use and maintenance of equipment;

- ensuring the rational use of the field;

- the fact that the established workplaces comply with the requirements of labor protection norms and rules.

When installing equipment:

- the main corridors along the service in the control area of the ham in the permanent stands of workers-2 meters;

- main corridors along the service of machines, dishwashers, local measuring instruments-1.5 meters;

- if it is necessary to show the apparatus to the service circuit, the width of the corridors between the apparatus and between the apparatus and the walls of the room-at least 1 m;

- the width of the aisles for inspection and adjustment of apparatus and instruments on a periodic basis – at least 0.8 meters;

- width of corridors between separate standing pumps - at least 0.8 meters;

- at an altitude of 0.6 meters above the floor level and more, the holes in the playgrounds, crossing bridges, stairs, Scrolls, Trestles should be blocked by a continuous covered fence with a height of — 0.9 meters, from below — 0.14 meters.

Equipment included in the range of objects at high risk should be placed in accordance with the requirements for the construction of pressure-operated containers, heat-operated devices, compressors, load-bearing machines and other equipment, as well as the safety of their use.

Aseptic rooms designed for the production of sterile products should only be equipped with basic technological equipment that directly provides the technological process. It is necessary to place auxiliary equipment in aseptic rooms in adjacent rooms.

Pipes passed over the floor should be laid in a ditch on the land of intersection with crossings or covered with crossing bridges (ramps).

All flange attachments of pipes that have passed over the top of the passages (where aggressive liquids and hot solutions and steam pass) must have protective devices.

Pipes should be in accordance with GOST 14202 "pipes of enterprises of industrial pharmaceutical production, special paint colors, warning signs and packing shittocks", depending on their intended purpose.

Fire-fighting pipes must be painted red in the places where they are connected, no matter what happens inside them, in the locking, adjusting iron parts and hoses, as well as other devices for extinguishing fires.

Disconnection devices must have signs indicating the final (open-closed) States.

For automatic adjusting caps and valves, such marks are usually not required. If it is not possible to specify the position of the cranes and locking devices in the way indicated above, it is necessary to mark with a directional arrow or inscriptions.

Control over the condition of the hooks and stems of the pipes should be ensured in order to avoid the risk of an accident and the passing of products caused by dangerous bending and deformation of the pipes passed over the ground. Any malfunctions detected on the hooks and stems of the pipes must be eliminated immediately.

When conducting pipes for crystallizing and gluing liquids, the possibility of cleaning them using Steam, washing them, and if necessary — disassembling them. Places that are convenient to disassemble should be connected by flange tool.

After overhaul, all locking devices for apparatus and pipes and iron are required to be tested for mechanical durability and Hermeticism using compressed air or inert gas pressure. These tests are performed after fitting and chilling-mechanical processing.

Transit technological pipelines with aggressive, harmful and potentially hazardous substances are prohibited from passing over or under buildings, structures and devices.

It is forbidden to leave sliding valves open on non-working apparatus or pipes.

Temporary non-working apparatus and pipes must be disconnected from working apparatus or pipes.

Frozen pipes cannot be heated using open grass.

The method of placement and transfer of pipes should ensure that the pipes themselves, the locking and adjusting iron and the installation, repair and maintenance of equipment that is connected or located directly on the ground near the pipes can be safely and conveniently carried out.

In the production of injection solutions in the ampoule, material pipes must be equipped with sterilizing devices and locking devices that do not allow products to get into the production rooms and into the drain. On the site of preparation of injection solutions should be a drawing of steaming equipment and communications.

Technological equipment.

There are many types of equipment for the production of medicines. This is the result of different dosage forms and the requirements for them. At the same time, there are basic requirements that must be met for any processes and types of equipment. Examples include the characteristics of equipment for the manufacture of rigid forms, requirements for water and compressed air.

Technological equipment must perform the functions required by this process and meet GMP requirements. These requirements are constantly improved, detailed and to some extent tightened, but the general logic of the requirements remains unchanged. The requirements of GOST R 52249-2009 (EU GMP) and the requirements of the US cGMP regulations are listed below.

Such requirements are true for any production, but for the pharmaceutical and medical fields they are strictly mandatory.

General requirements. GMP regulations (GOST R 52249) define the following requirements for technological equipment:

- equipment must be purposeful;
- the equipment must be suitable for cleaning and maintenance;
- cleaning products, inventory and materials should not be a source of pollution and collect pollution;
- it is necessary to design and place equipment, eliminate as much pollution or improper behavior as possible;
- the equipment should not compromise the quality of the product and pose no risk;
- the accuracy of the instruments and the measurement scale must meet the requirements for the parameters they control;
- parts of technological equipment that come into contact with the product should not react with it, release (or adsorb) substances that affect the quality of the product.

US requirements

Similar requirements, with some explanation, are established by CFR 21, parts 210 and 211 (cGMP rules) of US Federal Regulations:

Section D-equipment

Equipment design, its dimensions and location

(a) in the construction of equipment, such a design of surfaces in contact with starting materials or ready-made drugs used in processing should be envisaged so that they do not react to substances, do not release or absorb, and safety indicators, identification, effectiveness, quality or purity of drugs obtained from official or other established requirements.

(b) any substances, lubricants or refrigerants used in the work should not come into contact with starting materials, primary packaging materials, closing materials, materials used in the processing process or finished medicines, and should not allow the deviation of safety indicators. , efficacy, quality, or purity of drugs according to formal or other prescribed requirements.

cGMP regulations also define requirements for automatic, mechanical and electronic equipment, cleaning and servicing equipment and filters.

Parameter management. GMP regulations establish equipment management requirements and these requirements are tightened. Good manufacturers are ahead of regulatory requirements and include:

- control of equipment and equipment parameters;
- equipment automation;
- automatic cleaning and sterilization of equipment.

Monitoring parameters allow real-time, continuous monitoring of the critical process. This gives an objective idea of the process and quality of the product. It helps to find their cause, leaving the product characteristics aside from technical requirements. During the process attached to the statement of the series of products, the list of parameters serves as a documented confirmation of the compliance of the parameters with the specified requirements.

The purpose of parameter monitoring is to detect deviations from the norm and predict failures, i.e. failure of the equipment or process to comply with the specified requirements. To prevent malfunctions, a warning level and actions are established that allow you to determine and eliminate the cause of the accident in advance.

Automation of the process reduces or eliminates the influence of a person on this process. Pollution and distribution of the environment is human nature. Limiting or excluding

an individual's participation in the process as a whole is in the spirit of GMP and may be included in GMP regulations in the future.

Modern equipment provides automatic cleaning of surfaces in contact with the product and, if necessary, sterilization of equipment at the place of use without disassembling it.

These are the systems:

- my kinemestme-place of washing (WIP),
- on-site cleaning - on-site (CIP),
- on-site sterilization-on-site sterilization (SIP).

Cleanliness (infertility) of the equipment is a very important condition. Cleaning and sterilization processes must be certified.

In order for the procedure to be certified, it must be repeated Strictly and does not depend on the behavior or mistakes of a person.

Instrumentation

It is necessary to distinguish between measuring instruments used for general purposes, measuring instruments and control devices (calibers), which are part of technological equipment.

Measuring instruments used for general purposes (thermometer, hygometer, anemometer, voltmeter, etc.) should be checked in the order prescribed by Metrological organizations.

Measuring instruments installed on technological equipment are not disassembled and are not transferred to "inspection" for metrologists. This is a very important point. First, disassembly of the device leads to a violation of the integrity of the equipment and subsequently requires its certification. Secondly, metrologists can simply break the responsible device and will not be responsible for it. Thirdly, metrologists have neither methods nor tools for tracking most modern devices, such tasks as paying for their "services" and drawing up official meaningless documents are reduced.

The equipment included in the equipment as equipment is calibrated according to the manufacturer's instructions, and this procedure is accepted all over the world and meets the requirements of GMP.

Most control devices are not measuring instruments because they do not measure anything, only check whether the parameters are consistent with the given values, or perform an arithmetic function of calculating discrete quantities (particles, fragments, etc.

Appointment and certification indicators(tests)

General requirements. GMP regulations include a universal requirement for all cases: "design, installation and maintenance of equipment must meet its purpose" (3.34 GOST R 52249-2009 - EI GMP).

What is it?

The equipment must perform the functions assigned to it. Its purpose is determined by the technological process (technological regulation). Everything seems to be clear: you need to choose equipment whose passport data meets the requirements specified in the technological regulation.

But it's not so simple. Not all GMP requirements may be specified in process regulations. Passport data on equipment may be optimistic or not reflect GMP requirements.

If this equipment is very important, it must be tested (approved) before launch. How to certify? This question sometimes becomes a stumbling block. In fact, although not always simple, it is clear that there is a competent testing methodology (certification).

If this technique does not exist, then there can be no talk of certification, it will become a mountain of wealth and empty papers. The still existence of this question is the result of the

flaw of regulatory documents, the ignorance or dishonesty of those who interpret and install these documents.

Pharmaceutical manufacturers are not research institutes. In order to responsibly develop the methodology for testing equipment, they do not understand all the subtleties of equipment. If we go along this path, then the more users there will be, the more test methods, for example, tablet presses.

The methodology for this type of tablet press must be one and all users must use it. Only under these conditions can the comparison of different areas and the objectivity of the assessment be ensured.

The test procedure (certification) must be developed by the manufacturer of the equipment and included in the delivery package and the main package, but not in the selection. The manufacturer of the equipment is responsible for this.

The manufacturer of good equipment itself is interested in launching its equipment and impeccable operation. He himself is interested in providing the client with the necessary documents for testing, use and maintenance.

Tests (certification)

The main thing is to understand that it is impossible to certify poor-quality equipment or a bad process. Testing (certification) - this is only the installation and correct operation of a good unit - as presented in its design.

This is a simple and obvious rule. But many manufacturers who do not listen to the confidence of suppliers that "everything will be corrected and decided at the" confirmation "stage do not know it.

The supplier must issue a document (possibly signed) that meets the GMP requirements of the equipment. The supplier must provide a certification program (methodology). In the contract of delivery, it is necessary to establish the responsibility of the supplier in the event that the equipment has not passed the test (certification).

There is good experience in the US: the court recognizes that the requirements of standards and other recognized documents must be observed. It's very smart. Many subtleties cannot be taken into account in law or GMP regulations. These subtleties are known by the Society of standards developers and engineers, who describe them in detail in their documentation. Without taking these standards into account, it is impossible to build modern productions that meet safety requirements and Target and efficiency indicators.

Production of injection solutions in the ampoule

The main stages of injection solutions should be placed in insulated rooms.

Ventilation and air release in rooms with a large number of heat separations (bottling, ampoule soldering and sterilizing sections) should be carried out from above. The height of the rooms of the glass partitions should be at least 6 meters.

Ampoule softening ovens should be equipped with protective screens and local ventilation tugs in order to prevent radiant and convective heat from falling into the room.

The rooms should be diligently cleaned of glass fragments, unfit ampoules and glass dust.

It is necessary that the semi-machines forming ampoules are equipped with a centralized glass waste disposal system.

Cleaning equipment using compressed air from glass fragments is prohibited.

In order to reduce noise on the ampoule preparation plot, the walls of the room should be treated with soundproofing coatings.

When calibrating glassadrot, the distance between the workplaces must be at least 2 meters. The calibration of the drot must be mechanized.

It is forbidden to block corridors with glassadroti.

The bottle protector of ampoule forming machines should be installed in special tripods with a metal set.

When working on semi-machines and ampoule soldering machines forming ampoules, it is necessary to strictly follow the safety rules established for gas farming.

In the preparation and soldering rooms of ampoules, it is necessary to check the presence of carbon monoxide in the air on a periodic basis.

It is necessary to immediately stop the transmission of gas to the semi-machines forming ampoules and to the machines for soldering ampoules in the event of an accidental shutdown of electricity.

It is forbidden to assemble and clean semi-machines and ampoule soldering machines that form ampoules until they completely stop.

In order to provide heat in the operation of the ampoule softening furnace, it is necessary to monitor the temperature and tensile strength meter instructions if the gas is being applied.

The work of placing strong-acting preparations in ampoules should be carried out in insulated rooms in compliance with special precautions recorded in separate equipment, position instructions and safety equipment documents.

In aseptic rooms, air is sterilized by ultraviolet light through the installation of bactericidal lamp irradiation devices equipped with a screen that protects against exposure to the right Rays.

In order to prevent the vapors and dust of medicinal substances from getting into the body of employees, it is necessary that the poured solutions are washed in water, and the ampoules with broken injection solution are removed from the working rooms.

Phytochemical production

It is necessary to place processes involving toxic solvents in insulated rooms.

When the plant raw materials are crushed and loaded into extractors, dust capture and dust suppression measures must be taken.

When loading plant raw materials, it is necessary to use special transporters, pneumotransporters (on the pipe) or other mechanical devices that do not allow dust to escape.

The extraction and removal of Shrot from extractors must be carried out with the help of shnekli, hydraulic transporters and other transport devices that exclude manual labor. Before removing the Shrot, it is necessary to Steam diligently to eliminate solvent residues.

Samples must be taken using a vacuum through a special nozzle in the apparatus or through a special sampling crane with a local traction device.

In order to dry the medicinal substances and prevent dust from forming and accumulating in the combustion chambers, it is necessary to compact the equipment, close it to the grinder, mill and other equipment cabins with sufficient aspiration, get it through a cloth hose that does not pass dust, clean it in a damp rag every shift, take vacuum-assisted cleaning measures.

The transportation of solid medicinal substances for wrapping and processing should be carried out in special containers made of duraluminium or stainless steel, with a dense closure of the lid, equipped with devices for obtaining and supplied with a label.

It is necessary to carry out liquid extracts and decoctions, wraps of solutions and other preparations in insulated rooms.

It is necessary to use special washing machines for washing jars, sklyanka, vials and other glass jars.

For phytochemical production, plans should be drawn up to eliminate accidents in the prescribed manner.

Filling ampoules with solutions.

The application of solutions to ampoules is carried out using automatic or semi-automatic methods, in vacuum and using the method of parocondensation.

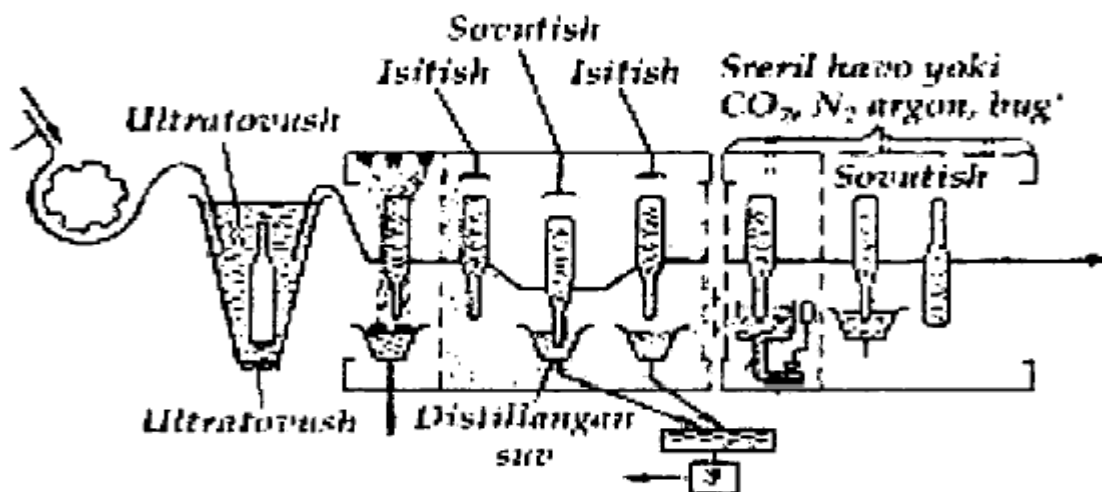
In the syringe method, the application of solution to ampoules is carried out using a special semi - automatic (Shtrunk - Germany, Autonan - England, Ponper-USA). This method has advantages such as the accuracy of the amount of solution poured into ampoules (2%), as well as the absence of solution in the capillary part of the ampoule. Productivity is 9000 ampoules per hour and does not meet eamon's requirement.

Vacuum method.

This method of filling ampoules with solution is carried out on vacuum-washable instruments. The vacuum depth at which the difference is generated must be precise, as it ensures that the required volume of liquid enters the ampoule. To remove any remaining fluid in the ampoule capillary, the ampoules are placed with the cassette with the capillary facing up on another vacuum instrument and filtered air is sent, in which the fluid passes into the ampoule body. This method is widely used in enterprise conditions, and 30-50 thousand ampoules per hour can be filled with a solution. The disadvantage: accuracy in dosing is - 15%, ampoule capillaries are contaminated with the solution, and its loss takes a separate time. 3-4 times more solution than the solution in which the ampoule will need to be filled is sent to re-filter. M.A.Seletsky and V.A. In the semi-automatic offered by rivkins, the division of the solution into doses and the vacuum level are carried out using an electronic controller and a vacuum contactor. As a result, the ampoule is filled with a clearly defined amount of solution.

Parocondensational method.

This method allows ampoules to be filled with solution by prof. F.A.Konev showed in practice. In this case, the filling of the ampoule with a solution is carried out as follows: after the ampoule has been thoroughly rinsed in a parocondensational way, the capillary of ampoules filled with water vapor is lowered into the doser where the solution intended for a single ampoule is stored, and the housing is watered. In this case, the ampoule is filled with a solution. This method determined the conditions for filling the ampoule with a solution. For example, after completely squeezing (vidavlivanie) water from a 1 ml ampoule to 250s in the heating zone (3000s) before filling with a solution outside this zone (250s), the filling time is up to 30 C with a solution. Only aqueous solutions are filled by the parocondensational method. It is possible to fill 30-50 thousand ampoules per hour. Ampoule filling accuracy-1%. The amount of injection solutions in the containers should be higher than indicated, since a part that is taken with the help of a syringe is spent on soaking (soaking) the inner wall of the solution container. The norm of solution applied to ampoules is given in XI DF.



Filling ampoules in a parochondensative way.

Ampoule capillaries cutting.

This process is carried out manually or with the help of Automata. In manual cutting, mainly Birch is used. The countertop will be reinforced to a seat made of special wood or metal. For this purpose in enterprises P.I. Rubber is used.

In doing so, the cloaks in the bunker fall into swirling drum pockets. During the rotation of the drum, the pulleys touch the cutting knife. At this time, a toothed rubber disc that rotates in reverse rotates the pulley around its axis, forming a trace on its surface. Then the ampoule capillaries are broken using a breaker disc. In this automaton, it is possible to cut 12.5 thousand pulkas per hour. Double ampoules are currently produced in glass plants. Cutting the capillaries from the middle of them and placing them on the cassette is carried out on a 3113-00-00ps machine gun. Note: this table is used when the ampoules are dried before applying the solution, if the ampoules are poured into the solution without drying, its concentration at the time of preparation of the solution should be stronger than the indicated concentration, and the solution of the specified volume is placed.

Soldering.

Before soldering the ampoules, the fluid in its Capillary is lost. Otherwise, the ampoule will thin out and will not be able to withstand sterilization. Ampoules are soldered using flames, electric current and plastic. In enterprise conditions, a more flame soldering method is used. Soldering in a flame can be done by melting the capillary tip and stretching it by melting it from the middle.

Small-scale ampoules are mostly Rezipin P.I. in the proposed Automaton, the tip of the capillaries is soldered to the melting Rod. It consists of a bunker filled with an automatic soldering ampoule, a band with pockets, several lighters and a collector. The ampoules come one by one from the bunker to the tape pocket, and when it comes to the burners by moving with the tape, each ampoule also moves around its axis and becomes tangled. Soldered ampoules are collected in a collector. The quality of soldering will depend on the capillary diameter, the uniformity of its length and the chemical composition of the bottle. Ampoules with a large volume are stretched until they heat their capillaries from the middle and form a thin "thread", then, using a flame, they are cut and soldered to melt the tip. Substances that ignite and explode under the influence of fire are soldered using an electric current. For this purpose, horizontal ovens are used, which are heated using an electric current. Soldering the capillaries of the ampoule, the tip of which penetrates into the oven, and the end is soldered until the ampoule moves using a tape (transporter) and presses a certain path.



Soldering equipment

The future of soldering ampoules using plastic polyvinylbutyrol is considered bright methods. Usually the soldering ampoule capillaries are dipped in a plastic solution and rolled around their axis, and when removed and cooled, the ampoule is hermetically sealed, but this method has not yet been introduced into production, since it has a number of disadvantages.

Solubility of solutions in an ampoule made of easy-to-oxidize preparations is solubilized using a special device by rapidly sending inert gas and steam. In this solubility medium oxygen in the air is compressed and replaced by an inert gas stream. Sterilize solutions in the ampoule. The quality of the soldered ampoules is checked with an unarmored eye, and their suitability is transferred to sterilization. Drug sterilization is carried out in physical, chemical and mechanical methods.

Physical method. Temperature resistant drugs 1200s temperature in the autoclave, 1.1 atm. at pressure 8-15 minutes or 1100s temperature, 0.5 atm. 30-60 minutes at pressure, 15-60 minutes at 1000 C at Steam flow, and substances that do not tolerate high temperatures are sterilized by the method of tindalization at 60-650S for an hour 5 times, or at 70-800s for 1 hour 3 days every day. In enterprises, sterilization is often carried out in a Krupin chamber. This camera is located between 2 rooms with doors on either side. Ampoules are placed on one side, and when sterilization is completed, they are taken from the other side. First, steam is sent to the Serpentine tubes of the chamber and heated, then steam is sent to the chamber itself. The temperature, pressure and sterilization time in the chamber are carried out automatically. During the sterilization period, liquid from broken, cracked, or uncolored ampoules will come out and the ampoule will be filled with steam. In order to facilitate the extraction of such ampulalarnite, when the sterilization time is over, the chamber is filled with room temperature colored water. When the ampoules cool, liquid enters the cracked or poorly soldered ampoules at the expense of the pressure difference and stains them. The liquid is then transferred from the chamber to the return tank using a pump. After opening the autoclave and receiving the ampoules, they are washed with boiling water and the color-painted ampoules are removed. The number of ampoules taken into each round of sterilization is referred to as the sterile series.

Chemical method. Drugs that are not resistant to temperature are chemically sterilized. For this purpose, methyl and propyl ethers of oxybenzoic acid are added up to 0.03-0.1% chlorbutanol, up to 0.5% cresol phenols. Since these substances are not indifferent to the body, they are used in small quantities, but at the indicated dose they prevent microorganisms in the solution from growing.

Sterilization by filtration. Mechanical sterilization of solutions is carried out by swimming through "Millipore", "Vladipore", "bacterial suppositories".

Gas-assisted sterilization. For this purpose, a mixture of ethylene oxide, methyl bromide, carbon dioxide, chladone (freon) is used. Sterilization is carried out in gasogenerators or microaerostats. In this case, the temperature is 18-55 5o 0s, the relative humidity is 80%, the sterilization time is up to 4-16 hours, the dose of the mixture of gases is 1200-2000 mg/dm 53 0 or can be sterilized under other conditions specified in the regulatory technical document.

Radiation-induced sterilization. In this method, sterilization is performed in gamma devices, electron accelerators, or other radiation sources. The dose used in this can be 15-25 kg (2.5 m/rad) or different doses depending on the conditions. Each item or type of drug is sterilized according to the dose and time indicated in the instruction. The sterility of injection solutions is controlled by a bacteriological laboratory.

Checking the cleanliness and quality of solutions in ampoules.

The purity of solutions in the ampoule is checked by 100%. This is checked in a darkened house using a 40-60 Watt reflector lamp on a black and white background. 5-10 ampoule capillaries are thoroughly rinsed facing down, observed with an unarmored eye in the light of a lamp. Floating particles in the solution are visible as a result of light refraction in itself. This method quickly exhausts the eyes and depends on the ability of each case. Therefore, vision

through a lens solusioscope with a magnification of 1.54-4 times has been put into practice. Thanks to this, it was possible to see particles up to 8 μm , and additional devices up to 2 μm in size.

An electronic-automatic device was created by the firm "Bayer" (Germany). Thanks to this, ampoules that have stored a foreign substance in the solution, have become incomplete and poorly soldered are excluded. The submachine gun is operated by one person. Work productivity is 8.5-9 thousand ampoules per hour. The result of the work is calculated in the form of a diagram. This indicates the number of ampoules that have undergone a general examination, have stored a foreign substance, have not been filled and are poorly soldered. An electronic device similar to this was also made and put into practice in Bulgaria. Its processing processes are as follows: ampoules are placed in 10 pieces on a centrifuge-like device disc, the disc is rotated 4,000 times per minute and stopped at once. In this case, the liquid inside the ampoule will still continue to rotate. The ampoule is illuminated by light. For comparison, an ampoule filled with pure distilled water is placed next to the solution. Light passing through ampoules is viewed by comparison using an electronic device. If there are side substances in the solutions, the light passing through the ampoule will not be continuous and will be interrupted, and this will be taken into account through a photoelement or electronic device. The scientific Production Association "Progress" in St. Petersburg created an instrument that works on this principle. With it, particles even smaller than 5 μm can be seen. But the state Pharmacopoeia does not specify the amount and large small size of the particles allowed. In practice, however, the smallest blood vessels (capillaries) are tested to have a diameter of up to 10 μm so that the solution does not contain any particles larger than that. This can be seen with an unbuilt eye. The current requirement assumes that the particle size does not exceed 2-5 μm .

The quantity and large size of foreign substances in injection solutions is listed in the first official state standard issued by the Austrian Ministry of Health in 1966. According to this standard, a solution of 1 ml should not contain more than 250 particles with a size of 3.5 μm . Later, such proposals were included in the pharmacopoeia of the USA, England, Japan. At the request of the Japanese pharmacopoeias of 1982, the detection of foreign particles is carried out using a microscope. In this case, a solution of 1 ml passed through a membrane filter is allowed to contain more than 50 particles with a diameter of 10 μm and up to 5 particles with a diameter of 25 μm . According to the UK Pharmacopoeia, no more than 1,000 particles of 2 μm in 1 ml of solution determined by conductometrically, and no more than 100 of 5 μm Liks. Injection solutions in the ampoule are tested for pyrogenicity and toxicity according to the methods listed in XI DF (XI DF, I juz, "Medicine", 1989).

The pH of the solutions is checked according to the method, while the color is compared to the corresponding default (etalon) solution. The amount of the acting substance is checked on DF, FM or VFM.

Determination of the average weight of dry drugs.

This is the first official method introduced in XI DF. To determine the average weight of dry matter in injectable drugs, 20 mouth-opened containers are pulled separately with an accuracy of 0.001 g. The substances in the containers are washed with water or other suitable solvents and dried for 1 hour at a temperature of 100-105 °C. Containers and Stoppers are pulled back. The difference of the weight of matter in each container from the average weight of 20 containers should correspond to table 10, as shown in the section "content for one container", but not exceed +15%. If the difference between the substance in two containers from the average weight exceeds the norm, but does not increase by 15%, the determination is repeated in another 40 containers. In this case, the difference between the substance in each container from the average weight should not be more than allowed in Table 7. The difference from the average weight of a substance in 20 containers should not exceed 5% of the amount specified in the private substance.

The characteristics of equipment for the production of sterile products the main requirements for such equipment come from its purpose-the production of sterile products. It requires compatibility with cleaning rooms, adaptation to the sterilization process, guaranteed implementation of their functions.

GOST R 52249-2009 (Annex I, paragraphs 56-60) imposes specific requirements on equipment working in the production of sterile drugs, specifically:

- if the conveyor belts are not constantly sterilized (for example, in a sterilization tunnel), they should not pass through the separation barrier between zones A or B and production zones with low air purity;
- The structure of the equipment should have the opportunity to place the front part in a clean room and the possibility of maintenance from a non-clean place;
- In the process of designing water treatment and distribution systems, selecting equipment, installation and maintenance, the necessary water quality must be ensured. It is not allowed to exceed the design capacity of water treatment equipment. Preparation, storage and distribution of water for Injection should be carried out in such a way as to prevent the proliferation of microorganisms, for example, due to the constant circulation of water at temperatures above 70 ° C.;
- The weight of critical equipment (sterilizers, air preparation and filtration systems, air and gas filters, water preparation, storage and distribution systems, etc.) must be tested (certified) and provided with scheduled service.

The requirements for equipment for the production of sterile drugs are considered in detail in the book.

Normal GMP incompatibility

Below are examples of equipment not meeting GMP requirements:

Technological equipment:

- Does not comply with GMP and is not certified;
- purchased before the start of the design and does not correspond to the project and design assignment;
- elements of single complexes are purchased from different suppliers, which makes it difficult to configure and certify;
- the equipment is outdated;
- foreign companies, under GMP equipment, supply of unsuitable products;
- there is no representative of the manufacturer, and if the user is deprived of assistance in working, it is difficult or impossible to return to a foreign factory due to the customs procedure;
- according to the documents and records located on the front panel, the equipment was produced in a country known for its high quality; when the equipment failed and the cabinet panel was dismantled, it was found that everything was done badly and in a completely different place in the world.

Lecture 12. Equipment for the production of solid drug forms in pharmaceutical production.

Plan

1. Equipment for the production of plant raw materials
2. Equipment for the production of solid drug forms in pharmaceutical production.

Base words and phrases: Equipment for the production of solid drug forms in pharmaceutical production.

Allocated time - 2 hours.

Equipment for the production of plant raw materials

Scientific research carried out in the last years shows that the possibilities of artificial drying methods (automated) in drying a medicinal plant are endless and optimal. In the process of artificial drying-firstly, time is saved, secondly, the quality indicators of raw materials are within the requirements, and thirdly, the sanitary condition of raw materials (in relation to natural drying) is satisfactory.

The duration of the drying time is reduced to several hours. The quality of the product (to natural drying) is higher, while the area required for drying (to natural drying) is relatively reduced. The sanitary state of production increases. The drying process will not depend on climatic conditions.

Allows you to change the drying period for the positive. In late autumn, prepared plant organs or disconnected wet fruit ensure that the raw material products dry out qualitatively and meet the requirements.

Currently, a variety of artificial (USK-2E and b.q) there are dryer devices and this is used purposefully in various industries.

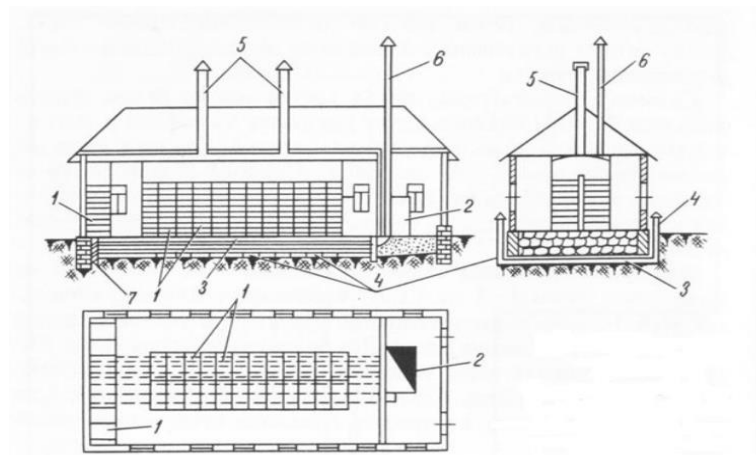


Figure 1. Artificial Quran building (Shi'ites)

1st stele, 2nd heat furnace, 3rd heat pipe, 4th conductor, 5th Air puller pipe, 6th tutin pipe, 7th lower groizontal barrier

Artificial solar-fuel drying devices. Dryers based on combined use of solar and conventional energy sources are named after solar-fuel devices. Combined solar-fuel dryers combined solar and artificial drying styles with the advantage sides to create compact, easy to transport, inexpensive, and less energy-intensive dryers. They are aimed at small and medium-sized processing enterprises.

When the following principles of improving the efficiency of solar-fuel dryers are developed, then:

1. Maintaining the set temperature of the drying agent at the expense of adjusting the heat source power mode;
2. The function of the outer wall of the drying chamber is combined with the light absorption panel of the solar collector to ensure the heat regeneration of the recycled drying agent;
3. The use of regenerative heat utilizers is envisaged, which ensure the effective use of the heat emitted from the drying chamber.

When drying agricultural products, the following distinctive features should be taken into account; that is, the long course of the process, the interconnection of their thermal-physical properties, the uniqueness of the pneumo-thymizimine, which provides optimal consumption of the drying agent, and other indicators.

To analyze the conditions for the use of drying agent energy and its regeneration, the possibilities of constructing the following rational technological process have been developed.

- step-by-step processing of the mass of the product, which is associated with changes in the laws of heat exchange

- use of the surface of the dryer chamber as the light-absorbing panel of the solar air collector to regenerate the heat energy lost through the solar thermal energy and the wall;

- the use of regenerative heating utilizer, which effectively captures the energy of the recycled heat carrier with a flat reduction in the power of the heat source;

- using a temperature adjuster that adjusts the power of the heat source evenly, taking into account the change in the ambient temperature during the day, as well as the heat Carrier heating and changing in the regenerative utilizer;

- to subsequently evaporate moisture from the inner layers of the product, applying the oscillation mode, which ensures the exit to its surface;

- ensure the smooth transfer of heat in all layers of the product to ensure that the moisture content in the finished product is even;

- creation of a system for adjusting the power of the heat source in accordance with the technological process;

- development of a technological process that provides adjusting thermal processes in solar fuel drying devices.

In order for the issues listed above to be solved, it is specially required to study the change in the dynamics of the technological properties of the product and drying agent, as well as the change in the thermal technical characteristics of the product.

Primary processing technology for medicinal plant raw materials in the USK-2E dryer

Dryers based on combined use of solar and conventional energy sources have borne the name universal solar fuels. They combined the dominant aspects of solar and artificial drying techniques to create compact, easy to transport, inexpensive, and less energy-intensive dryers. They are used by primary processing of small and medium medicinal plant raw materials,

intended for processing enterprises. The Universal drying device mainly provides for the technology of processing and drying plant raw materials.

Before drying the raw materials of the medicinal plant(green mass) (in order to stop the physiological-biochemical processes in them and maintain their quality), preliminary processing should be carried out. In this case, the infra on the raw material of the plant is processed initially using red rays. In this process, protein molecules as well as enzyme systems are denatured. This circumstance leads to a rapid cessation of various physiological-biological processes passing in the tissues of medicinal plant raw materials, and the breakdown of biologically active substances is obtained. With this, it is possible to achieve a high-quality dried product.

It is necessary to give the processed plant raw materials the optimal drying mode using the electronic control unit of the dryer. To do this, its thermorostator control unit must have an

extended adjustment diapozone. When raw materials prepared by cutting and grinding into drying are dried in universal dryers, the drying process in it does not exceed 50-60 OS in the following haroart, which is variable. In this situation, the raw material can maintain its primary green color, and the minimum loss of biological FA'ol substances in it can be observed. In this method of curbing, no harm is caused to the environment, an environmentally friendly product is produced and a high economic effect is achieved.

The Usk-2e solar fuel unit operates as follows. By means of the loading door, the drying material (medicinal plant raw materials) is placed on the drying seats (padnices). In the device (USK-2e), part of the upper air is transmitted to the atmosphere, and the rest to the contour of the recerculation, formed by the camera wall and a film. There, the air rose at the expense of the darkened wall and the convective heat exchange, walking from the surface of the wall. Air moves between the chamber wall and the film to form a turbulent flow. Which is the heat

increases the speed of the exchange process. Such devices allow you to save up to 40% of conventional energy sources.

After that, the camera doors of the USK-2e dryer are closed, the centrifugal fan and calorifer are activated, and the flow of hot air is pumped into the chamber. In order to have a clear idea and information on how the process is going, each of the four trays in which the raw material product is placed every hour is measured using a weigher.

Equipment for the production of solid drug forms in pharmaceutical production

Concept of grinders. Plant raw materials can be ground initially and repeatedly, depending on what purpose they are used for.

The process of grinding plant raw materials is carried out using grass and root shears.

Grass cutter the simple arrangement is disc and drummed.

Curved line cutter knife in drum grass cutter. the swing wheel (maxovik) would be strengthened into a kegay (spisa). 0 ' raw material using a tape under the knife will be sent. This ensures that the grinding is large and small, depending on the speed of movement of the tape or knife.

Of the root Clipper there will be two blades. The upper blade is fixed to the eccentric bo4ib, moving up and down - di. the one below is crumpled.

The crushed raw material moves between the Blades - the gan is sent through a tarnovcha. The degree of grinding of the product is determined by the large-small size of the range of blades.

If the plant is dry, it is difficult to cut bo4sa. in advance, it is wrapped in a damp cloth.

When grinding raw materials to the end, tegir - Mon of different structures are used.

Smooth and toothed-tapered Mills. This depends on the structure of the surface of the workpiece of the grinder. Gear-tapered Mills also have the ability to grind a much larger slice compared to a smooth surface. Such mills are used in food, chemical industry and other industries.

Disc Mills it consists mainly of two discs installed in an upright position, one of which can be a rotating disc and the other is a circular disc. On the surface of the discs, several rows of rounded teeth are dead. These teeth enter between each other when the disc is closed.

When the disc moves, the crushed raw material falls between the teeth and is hit with great force, cut and crushed. Such a mill is called a dismembrator (Figure 1).

Hammer mill the body, the inner wall of which is made of armored thick metal, will consist of a disk mounted on the central axis, from the center of which several Hammers towards the wall will be fixed so that they move around their axis. A removable (removable) sieve is installed at the bottom of the body, so that the crushed substance continues to pass through the sieve without interruption. This accelerates the grinding process.

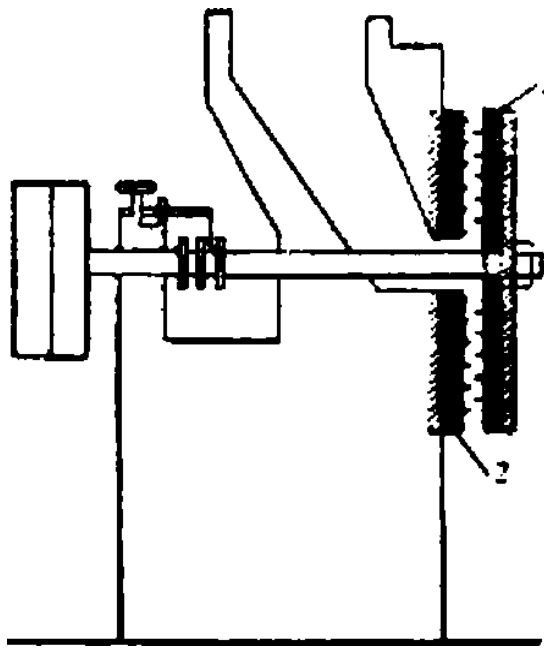
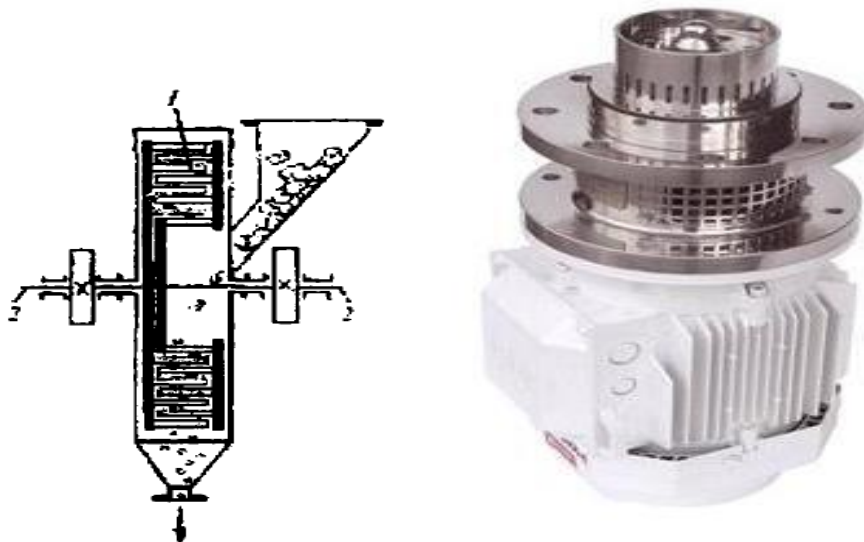


Figure 1. Dismembrator (Excelsior;
1-rotating disc. 2-non-rotating disc.

If both of the mill discs are in motion, referred to as a disintegrator (Figure 2).



Mill that works in the opposite flow. This is a small - lagich bomit (camera), a boiib consisting of flutes located opposite each other, inside which a thin tube will be located, the tip of which accelerates the flow of incoming air at great pressure (6 atm). The feedstock falling into the tube from the hampa is forced out of the accelerator tube (800 m/SEC) by a stream of air coming at great speed and colliding with particles of feedstock coming in the same way from the opposite side. In this case, particles of hardness up to 59-80 μm are formed.

Zoldyr Mills drum and insert into it-Gan is a boMadi of various sizes (up to 50-150 mm) made of steel or porcelain. In the movement of the mill at a certain speed, the oppressors move up under the influence of centrifugal force, and the oppressors when they overcome this force he goes down and crushes the raw material by striking it with a hammer. Among the oppressors-gi raw materials are also crushed under the influence of friction force. The speed is highest when the operating performance of a leech mill is calculated using the following formula:

$$n = \frac{32 - 37}{\sqrt{D}}.$$

KoHloid Mills to get a very small amulet (yna), work is done. The mill consists of two fast-rotating conical shafts with a connecting interval of 0.005 mm. The body is crushed by passing through the same interval.

There are different types of grinding salt for various compounds, alloys, which are: disc, hammered. the opposite flow is divided into a working Turla, while vibrating action and colloidal mills use a slash-and-root shears.

Elacid machiniar

In pharmaceutical enterprises, the two types of sieving machining Aso-san are used:

1. Flat (flat) sieve machines.
2. Drum (drum) sieve machines.

Flat sieve machines include vibrating and barking sieves.

Vibrating sieve machines. In this case, a sieve placed on the Wheels (roller) at a slope of 2-4° moves forward between the two guides using an elbow axis. It oscillates between 50 and 200 times per bar second with an amplitude of 200 mm. In a much more perfected machine, the sieve box (Korobka) is mounted on a reciprocating (sharnir) hanger (podvec) or on a tilted shutter lever (opora), moving in reverse.

In this case, 2-3 vibrating sieves will be placed by placing them on top of each other. For example, it is advisable to sift the crushed raw materials into two successively located sieves before tinting or preparing the extract. Raw materials are sifted into a small bongon sieve in the hole of the hampadan. In this, boMgan particles smaller than 0.5 mm in diameter pass through. All particles less than 3 mm pass when the raw material, which is cleaned of dust and small particles, is sifted through the second sieve, while the rest in the sieve is sent back to the mince.

Barking sieves. Zirilizer (vibration) sieves are divided into electro - magnetic, gyratory and inertial sieves. It is advisable to use barking sieves when sifting small tolls, since the barking action prevents the plug from clogging into the sieve holes.

The electromagnetically zirilizer is achieved by alternating magnetization and demagnetization of the yakor, which is advanced in the sieve. When the instrument is connected to an electric Tan, the electromagnet attracts the yakor and the sieve attached to it, during which the connector on the right side is disconnected, and the yakor is demagnetized. the back movement of the sieve is carried out using strong propellers. This process will continue 200 times, without interruption with a 3 mm amp - tuda.

Triboelectric phenomena in Elash. The formation of electric charges by friction is said to be a triboelectric phenomenon. Sunday phenomena sometimes occur even in the treatment of the drug substance, in which the resulting charged charge be opposite polarity wax-kin. For example, sulfur and lead oxide are negative due to the friction of the individual-alo - hida particles, and together they produce different (sulfur negative, lead oxide positive) Zai ads. Some electrically active substances form solid (prochny) lumps after loss or release of charge

(utechka). Sunday substances include lead oxide, wheat starch, sugar, etc. Since triboelectric events make sieving difficult for the process, its formation must be prevented. The most convenient way to do this is to change the sieve material or sift the tolls in different ways.

Determination of the fineness of tolls. The ground of the tolls - determined by the omchov of the sieve hole, the ground Tolg should shoot from it to. Tolls depending on the size:

- major;
- medium large;
- medium ground;
- Maida;
- very tiny;
- extremely small sinks.

If a hammer is sunk with no degree of fineness specified, the charge of the particles should not sink greater than 0.150 mm. Table 1 of Xi DF bot 2 includes 23 sieves with 7 different spindle levels. This is the shape of the sieve hole in the table. the optimal (nominalny) measurement of the hole (mm), the number of the sieve material by vaNTH, the number of the material from which the sieve is made, the degree of size of the sawdust will be indicated (t-table). The sieves will be textured, perforated and graced.

Woven sieves - silk, from Capron threads, steel. it is woven from brass and copper wire. Sieves woven from silk and Capron work to sift fine and medium - large tolls of various types. They are robust and ensure uniformity of the material being sifted. Wire woven sieves are used to make large tolls of all categories.

Perforated sieves - pieces of galvanized iron are made by perforating in a round or rectangular shape and are used in the grafting of large crushed material. These sieves are robust, resistant to various mechanical influences.

Lattice sieves - it will consist of a complex of metal fibers located in parallel. They are extremely robust and are fired at hammer mills powered by percussion.

Elashor sifting is a classification. it is said to divide the particles in each xlil measure into two and more parts using sieves.

Typically, crushed raw materials are classified by threading through sieves in Table 1. When the bulbs to be classified are large, medium-large and small to 0', they are sieved manually or mechanically for 10 minutes by taking 25-100 g and placing them in a sieve with a well-fitting lid and bottom. If the tolls are clogged into the sieve hole during the sieving process, cleaning is allowed from the bottom.

Production of tablets

The production of tablets is allowed on the condition that the use of milling machines, granulators, dryers, guards, tabletpressers, dragging boilers, tablet packaging and wrapping machines, which are considered the main equipment of enterprises of pharmaceutical production, have certain types of barriers and blockages.

Due to the possibility of dust separation, which is dangerous in terms of explosion in the production of tablets, the organization of the technological process and the use of equipment is carried out by OST 64-031-87 SSBT "technological processes for the production of ready-made medicines. Production of pill formulations. It should be carried out in accordance with the requirements of" safety requirements "and" recommendations for ensuring a safe working order in tablet production".

It is necessary to design tablet manufacturers and introduce devices that allow you to perform several operations in one unit when using them.

In granulation operation, it is necessary to take measures to prevent the formation of an explosively hazardous amount of vapors of the specified type in the room when quick-firing liquids are applied.

The production of medicines in the form of tablets, in which strong irritants and toxic substances are used as ingredients, should be carried out on specially designated equipment and separately allocated plots.

The products of medicines in the form of tablets, which contain strong dyes and dyed dust-emitting substances (dry extracts, activated charcoal, etc.), should be stored in separate rooms separated from other rooms.

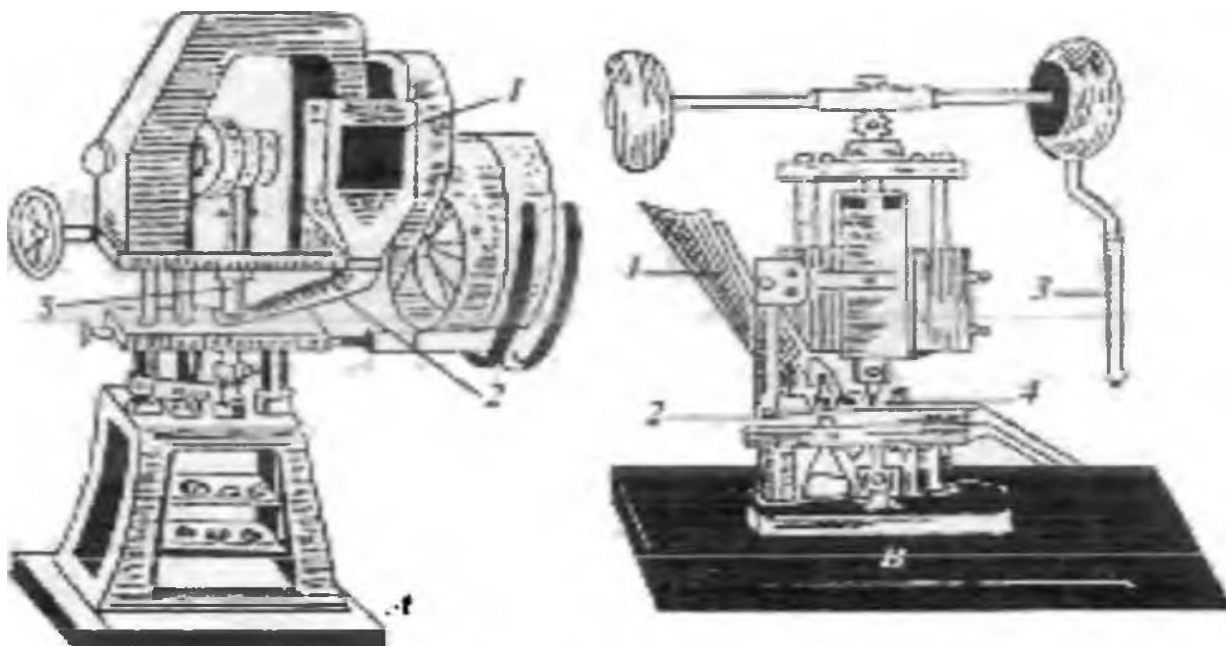
Cleaning tablets from dust is carried out through special devices using vacuum cleaners or vacuum cleaners.

Tablet review and unfit separation tables must be equipped with local lighting instruments and air traction ventilation.

Dragging boilers should be equipped with special support barriers and have sufficiently efficient air traction as well as vacuum cleaner devices that do not allow dust to fall into the room.

Tablet making machines. Tablet layering machines are eccentric in the process of operation. a tattoo worker, Rotary or revolver is immersed in groups. They are made up of three main parts: the actuator, the Switch and the operating settings. Other parts of the machine ensure the automatic operation of the above parts in accordance with the purpose.

Percussion machines. The salt of these machines consists of a simple bomb, the working setting consists of a mold, an ostki and an upper Poon, as well as a hampa. Depending on the work process of the hampa, this type of machine can be hammered with a headband and a slip (figure 38).



Draw 38. Tablet machines:

A-thump; 1-hampa; 2 - thump; 3-poanson. V-slip; 1-hampa; 2 - syrpanghch; 3 - actuator; 4-mold.

The mold is made of a special steel cylindrical shape bomb. it has one or more Super - smoothed holes. The mold is designed to measure the substances that need to be planked and give it a shape.

The mold is secured to the tablet - making machine table using special bura-ma nails. In this case, the surface of the mold should be suitable for the surface of the table and not interfere with the movement of the hampa - gi.

The lower puanson has a super - smoothed flat or bottomed surface in the form of one or more cylinders, and the bottom of the mold is cast-clay. In the process of work, the lower puanson moves up and down in the mold. The size of the orifice inside the mold is determined by adjusting the drop rate of the puanson. The Puanson is coccaged to the table surface by a hole in the mold. the tablet-gan pushes the tablet out, then the spike pushes the tablet down and the mold hole is filled with the substance to be planked again.

The upper puanson has a super-smoothed flat or bottomed surface in the form of one or more cylinders, connected to the eccentric device of the machine boiadi.

In the process of work, it moves up and down. At the time of moving down, the substance is planked, entering the mold. The pressure force of tablet-making machines is determined by the degree to which the high poanson drops down (into the mold). This is done using an eccentric.

Hampa is a mass intended for the preparation of tablets place - to-place. In percussion tablet-making machines, the hampa is mounted on the body of the machine, with the two parts ibo - rat; the immobile part (mass - storage) and the mobile (mass - to-mold) part-head; and in sliding tablet machines, the hampa moves back and forth, sliding across the table. In the process of work, a mixer will be placed inside the hampa so that the mass does not become stratified.

All parts of the machine are customized, according to the speed of operation, the hampa will come over the mold hole, fill it with mass and roll back. Then the process of laying the board and pushing the tablet on the board occurs - di. The Hampa drops the tablet into a round - bottom collector before filling the next mold. This process does not exceed 80 times per minute. Since machines of this type are simply structured, it is in accordance with the purpose of using it in laboratory - ya conditions (research and research institutes) in the production of small amounts of tablets.

Underdog: not high production productivity. due to the noise operation, the pressure is with one-way tattoo, the tablet quality can be compromised and dust can rise in the air.

Rotary, revolver type tablet making machines (RTM)

Revolver or rotary tablet machines! having a complex salt-Lish, the molds count! 10 to 65 boiishi wax - kin. Matrices are placed on the table in a circle. Synchronously, the lower and upper poans are also in motion with the matrices. The number of hampas depends on the amount of matrices. they can make one, two or more bombs, but in practice often have two bombs, and they are fastened to the body of the car without moving. Currently, there are more than 80 machines of this type of boMgan with different structures (table 17). They are equipped with electronic devices, working with high performance. includes machines that work on the basis of a specific program. With the help of such devices, it is possible to control the process of operation of the machine. The mass, pressure force and quality of the cum - ladan tablet are checked (figure 39).



Draw 39. Rotary pill machine

Working process: poansons are reinforced to wheel poanson holders - bo4ib. the upper poans are the upper track. lower poansons move along the lower trail (figure 40).

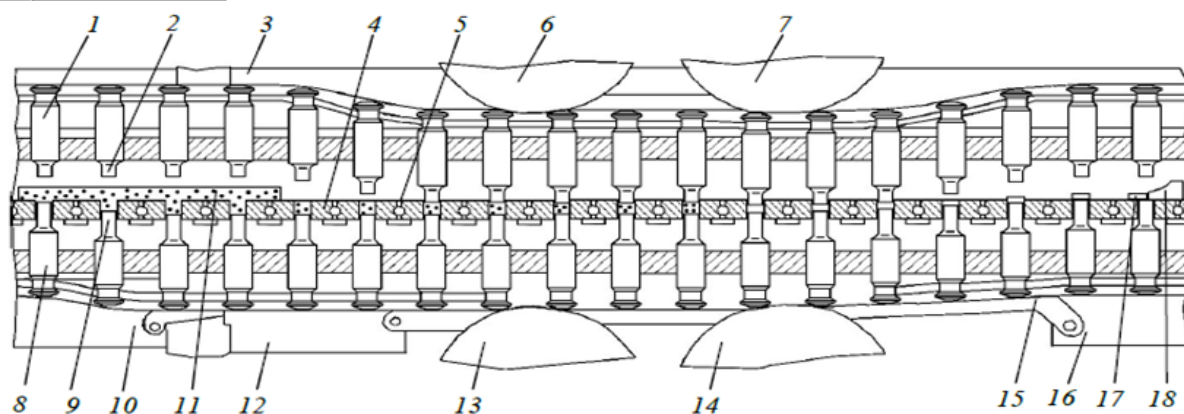


Figure 40. The operation process of RTM.

3,10-upper and lower tracks (copper); 6,13 - driving wheels; 7,14 - pressure generating wheels; 2,9 - upper and lower poansons; 4 - matrix.

To adjust the pressure of the roller above, the size of the hole of the matrix of the lower roller. serves to determine the depth. At the moment when the lower puanson comes to the

lowest point of the copper (trace), the upper one to the highest point, the mold passes under the hampa and The Matrix hole fills with mass. After that, the poansons moving along the double-sided cupola gradually spread the mass to the tablet - di. The puansons then slowly begin to kochagia until the lower puanson pushes the tycoon tablet onto the table surface. This tablet - ka falls into the receiving container using a collector. In the process of work, the hampa will be equipped with stirrers to ensure that the mass falls in one norm and does not become stratified.

The advantages of this type of machine are; noise - free operation with high unum, increased pressure in a two - way standard, layering while the tablet mass is falling from hampa, etc.

The disadvantage; the complexity of the machine, its adjustment. replacement of the working part, requiring a specialist to transfer from one type to another.

The parts of the tablet - making machine in which the tablet is directly involved in the jaray-Oni (press-form) must be made of high-grade pomate. Because this process takes place in murak - kab conditions: as a result of strong friction, molds can heat up and expand, decay, rust, break. To obtain a material with the desired property, various elements are introduced into the composition of the steel ("Technologie metallov I drugix constructionnix materialov" N.F. Kazakov, A. M.Asokin. A. R. Shishkova. - Moscow. 1976.). Depending on which element is included, steel is labeled: it is 8, 9xc, 12xh 2, XVG, BK16, X6VF, TBK, etc.k. In this case, the number in front of the elements determines the average amount of carbon. if a two - digit number is set, one hundred-to-one percent of carbon is shown, and such a steel grade is jmrited as a structural poMat. This variety is called instrumental steel, indicating a tenth share of carbon if it is a one-digit number. The number placed behind the item indicates its percentage amount. If the carbon content is up to 1%. it is not displayed on the tab. If the item itself is shown.indicates that if the number is not specified, it will save from one percent of these elements.

The Granulator is an instrument used for donating. electrician, a cylinder whose walls consist of holes of a certain diameter. consists of a shovel and a receptacle (figure 44).

The mass that needs to be granulated will fall into the cylinder-di. Centrifugal force helps the cylinder wall pass through the holes of the shovel wall, which rotates inside the mass being hit. The granulated mass that passes through the hole falls on the Collector.

Working in a different way. there are also granulators with yami Schneck. One of the main disadvantages of donating with a wet method is the long drying time. the use of dryers is that various physical and chemical changes can occur in this process.

Granulation with grinding. The medicinal substances used in the preparation of the tablet use the method of grinding and granulating in case of large immersion in the granular form.

Donating by briquetting. The planking mass is brought to the briquette state with great force before. Then passed through the granulator, the maTum is brought to shape and size. Advantages of this method: no binders are required, no physical and chemical changes occur due to the absence of a drying process. A device designed to form a briquette from a mixture of tolls used for this purpose, grind it and divide the resulting granules into large-small ones is considered effective (figure 45).

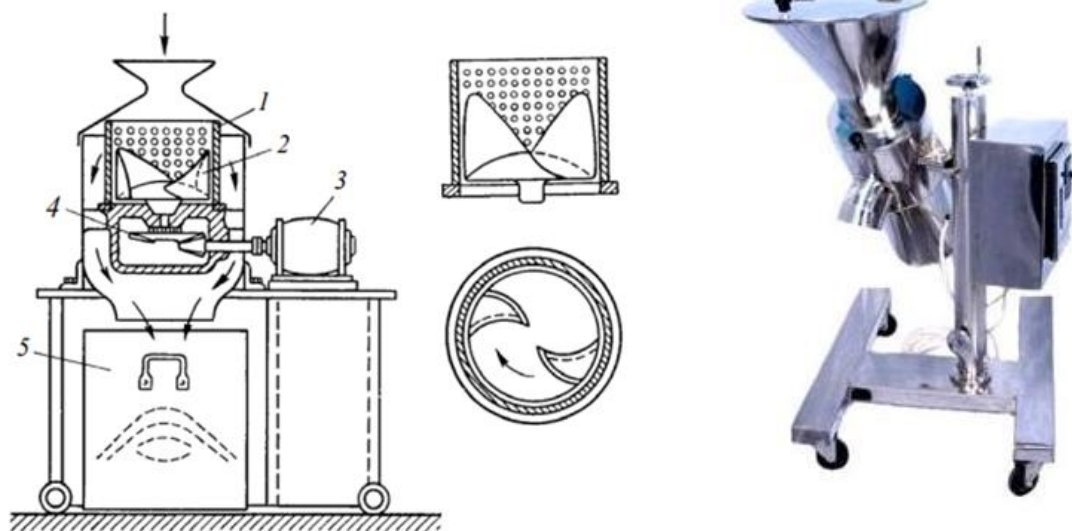


Figure 44. Universal granulator;
1-spherical cylinder; 2-crankcase; 3 - receptacle.

In quirlma, ktikuns passed through a blender. the chicks are planked in between, then ground in a grinder. the vibration is collected in a container in a sieve. The remaining large and small part is transferred to the tax takachlik again.



Powder cleaning equipment

Shell tablets (Tabulettae obductae)

The tablets are covered with a shell in order to preserve them from the effects of the external environment, to increase stagnation, to achieve an effect on a certain part of the body or in the long term, to obtain tablets from substances that react with each other, as well as to improve their aesthetic appearance.

Shell sawing. obakylation (drajirovanie) is performed using curtain formation methods. A tablet covered by Obakilash should not be more than twice its weight until it covers its weight (figure 50).

In the planking method, the shell weight is from 50-100% of the tablet inassa. and when covering with a thin veil, it should not exceed 3 %.

Obakilization method. This ancient and simple method was sunk, made of special red copper and known. the form is carried in immersed obakilash boilers. The obakylation process consists of 4 steps: nanification, layering, grinding and finishing.



Wetting. The tablets placed in the Obakilash pot are mixed with sugar first in the tar and then mechanically. In this case, each tablet level is moistened in one norm. Then make a pot-wheat flour with raagnium oxide, prepared in a ratio of 1 to 1 g lida

add the mixture. stir until the tablet top is evenly coated-di, then dry by sending filtered and desired fresh air into the pot. This process is repeated 3-4 times.

Grounding. The tablet is folded 3-4 times using porridge prepared by adding sugar juice, wheat flour and paint. After each layer is formed, it is dried.

Grinding. The top of the tablets does not fold evenly. Therefore, they are polished to ensure that the finishing stage is of good quality and fast. To do this, the tablets are passed in a clean obakilash boiler. the boiler is used for a certain period of time. In this case, the tablets are smoothed and smoothed as a result of rubbing between them and with the pot wall.

Grooming. The polished tablets are sifted, cleaned of fine particles and transferred to an obakilash boiler. With the help of a finishing agent prepared from a separate recipe silane, the tablet level is covered with a thin beautiful layer. After a certain period of drying, the finishing is repeated another 3^ times. It is then used for a certain time. In this case, the tablets are polished, polished as a result of rubbing against the wall level. Wax to the composition of the finishing Mass. paraffin, vegetable oil. stearines can be ingested or prepared in another retsep - turada.

Obakilash method is widely used and simple, requires a lot of time and knowledge. So far, the thickness of the bagiama on the tablet is theoretically based. In the process of obakilization, the tablets will stick together if the floors do not retain moisture in moderation, while the coating process does not give a specific subtle attention. In the case of ready-made bomban tablets, however, as a result of the return of tension, it can darken. Currently, the obakilization process is carried out in a way in which half of the automaton works. The bos described above are carried out step by step according to the pre-designed program.

Lecture 13. Equipment for the production of soft and liquid drug forms in pharmaceutical production.

Plan

1. Equipment for the production of liquid drug forms in pharmaceutical production.
2. Equipment for the production of soft drug forms in pharmaceutical production.

Base words and phrases: Equipment for the production of soft and liquid drug forms in pharmaceutical production.

Allocated time - 2 hours.

Materials used in swimming and swimming

Swimming - is a complex hydromechanical process. its unum-doricity will depend on the suzish process, the sbaroites, and the zicbicity of the material tesbics used. The bulk of any suzish Kuril - Masi is glorified by porous barriers. These are the three groups of porous barriers used in Suzish ucun;

Group 1 compressible porous barriers - These include fabrics woven from cotton, artificial or tabby fibers: perchlorvinyl, gauze, chalk, belting, silk, surp, Capron, nylon. perlon etc.

Non-compressible porous barriers to Group 2 - melall, kerami-ka. glass and similar porous fences are included. Sunday floats are removed in the form of candles, plates, saucers and prepared at high temperatures. Granular barriers to Group 3-activated coal. sand. caterpillars include.

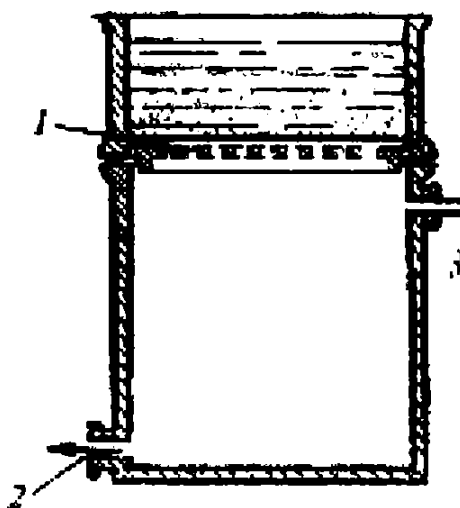


Figure 1. Nutch swimmer:

1-porous barrier; 2-Tap; 3 - air sucker tap.

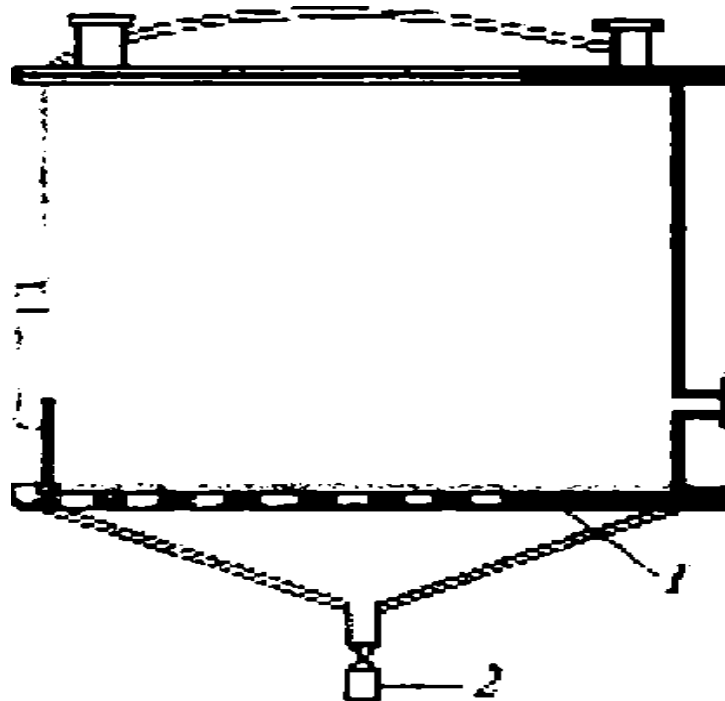


Figure 2. Druk swimmer:

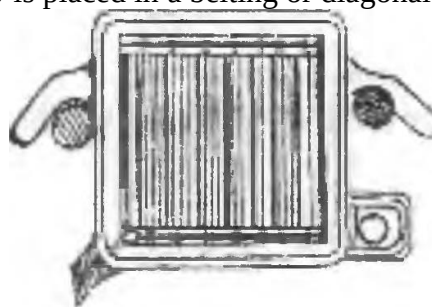
1-porous barrier; 2-Tap

Nutch and Druk floats. Very simple both in terms of structure. it will be a cylinder - cement made of metal, ceramic or plastic. The notch float is designed to work by sucking air (under vacuum), and the druk float to work under pressure. The liquid is placed at the top of the container in a notch float - the float, which is mounted on a GAN lattice disk, is suspended through the fabric due to the absorption of air from the pasti (Figure 1). In a Druk float, however, the porous barrier will be located at the bottom of the container. The fluid is suspended through the fabric above the barrier at the expense of the weight of its own height, or artificially from the outside, at the expense of the beri - ladigan pressure (Figure 2).

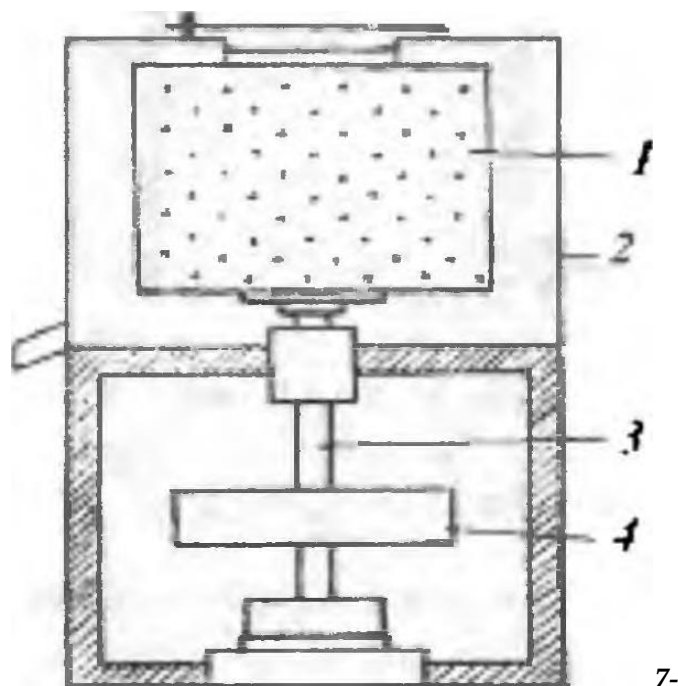
There must necessarily be a pressure difference for any solution to pass through the float. This is done by absorbing air in vacuum - powered floats, and in those operating under pressure, at the expense of a layer of suspended fluid or at the expense of generating artificial pressure.

From the float-press it is widely used in enterprise conditions. The working surface of this float will be high in performance due to the large bump. The float-press is arranged in several rows

the cast iron consists of frames and is tightly fastened to each other. The rough fabric used for swimming between the frames-is placed in a belting or diagonal position



6-rasm. Suzgich-press.



The suspended fluid is sent to the float by one at a pressure of 12 atmospheres. By the second, a clear, clear liquid is obtained from foreign substances (Figure 6).

In some cases, a float - press is also used for the purpose of extracting the bongon irritants in the sediment. Float-press is used in continuous operation-digane processes, as it has a large volume.

Centrifugal force-based floats.

In some cases, even in the context of the enterprise, it is worth using this method. The centrifuge has a hollow inner cylinder wall. a float cloth is placed on it. Deploy to centrifuge-ganda. under the influence of centrifugal force, the fluid floats back - to-back. Productivity depends on the speed of rotation and the amount of particles in the liquid, as well as large-small. The centrifuge has a rotation rate of 1,200 times per minute, and up to 5,000 times in supersene - trifugas. in some species, up to 25,000 boMadi (Figure 7).

Thermal processes

In production, the process of heat transfer or cooling occurs. Heat transfer occurs as one body moves from one body to another. This process takes the form of heat transfer, convection (mixing), and light scattering.

In practice, complex heat exchangers are also used. In production, heating and cooling jara) ons are carried out, which work according to these methods.

Steaming.By heating the separatoringwhich evaporates the solution, the increase in the concentration of the solution is called bug4atish. The evaporated solution in Bun should retain the property of fluidity. Bugiatish is carried at moderate, low (vacuum) and high atmospheric pressure. In production, single and multi-layer devices under vacuum are often used.

One-cell vacuum vaporizer. the main part of the lining is the refrigerator, refrigerator. consisting of a collector and air suckers. A drop holder (ressiver) is installed between them so that air does not pass a drop into the suction cup. At the top of the bugriatkich, devices are installed that control the bugiatishjarayon, the level and temperature of air absorption.

In a multi-body (Three-Body) vacuum device the heat is much more saved. Because only high - temperature steam is sent from the enterprise steam room between the two-story wall of

the first slot, and the "secondary steam" formed from the separation" is spent on heating the second and third boiler. Such a device is correct or opposite can work on the flow. Go! in the case of hot - liquid on the one hand, and evaporating liquid on the other. Bugiatkich works without interruption, but the work performance is not very high. In the process of vaporization, events can occur without bar xil co^ngil. Precautions should be taken to prevent such incidents. Otherwise evaporate, slow down the body-di, a lot of heat is spent, the quality of the evaporating substance will spoil. Well. foam formation, droplet outflow, hydraulic and hydrostatic and temperature depressions are among the undesirable phenomena.

Well formation heat reduces conductivity, and as a result, a lot of heat is spent, in which the temperature of the evaporated liquid increases. Mixing in the steaming process to prevent this phenomenon. level of airlessness. it will be necessary to ensure that the temperature and the thickness of the liquid layer are to a certain extent.

Foam formation in order for the liquid to not get o4ib to the condenser with foam, the installation of a holder in the vaporizer and refrigerant range should ensure boiling in moderation, add foaming reducing (extinguishing) SFM, select the level of airlessness and expand the steam environment in the evaporator.

Hydraulic depression is formed by the dissipation of heat into the environment. To reduce this phenomenon, the tube between the evaporator and the condenser should be shortened and it should be limed with heat-repellent fiberglass cotton.

Hydrostatic depression - causes the lower layers of the evaporating solution to overheat. To do this, the evaporating solution layer must be reduced.

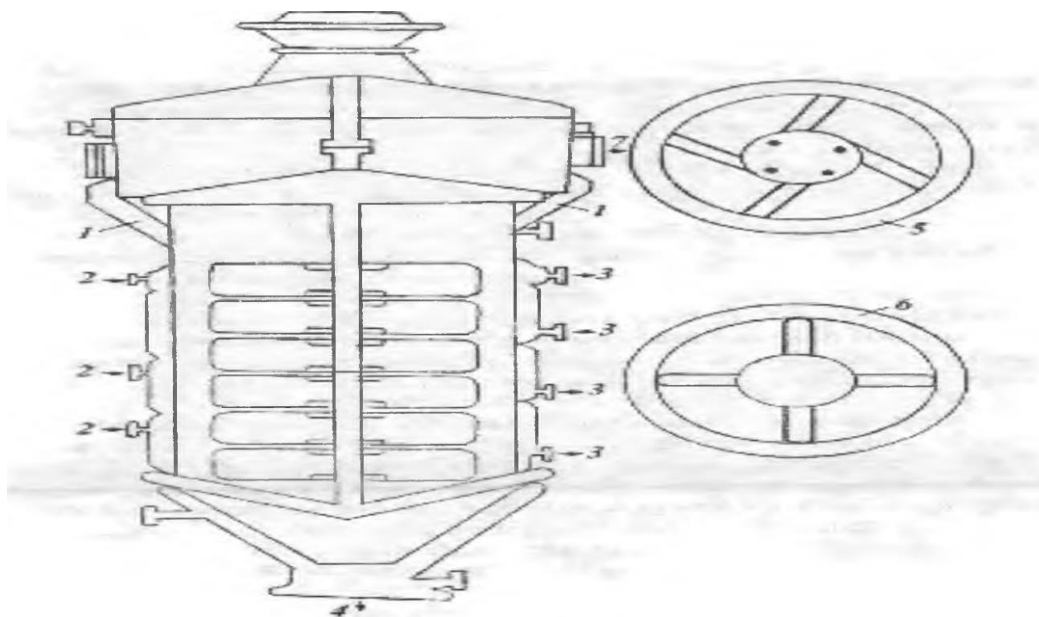
Temperature depression that is, the temperature difference between the temperature of the evaporating solution and the pure solvent is said to be. As a result of evaporation of the liquid, the temperature in its surface layers is lowered, and the process becomes slower. Boiler to prevent this phenomenon

the temperature of the " Steam " being sent to the walls or the degree of absorption of air in the boiler should be increased.

Due to the number of disadvantages of the above - mentioned instruments, in the following years, equipment began to be used that works continuously in the industry, with high work-lab output productivity. Evaporators with a rotor and vaporizing by forming foam are included.

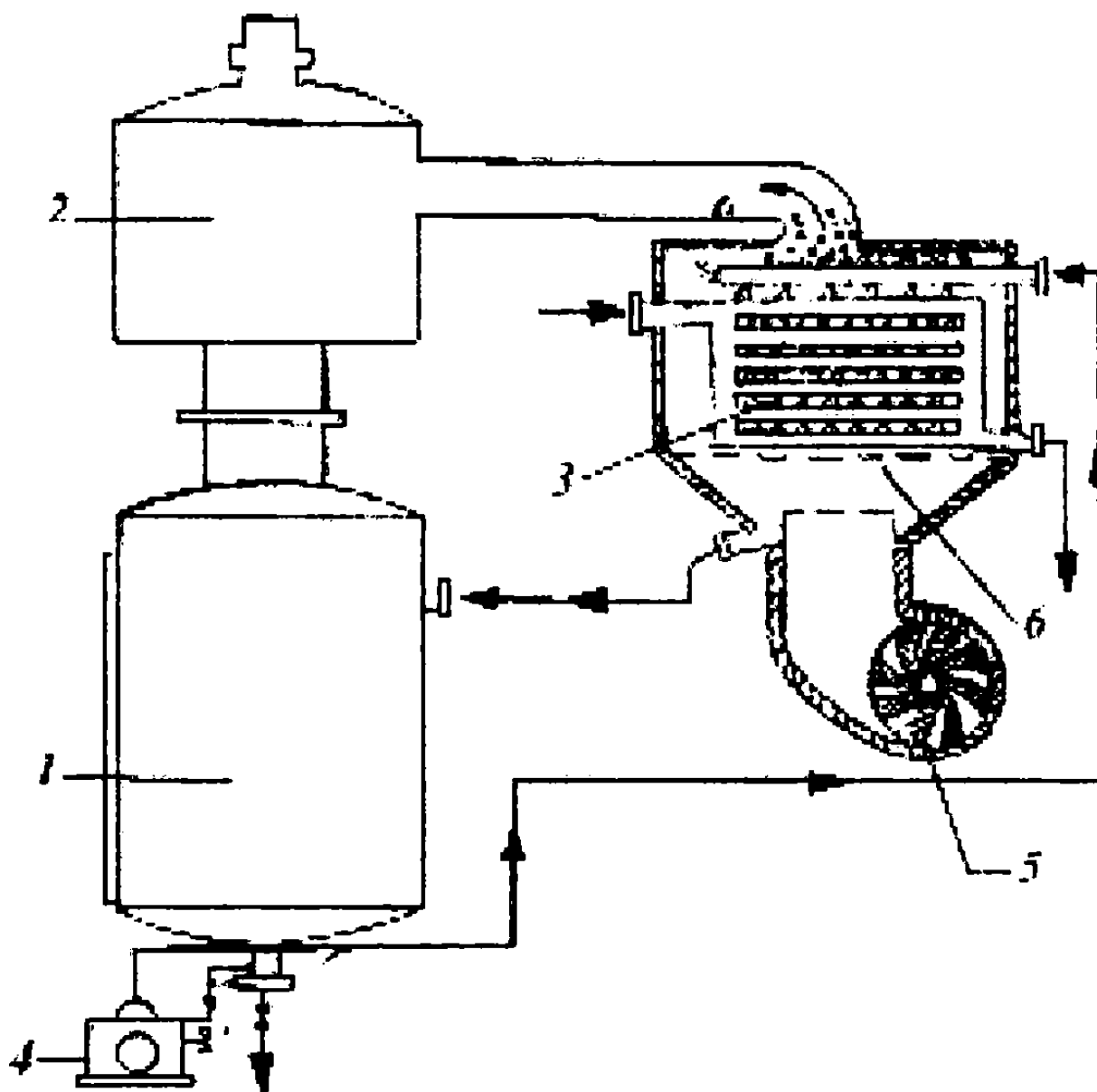
Rotor steamer it consists of three sections. the bar is heated separately using a split **WATER** vapor. A rotor is mounted on the central axis of the steam engine to which the sprockets are secured. As a result of the large-speed rotary motion of the rotor, the sprockets splashed the liquid into the overheating wall. forms a thin layer. In a thin layer, the separator evaporates easily and quickly. The separation moves downwards along the wall and is harvested. Production productivity 450 l / h (figure 9).

Foam vaporizer - this device consists of a container in which the separator is stored, a separator (separator), a heat exchanger (teploobmenniki), a floater and parts from which air is sent (Figure 10). The separation is sent through the tube to the upper sleeve of the heat exchanger - the air dispenser is sent over the mesh. The air purified from the bottom is given by pressure, which causes the liquid to bubble. The foam sticks to the surface of the heat exchanger (radiator), forming a thin curtain. The result is a process of evaporation. A partially evaporated separation collector (collector) falls into the container, and the process is repeated. Together with the "Bug", small separation particles can sift upwards. They are caught using a separator and returned to the separation storage tank. The separation is evaporated at a temperature of 40-80 °C. It was P who created the device. N. Makarenko et al from Kharkiv ..Zdorove "was used to vaporize the Zub - turum aqueous separation in the production merger, until - lik is also introduced in the" O'zximfarm "" merger in Tashkent. In this case, the separation is bugianadi at temperatures below 100 °C without vacuum.



9-rasm. Rotorli bug'latkich:

1 — ajratma; 2 — isituvchi bug'; 3 — sovugan bug'; 4 — quyultirilgan mahsulot; 5. 6 -kurakchali rotor; 7 - „ikkilamchi bug'“.



10-fig. Foam vaporizer:
1-separator container; 2 - separator; 3-heat exchangers; 4-float;
- suction cup in which air is sent; 6-radiator.

Drug drying technology

The drying process is carried out in the extraction of dry matter (powder) from the liquid, in the preparation of dry extracts, and in the production of pill medicine.

The change in the nature of substances during the drying process is wax - quinine. this depends on how the drying process is organized. Drying is carried out mainly in convective and special ways.

Convective drying - in this case, the substance being dried is in direct contact with the heat source. For this purpose, bodgan dryers with different salts are used (shelf, chamber, tonelli, strap. drum) is used.

In pharmaceutical enterprises, chamber and tape dryers are used a lot. Jovian dryers in particular are distinguished from others by the simplicity and cheapness of their salt. In this case, the flow of hot air is added by the substance being dried in the process of moving the lip. The disadvantage: the construction process takes a long time, production productivity is low, heat is lost.

The strap dryer can be made of one-strap and multi-strap bodysuit. As a result of the movement of the tape, the substance being dried falls from the upper tape to the lower tape. Due to the fact that the substance being dried is boded in motion, its particles are exposed to heat from all sides, and the construction process is accelerated (Figure 11).

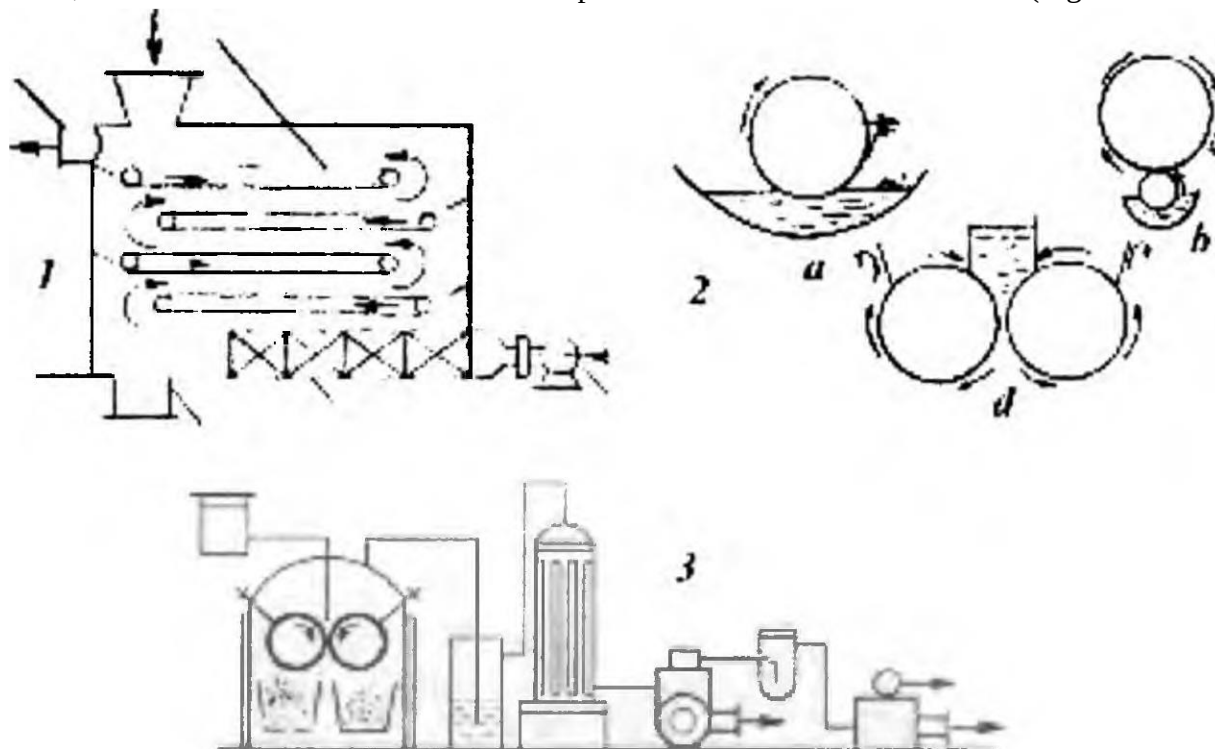


Figure 11 dryers;
1-tape dryer;
2-Tap dryer: a) one tap dryer; b) wheelbarrow exchange; d) two tap dryer;
3-vacuum tap dryer.

False boiling surface dryers. Sunday in dryers insist without hanging a drying substance. hot air passes by all of it. Uiar will look different in structure. The substance to be dried falls from the hampa through the Schneck to the working part of the dryer. Heated and purified air from the lower side to a certain temperature is sent into the dryer with pressure - di. The density of air is in the dara-jaw to capture particles of moist matter. As a result of the mutual friction of the particle, they become smooth and fall into the Collector, forming a relatively round shape. And small particles that fly upward with air flow are collected in the device and returned to the interior of the dryer (Figure 12).

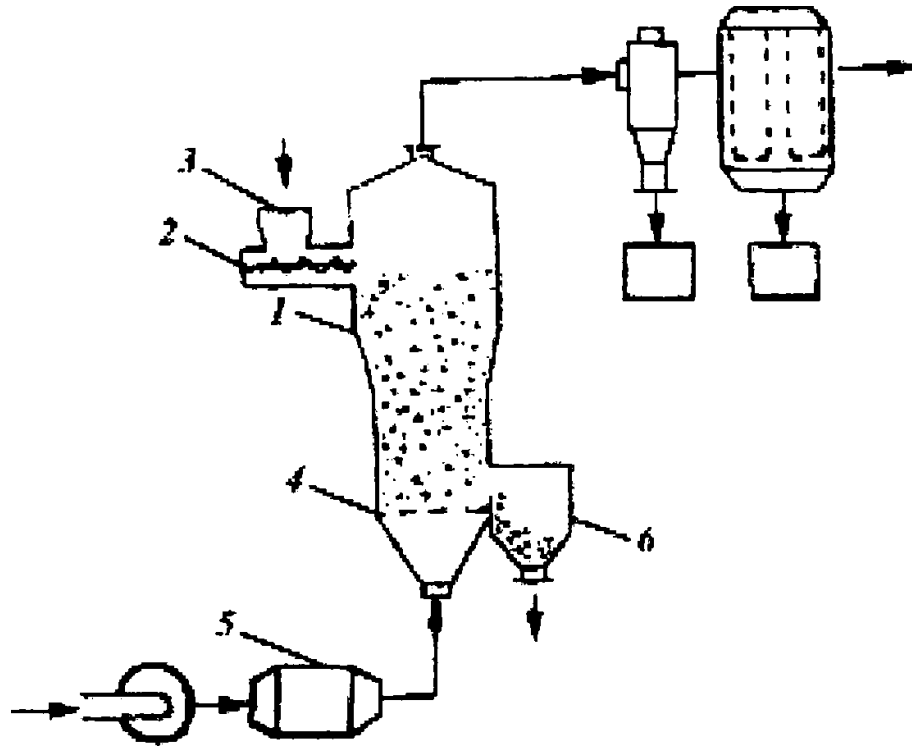
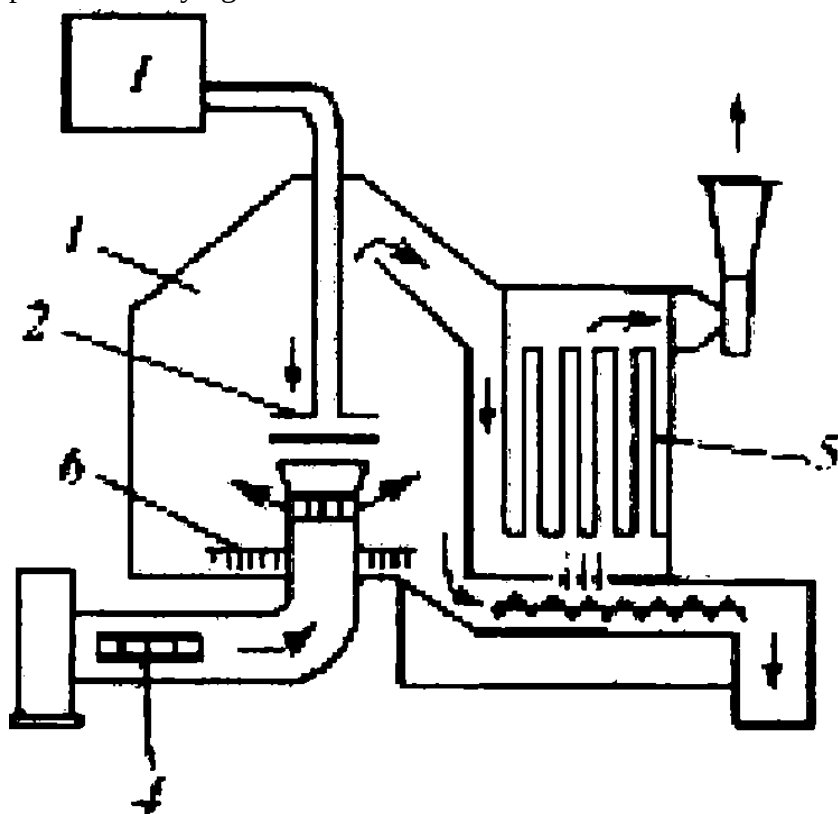


Figure 12. False boiling surface dryer:
1-dryer Camera; 2 - Schneck; 3 - hampa;
4-heat distribution grid; 5 - calorifer; 6-collector.

Of these, the most used in enterprise conditions is SP-30. 50, 100 and SG-30s. The numbers in these indicate the capacity of the container to be placed (kg). The main working part of SP laming is the capacity (cart) where the drywall is placed. its bottom consists of a two-layer wire mesh, a star-shaped mixer. It has 4 wheels and a holder. Javon ildci tawaqali bo4ib, who was given a mirror.

Spray dryers. Such dryers are used in liquid drying, in which the drying process goes very quickly, and the productivity of the work - lip release is high. Spray dryers are a camera, a spray, a shnek that pushes the dried product out. a device that heats the air into the drying chamber to the temperature of the mortar (calorifer), is made of artificial fabric to trap small

particles flying with air flow - GAN consists of floats (Figure 13).



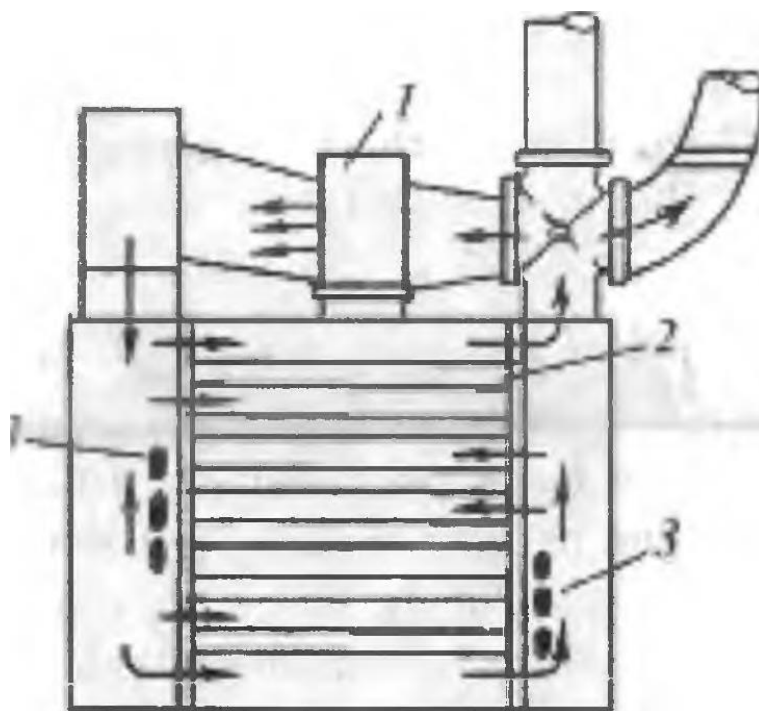
Draw 13. General appearance of spray dryers:
Pot 1; Disc 2 (forsunka); 3 - dryer Chamber; 4-caloriter;
5-float; 6-broom.

Non-warty allocations are forsuncular. the flakes are then dried in disc dryers. The liquid is sprayed into the chamber through a sprayer. In this case, the size of the particle will be at a circumference of 10-50 μm . It is given for drying from the bottom of the chamber - gan reaches an air temperature of 150-230 $^{\circ}\text{C}$. Each particle takes 0.04-0.08 seconds to dry. therefore, the tay-yor product does not deteriorate under the influence of temperature. Such dryers are used in industry to dry mahsu - lots (milk, eggs, etc.), which are rapidly degrading under the influence of medicinal substances and temperature. When using a Bun-day dryer, the substance (liquid) being dried should not be scaly. If it is fluffy. instead of forsunka, a disk is used.

In the drying of granular matter (granules), pneumatic worm - blades (SG-30, SP-60, SP-100, as well as drykicbs with bar type structure, produced in Switzerland and England) are used.

Communication (contact)drywall. In such drierkicbs, heat passes through the wall of the tool to the drying mabsulot. They are continuous or continuous. it can prove under moderate pressure and vacuum.

One of the continuous-proof drydockicbs is the boigan tokcbal drydockicb, which has a simple structure. Such tokcbas are glorified from a necba floor naicbas, the naicbas are heated by water vapor. A drying substance is placed on the tubes, evenly spread on the trays 2-3 cm thick (Figure 14).



Draw 14. Shelf dryer

1-calorifer; 2 - tokcbas; 3-air heater.

Vahti-vahti bilan yuqori tokchalardagi patnislar pastdagilari bilan o'rinlari almashtirib turiladi. Qurish jarayonida patnis yuzasida yupqa qatqaloq hosil bo'lib, kapillarlar suv chiqishini qiyinlash- tirishi mumkin. Bu holatning oldini olish uchun patnisdagi quriti- layotgan mahsulot aralashtirilib, qatqaloq yo'qotib turilishi lozim. Bu quritkich tuzilishi jihatidan sodda boiishiga qaramay, ko'p joy- ni egallaydi, quritish uchun ko'p vaqt ketadi, qo'l kuchi talab qili- nadi. Quritish jarayoni havosi so'rib olinadigan (vakuum) javonlar yordamida tezlashtirilishi mumkin.

Jo'vali (вальсовые) quritkichlar uzluksiz ishlaydigan. bir va ikki jo'vali boiadi. Jo'vaning ichi bo'shliqdan iborat bo'lib, bug' yoki boshqa issiqlik manbalari yordamida isitib turiladi. Sunday quritkichlar asosan ekstraktlar olishda ishlatiladi. Qu) uq ajratma jo'va yuzasiga bevosita yoki jo'vali so'rg'ichlar yordamida yupqa qilib surkaladi. Ikki jo'vali quritkichlarda jo'valar oralig'i 1 mm bo'ladi. Ajratma ikki jo'va oralig'iga beriladi, jo'valaming qara- ma-qarsBI tomonga harakati natijasida yuzaga ajratma surkaladi. Jo'valar to'la bir marta aylanguncha yuzasidagi yupqa ajratma quriydi va u pichoqlar yordamida qirib olinadi.

Jo'vali vakuum quritkichlarda qurish jarayoni tez kecha- di. Sunday qurilmalarda pektin, shilimshiq moddalar saqlagan qovushqoq ajratmalarni quritish maqsadga muvofiq.

Maxsus quritish usullari. Bularga termoradiatsion, dielek- trik. sublimatsiya va ultratovush quritkichlar k From time to time, the trays on the upper racks are fixed with those on the bottom, leaving the places unbuttoned. In the process of drying, a thin layer of yogurt is formed on the surface of the tray, and the capillaries can make it difficult to get out of the water - scratch. To prevent this condition, the drying product on the tray should be mixed and the yogurt should be lost. Despite the fact that this dryer is simple in structure, it takes a lot of space, it takes a lot of time to dry, it requires hand strength. The drying process can be accelerated using air-absorbable (vacuum) shelves.

Tapered (valsovie) dryers run continuously. boiadi with one and two chicks. The tap consists of a hollow inside and is heated using Steam or other heat sources. Sunday dryers are mainly used in extracting extracts. Qu) uq separation is applied to the surface of the Chick directly or thinly with the help of Chick suckers. In two-Chick dryers, the range of the chicks will be 1 mm. The

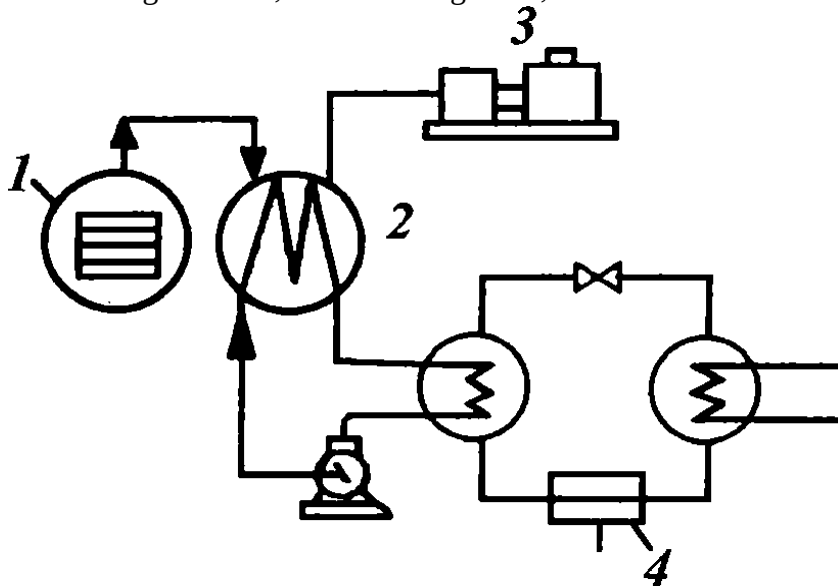
separation is given to the range of two chicks, the separation is pushed into the surface as a result of the movement of the chicks towards the Look - ma-qarsi. The thin separation on the surface dries up until the chicks are fully rotated once, and it is scraped off using knives.

The construction process in tap vacuum dryers is fast Night-di. In Sunday devices, it is advisable to dry the viscous secretions that have stored pectin, mucus substances.

Special drying methods. These include thermoradiation, dielech-trick. sublimation and ultrasound dryers include. Sublimation and ultrasonic dryers are often used in pharmaceutical enterprises.

In sublimated dryers, the substance to be dried is liquefied, frozen, and as a result of absorbing room (chamber) air, the ice evaporates into the liquid without a slurry. The dryer consists of a sub-Liming room, a refrigerator, an air sucker, freezers (figure 15). Sublimation and ultrasonic dryers are often used in pharmaceutical enterprises.

In sublimated dryers, the substance to be dried is liquefied, frozen, and as a result of absorbing room (chamber) air, the ice evaporates into the liquid without a slurry. The dryer consists of a sub-Liming room, a refrigerator, an air sucker, freezers (figure 15).



Draw 15. Sublimated dryer:
1-drying chamber; 2-refrigerator; 3 - air sucker; 4-freezer.

In this way, the drying process goes in three stages: I - freezing; II - sublimation; III-loss of residual moisture.

This method is protein. it is very useful in drying enzymes, antibiotics, vaccines, serums.

Ultrasound dryers. To efficiently dry drugs using ultrasound, their vibration speed should be 6-8 kHz. The dried liquid is decomposed into particles in may under the influence of ultrasound drips. each particle moves in the oscillation period Iczlik. This action causes friction to occur, causing the liquid - liquid to evaporate.

Technologlk processes for the production of lubricants

Technological processes for the production of lubricants include the following stages:

- production preparation:
- preparation of medicinal substances and auxiliary substances;- dorivor moddani asos tarkibiga kirgizish:

- homogenization (mixing);
- packaging and marking of finished products;
- waste processing.

When applying the drug substance and auxiliary substances and entering the base composition, it is necessary to take into account their physicochemical properties, the type of dispers system and the type of base.

The stage of preparation of medicinal substances and excipients - includes their grinding, clash, pulling, as well as eridant processes of the medicinal substance. The substances contained in the grease base will need to be dissolved, mixed or emulsified and filtered to get rid of foreign particles.

Heterogeneous type surtmalami is often when mixed in reactors. the necessary level of dispersion of the medicinal substance in the base cannot be ensured. Therefore, a large amount of ready - to-run surtmalami homogenization is carried out at a high temperature (40-70 °C). For this purpose, various types of lubricants are used - colloidal Mills, rotor-pulsating apparatus, etc.

It is currently being extensively foiled from rotor-pulsating apparatus (RPA). RPAS can be mounted dead and flowing.

RPA fixed type. This type of RPA performs the mixer task and it will be placed in the reactor. This type of RPA includes a rotor type of hydrodynamic apparatus. They ..At the tallinsky khimmashstroenie plant, a serial reactor is produced in the form of a homogenizer (fig.

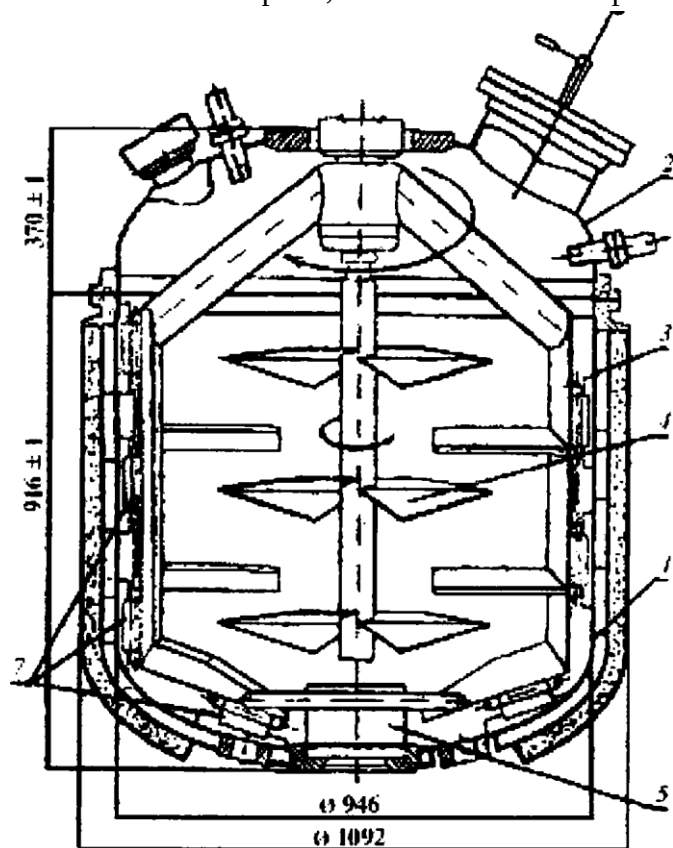


Figure 51 reactor-homogenizer MACEF PH-500B,, OLSA“ firm (Italy:

1st Hull; 2nd Hull; 3rd Hull mixer; 4th Hull spacer; 5th turbine agitator Polytron; 6th agitator;
7-Teflon clamp.

Add this RPA to other types of mixers. it is installed in order to increase the mixing efficiency. This homogenizer, which is simple in structure it cannot provide the same intervention of large amounts of grease. Therefore, it will be advisable to use it when mixing small - sized brown-gi-less masses. Type RPA streamii. Currently, the flowing type of RPA is widely used in miqiyos (figure 52).

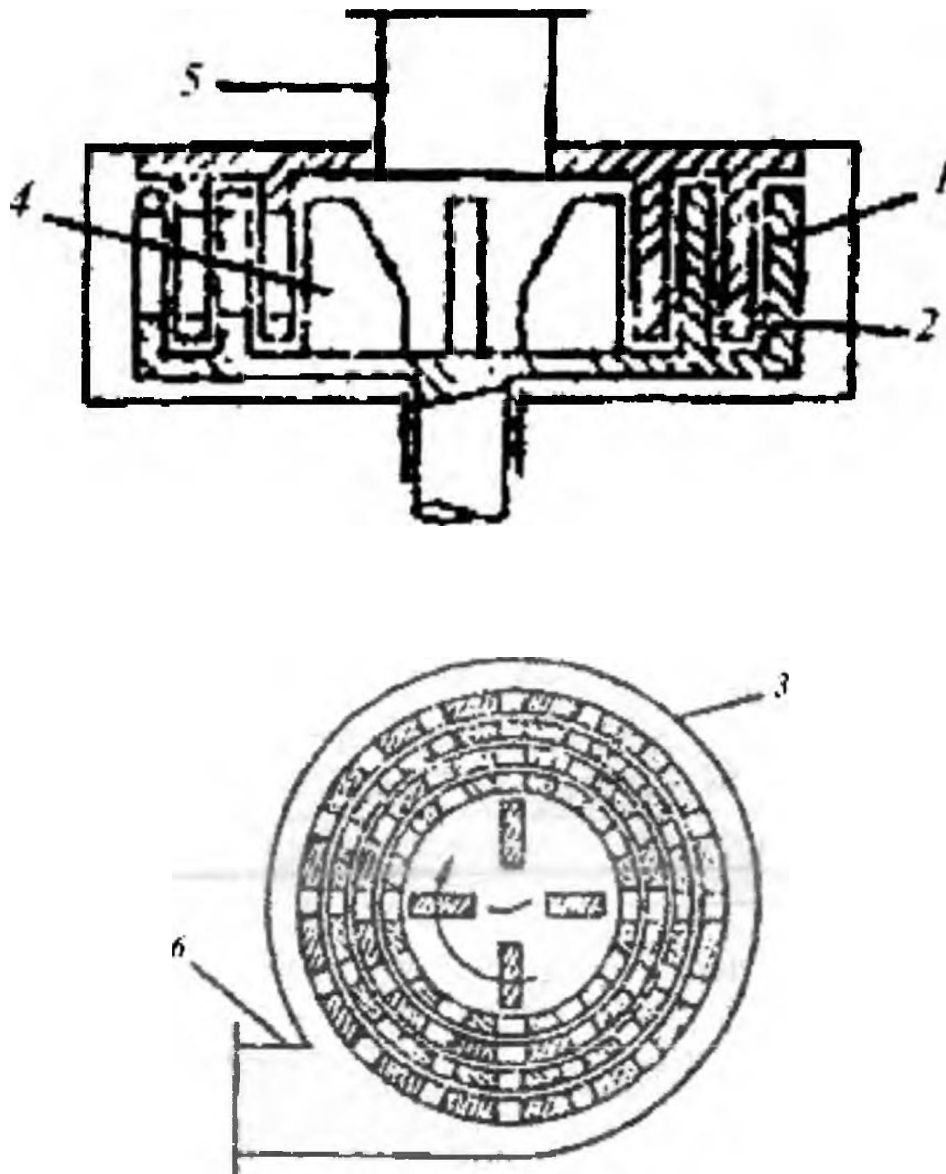


Figure 52. Drawing of a Rotor-pulsating instrument:
Rotor No. 1; stator No. 2; Hull No. 3; stern No. 4; 5,6 - in and out.

It consists of a boom made up of a rotor and a stator, which are in the form of cylinders or concentrically located gears with holes located in the body in a row - ma-row. On the inside of the Motor is a bombad, on which there are shovels or knives. These provide improved grinding and mixing conditions of large dispersing media and shift of the medium being processed.

In the preparation of soft drug types from substances with solid particles and antibiotics, it is recommended to benefit from roller apparatus. On these apparatus, additional rollers will be located between the rotor and the stator. Streaming and roller RPAs are available in "Progress" (St. Petersburg), "Janke and Kunkel K.G." (produced in Ger - maniac).

Production of soft medicines

In order to prevent thermal burns, it is necessary to carry out work with solutions of Vaseline, lanolin, other substances applied to the preparation of spermacete in appropriate special clothing, subject to the temperature and time regime in accordance with a separately carefully prescribed procedure using protective equipment.

It is necessary to grind, sift and mix the powdery substances that are part of the flavors into boxing with as high a compaction or aspiration as possible.

In the process of processing the concentrate in colloidal Mills, shesterenka pumps and uving machines, it is necessary to control that the equipment is equipped with a wire connected to the ground from static electricity, the rotating and moving parts are protected by cojuses and fences.

Packaging and packaging of flavors and pastes should be carried out in automatic networks.

The process of using automatic networks for the preparation, packaging and packaging of soft forms of the drug should be carried out in strict compliance with safety rules.

It is forbidden to carry out cleaning, troubleshooting until the networks are completely stopped.

During the conduct of the technological process in order to avoid accidents, oils that have fallen on the floor should be regularly washed and cleaned with soapy water and other detergents.

It is forbidden to use paraffin, gasoline and other organic solutions for washing.

It is necessary to collect oil-soaked wiping materials into a special metal container and remove them from the production rooms in time.

Production of binding materials

Band-wrapping and band-cutting machines must be installed on local sideboard devices.

Pull zones should be installed in front of the loading and unloading windows of the dressing drying chambers and sterilization chambers.

There must be reliable barriers and blocking devices of rotating and moving parts and mechanisms that prevent mechanical injury in bandage-wrapping and bandage-cutting machines, presses, transporters.

In the case of tie materials, the production staff should not have ties at the front and side of the gown, the gown leg should be higher than the elbow. It is necessary that the hair of the staff is folded under the hood. The production of binding materials belongs to the category of Fire-Hazardous Productions, therefore, the production rooms must be equipped with automatic fire extinguishing tools and the necessary fire extinguishers.

**Lecture 14. Primary raw materials, primary and intermediate packaging materials.
Requirements for them
Plan**

1. Primary raw materials
2. Primary and intermediate packaging materials.
3. Primary primary and intermediate packaging materials

Base words and phrases: primary raw materials, primary and intermediate packaging materials. Requirements for them.

The allotted time is 2 hours.

The preparation of medicines from medicinal substances is the main goal of the pharmaceutical enterprise. In this case, the first raw materials and auxiliary, cutting and labeling materials are used.

A well-structured package of documents as necessary is an integral part of the quality assurance system of finished products. It must be associated with all sections of this rule and reflect its basic requirements.

The production process must be carried out in strict compliance with the technological regulation, in which the requirements of the rule are reflected. This ensures that the finished product of the desired quality is obtained.

Primary raw materials

Pharmaceutical enterprises must have a regulatory and technical document approved in the prescribed manner for primary raw materials.

The production enterprise must have an approved enterprise standard and include;

- raw material statement containing name, conditional mark and code;
- links to existing regulatory documents;
- to indicate those who are likely to supply raw materials, to agree with them regulatory documents, to indicate the size and duration of the raw materials to deliver;
- guidelines for sampling and access control;
- requirements for quality, taking into account the production classification;
- precautions when using raw materials and storage in appropriate conditions;
- term or date of use of raw materials. Further quality inspection is required after this;

When receiving raw material series, the presence of documents indicating the information on the supplier's Whirlpool blank, the analytical passport, the correctness of the shipping letter and labels, the non-damage and cleanliness of the packaging, the quality of the raw materials is checked. Each series of raw materials being obtained is registered.

If at once the same raw materials from several different series were obtained, the sampling should consider each series separately, carry out access control on the basis of a regulatory document, and provide an indication for use in production.

The resulting raw materials are subject to access control based on the current documents, for which the average naamuna from all series of raw materials is selected.

Samples are selected in specially equipped rooms, subject to conditions that prevent additional contamination of raw materials. As far as possible, the sampling should be taken under the supervision of another employee, only an authorized employee of the quality control department. Controlled samples should be kept under appropriate conditions for another year

after the expiration date. Deviations from the requirements of the regulatory document, as well as damage to the packaging, which can affect the quality of the initial raw materials, must be registered.

The raw materials obtained must be provided with a label and the following information:

- product name, conditional mark and or code;

- serial number;

- shelf life or date. Further quality inspection should be required after this. In this case, it is advisable to use a color label. In the process of passing the control stages, labels are replaced (for example, raw materials were given or deemed unsuitable for use).

Raw materials should be stored in rooms separated from the main production. In order to prevent the mixing and contamination of raw materials, separate rooms or places should be allocated for the purpose of making, storing and giving the bark. Employees who are competent in storage should have easy access to the room where the raw materials are stored.

At the time of working with raw materials, it is required to strictly adhere to the applicable sanitary, hygienic and technical safety standards.

If the raw materials comply with the requirements of regulatory and technical documents, the technical control department is transferred to production with the spirit. It is necessary to register raw materials that are being transferred and reserved.

It is necessary to leave a sufficient number of samples from each series of raw materials for repeated analytical control.

First of all, the series that fell before the enterprise, with the spirit of belonging to the quality control department, should be used.

A competent sex worker must carry out weighing and measuring raw materials used in production on the scales on the basis of a written instruction. Before weighing and measuring on the scales, it is necessary to make sure that the raw material can be used and the capacity is branded. Weighing on the scales should be carried out under the supervision of one employee 2

In order to prevent secondary contamination, it is necessary to attach special importance to the conditions of delivery of primary raw materials to the production site.

All components that are part of sterile drugs must be subjected to regular microbial contamination testing.

All components that are part of the sterile drug should be examined for regular sterility or microbial contamination, and, if necessary, pyrogenicity. The expressed amount of microorganisms must be specified in the enterprise standard separately for each type of raw material. It is necessary to determine the amount of mechanical particles in primary raw materials at the required points.

The re-labeling of raw materials deemed unsuitable must be returned to the supplier or disposed of. It must be formalized with relevant documents.

Raw materials should be obtained only from suppliers registered by the main Department of quality control of medicines and medical equipment of the Ministry of health of the Republic of Uzbekistan.

Intermediate products, if necessary, must be tested in accordance with the requirements of the industrial regulation.

It is necessary to enter and verify in the minutes that the amount of the intermediate product deviates significantly compared to that of the approved or project (including the Unpacked

product).

In the packaging of ready-made medicines, the types of packaging can be primary or secondary. Primary packaging types will be 3 different:

1. Solid packaging: — metal packaging (balloons, greases, creams, pastes, liniments and tubas for gels) for aerosol drug types; — glass packaging: cans (powders, granules, tablets, dragees, capsules, pharmaceutical solutions, greases, creams, pastes, liniments, gels and infusion solutions) and ampoules (injection solutions); — cans made of polymers (powders, granules, dragees, capsules, pharmaceutical solutions, greases, creams, pastes, liniments, gels and infusion solutions). 2. Semi-finished packaging: — packaging made of cardboard paper (medicinal plant raw materials and assemblies made from them); - packaging made of polyethylene: syringe-tubes (for injection solutions), tubes for drops (m for ingested solutions for the eye), contour — slots (for suppositories); - combined cans: blisters (for capsules, capsules and suppositories). 3. Soft packaging: - Polymer Packages (for powders, granules and plastics); — paper packages (for tablets, dragees, plant raw materials and assemblies made from them; - convolutions (for tablets, dragees and capsules). The operations of the technological process should be carried out in previously clearly defined styles. In order to obtain a quality product, they must obey the Basic Rules of good production practice, have the appropriate license for production and a full set of recording documents. The technological process should be carried out and monitored by employees who have the authority to it.

Actions such as obtaining substances, materials and products and quarantining, sampling, labeling, preparation and distribution, processing, packaging and distribution should be carried out on the basis of written methods or instructions, and, if necessary, formalized in the form of a statement. All incoming substances and materializing must undergo inspection to guarantee compliance with the order. When necessary, the packaging container must be cleaned and labeled with the necessary information provided. All sorts of reasons that may indicate an unpleasant effect on the quality of a substance or material, or a violation of the packaging container, formalized as a statement, information about which should be communicated to the quality control department. Incoming materials and finished products must be quarantined separately or through appropriate administrative measures from the time they are obtained or processed until their use is allowed. In cases where intermediate or unpackaged products are purchased, they must be treated as raw materials.



All substances, materials and products must be made in the appropriate order for the series created by the manufacturer and the Reserve turnover in the warehouse to be kept separate. To make sure that there are no deviations from the permissible norms, it is necessary to check the outputs and compare the amounts. Except in cases where there is no risk of intermingling and cross contamination, work related to different products cannot be carried out

at the same time or at the same place. Products, substances and materials must be protected from microbes and other contaminants at each stage of processing. In the case of dry matter and products, precautions should be taken to prevent dust formation. This is especially important in work involving sensitizing and strongly acting substances. All materials used, unpacked product comb, basic equipment and, if necessary, rooms must be labeled with the name of the product or substance being processed throughout the process and its activity (if necessary) and serial number. In possible situations, such tabs should also indicate the stage of the technological process. Labels glued to Tara, equipment or rooms should be understandable, represent a single m organ, and their shape should be in the form adopted at the enterprise. In many cases, in addition to the information presented on the label, it is very useful to have them in different colors (for example: in quarantine, accepted, unsuitable, clean, etc.).k.). Inspections should be carried out that assess the correct connection of the pipes and other parts of the equipment used in the transportation of products from one zone to another. It is necessary not to deviate from guides and styles as much as possible. If deviations from them are observed, this should be recorded in writing by a competent boigan employee, with the participation of the quality control department when it is found. Access to production rooms should only be allowed to employees who are authorized to do so. As a rule, non-medical products should not be prepared in zones and equipment intended for the production of medicines.



Starting raw materials and specifications of primary or printed mower materials, if permissible, must maintain the following:

- a) classification of raw materials or materials, including: - a link to the given name and internal code; - a link to the pharmacopoeia monograph, if any; - the name of the approved suppliers, if possible, the manufacturer of the product; - a sample of rolling materials;
- b) links to guidelines or styles for sample selection and testing;
- d) requirements for qualitative and quantitative determination with the indication of permissible limits;
- e) storage conditions and precautions; maximum shelf life up to re-Control.

Intermediate and non-packaged products must be purchased, sold or intermediate product m advantages to assess the quality of the finished product, to which there are specifications. the same specifications should be compatible with raw materials or finished product specification i series. Finished product specifications may include: a name given to the product and a reference to the code in the case of need; content or reference to it; exhaustive

information on the classification and packaging and label of the drug form; instructions for sampling and analysis reference to this method; requirements for qualitative and quantitative clarifications with the indication of permissible limits; storage conditions and, if necessary, what special precautions in drug circulation; shelf life. Packaging materials and requirements for them should be instructions on the packaging, which is officially approved for the size and type of packaging of a drug. As a rule, they contain the following information or links to them: the name of the drug; classification of the drug form and, in cases of need, the mechanism of its action (activity, concentration or mass of the drug substance); quantity of preparation expressed in number, mass, or volume in the last wrapper; full list of all the Reaper materials you will need for a standard size series, each Reaper material specification with size, including quantity, code, or number, given size and type; appropriate printed Reaper materials luiuunas or copies and samples of them with product serial number and shelf life; special precautions subject to compliance, which include inspection of the zone and equipment, to make sure that the line is cleaned before starting work;-classification of the winding process along with all the main auxiliary operations and the equipment used in this; —complete classification of control in the production process with sample selection instructions and permissible limit indicators. The minutes of each prepared Series or the series of scrolls on its part should be kept. It should be based on the relevant parts of the instructions on the scroll, and the method of preparing the statements in question should not cause errors in copying. The statement must indicate the serial number and quantity of the unpackaged product, as well as the planned quantity and series of the finished product to be obtained. Before starting any trench operations, the tool equipment and work zones must be checked and stated that the previous products, documents and materials that are not required for the planned process are exempt, and the tool equipment is clean and ready for use. The information on the actions that each will do must be stated; when the operations are completed, the statement must be agreed, the date must be indicated and signed by the person in charge of the packaging operation and include the following information: - product name; - the date and time of the packaging operation; - the signature of the responsible person who carried out the packaging operation; - the surnames of the operators of various important stages; — the details of the verification of exactly the same and compliance with the instructions for the packaging, including the results of production control;-detailed information on the operations carried out on the packaging, including; - displays serial numbering, shelf life and other additional printed records, including samples of used, printed scroll materials, in cases where possible; complete information on particular problems and unusual circumstances;

The production or manufacturing process is a process that involves the production operations of ready-made medicines, i.e., the purchase of raw materials, primary reeds, labeling materials and additional, semi-finished (in bulk) products, to prepare, wrap, obtain references to sales, store, transport and control the quality of finished products. The production process is necessarily carried out under strict control. It is part of the production process control, environmental and equipment cleanliness control, implementation of the types of step-by-step control of the introduction of adjustments to the relevant technological indicators in order to ensure the quality of the finished product complies with the requirements of the regulatory document. Packaging-all stages and operations in the placement, labeling and organization of medicines on the materials of the mower. In the production of sterile drugs, the primary wrapping filling (primary wrapping material, packaging or pouring) does not enter the wrapping stage as a rule. A product that is filled, but not wrapped with a primary wrapping material, should be considered a semi-finished (in bulk) product

. Sickle materials-materials used in wrapping or dosing, as well as in the storage of ready-made medicines (except for the transport comb).

They are divided into the following types:

1. Primary mowing materials-materials that directly touch the forms of the drug.
2. Secondary wrapping materials are materials used in wrapping ready-made medicines (boxes, cardboard, film, foil, etc.).

Primary packaging types will be 3 different:

1. Solid packaging: — metal packaging (balloons, greases, creams, pastes, liniments and tubas for gels) for aerosol drug types; — glass packaging: cans (powders, granules, tablets, dragees, capsules, pharmaceutical solutions, greases, creams, pastes, liniments, gels and infusion solutions) and ampoules (injection solutions); — cans made of polymers (powders, granules, dragees, capsules, pharmaceutical solutions, greases, creams, pastes, liniments, gels and infusion solutions). 2. Semi-finished packaging: — packaging made of cardboard paper (medicinal plant raw materials and assemblies made from them);-packaging made of polyethylene: syringe-tubes (for injection solutions), tubes for drops (m for ingested solutions for the eye), contour — slots (for suppositories); - combined cans: blisters (for capsules, capsules and suppositories). 3. Soft packaging: - Polymer Packages (for powders, granules and plastics); — paper packages (for tablets, dragees, plant raw materials and assemblies made from them; - convalutions (for tablets, dragees and capsules). The operations of the technological process should be carried out in previously clearly defined styles. In order to obtain a quality product, they must obey the Basic Rules of good production practice, have the appropriate license for production and a full set of recording documents. The technological process should be carried out and monitored by employees who have the authority to it.

The following requirements are imposed on the primary cutting materials used in the manufacture of medicines:

- protection of drugs from the effects of an unfavorable external environment;
- avoid mechanical influences;
- easy to use daily;
- to be tasteful in appearance.

In the preparation of primary mowing materials (ampoules, vials, jars, caps. valves, plugs, etc.) it is necessary to use materials that do not affect the irritability of drugs and the properties of pharmacotherapy.

Possible deviations from the shape, size and size of the primary Reaper materials must meet the requirements of the relevant standards.

All primary mowing materials must comply with specially designed and approved network standards or enterprise guidelines and must come from suppliers to the enterprise in a packaging that ensures their entire storage and prevents secondary contamination during the storage period.

The cutting material must be kept in a separate room in conditions that do not mix and do not get dirty. First of all, the cutting material with the appropriate spirit of the quality control department, obtained before the enterprise, should be used. It is necessary to destroy old or outdated primary cutting materials and formalize it with a document.

PACKAGING OF MEDICINAL PLANT RAW MATERIAL PRODUCTS

Placement of medicinal products in containers (packaging). When packaging medicinal plant raw materials, special attention is paid to the types of raw materials and its volumes. Currently, methods of fastening, pressing and briquetting from packaging are widely used.

Tuning (folding)— is carried out on Special Tuning machines.

Pressing (cipslash)– is carried out in special presses for herbs and bark (provoditsa dlya trav, kor v spetsialnix pressax: utilnix ili sennix).

Briquetting is a way to carry out pressing of crushed raw materials in small volumes. In most cases, briquettes are sold in pharmacies as a ready-made medicinal product in their condition.

Some types of raw materials require separate packaging: poisonous, psychotropic, fast-acting substance storage plants (69 species in Group A) are stored in special safes, sealed with a thick-glazed lid.

Medicinal raw materials brought to standard condition are packaged differently depending on the type of products. The placement of medicinal products in containers medicinal raw materials brought to standard condition are packaged differently depending on the type of products. The placement of medicinal products in containers (packaging) should ensure that they are protected from external influences (from spilling, scattering, preservation within the period of use without changing its quality and appearance, as well as shipment and transportation in vehicles).

Product placements include bags, bags (packages), crates and cuticles made of board and cardboard paper, and folding crates, etc. The dishes used should be dry, clean, without any smell, and the same for each party.

Ragoja Meshkovina

Phanereal yatshik



Рагожа



Мешковина (коп)



Фанерали ящиклар



Картонли ящиклар

Types of dishes (tara)

The dishes in which the products are placed, the weight of the products in the container is determined by the type of medicinal products, and they are found in the relevant regulatory documents (for example, in the pharmacopoeia article (FM) and GOSTS)



< BR > :

Dried medicinal raw materials for the packaging of products (according to the rules of the FS), the following containers are used;

Cloth bags (according to GOST 19317-73 or gost 18225-72) are bags woven from linen-jute-hemp fibers. These bags can be used as one or two floors. The mouth of the bags is sewn by hand (according to GOST 17308-85 with a hemp thread) or by machine (according to GOST 14061-85 with a thread made of flax fiber). The weight of the product in the bag should not exceed 40 kg.

Multi-layer paper bags (according to GOST 2226-75 and according to GOST 24370-80) are two-or one-layer paper bags. Paper bags filled with the product, the mouth of the bags is sewn by hand or by machine with the above-mentioned threads.

For the preparation of one or two floor bags, special papers (according to GOST 2229-81 e and GOST 1760-81) are used. No more than 15 kg of products should be placed in a paper bag, no more than 5 kg in a paper bag.

Long and six-pointed thick-shaped feathers made of fabric (according to GOST 19298-73). Toys are loaded with no more than 50 kg of medicinal product, and their mouth is sewn by hand or by machine with the threads mentioned above, indicated in the corresponding GOSTS.

Tiers that are not sewn around the top with fabric are also sometimes used.

Wooden (according to GOST 5959-80) crevices. Inside the crates, A B - brand paper (GOST 8273-75) or a bag of stitching paper (GOST 2228-81) is placed, which is indicated on the corresponding GOSTS, and then filled with a medicinal product. Wooden crates are placed with a medicinal product weighing up to 30 kg. Then its cover is nailed.

Crates made of cardboard (according to GOST 15629-83). Before filling these crumbs with medicinal products, appropriate papers are placed in them. At the end, special glue paper tapes are glued on cardboard crates or wrapped with steel wire from two check places (GOST 32822-74).

The weight of the medicinal product placed in cardboard crumbs should not exceed 25 kg.

The dishes that are necessary for the placement of medicinal products are selected according to the appropriate GOST, depending on the type and nature of these products.

For the sale of medicinal products to the population, tea boxes made of paper (cardboard) according to GOST 64-026-87, paper and polyethylene bags, among others, are used in the packaging.

The norm of packaging a medicinal product for the type of packaging containers (just as well as what glue the mouth of bags and cans should be glue, how many bags and cans should be placed in crates for shipment to pharmacies and warehouses) is indicated in the relevant regulatory and technical documentation:

After the medicinal product is placed in jars, complete information about the same product is written (branded) or a corresponding label is hung on the container in which they are placed.

According to GOST 17768-80 on a container of medicinal products (cardboard box, polyethylene bag, crate, etc.) issued to pharmacies for sale, the following must be written;

- ministry, prepared enterprise and its trademark; name of the product in Latin, Russian and Uzbek; weight of the product in the most permissible state of moisture, method of use, storage conditions, taken into account number, serial number, shelf life and recognition price (price).



On top of the container of medicinal products to be shipped in a vehicle, gost 14192-77 should be written: Ministry (institution, administration), name of the korkhana that sent it, product name, net weight of the product in the state of most moisture, joint (brutto) weight with the container, year and month of preparation, party number, level and number of the normative technical document (MTX) of the specified product.

Designation of medicinal herbal raw materials (marking). The purpose of marking (marking) of raw materials is used in the processes of storage and transportation of raw materials in the control of the implementation of the activities established for these types (to avoid confusion in storage and transportation, to comply with the shelf life and conditions of storage of raw materials, etc.). Marking (marking) documents include: raw material data document (vkladish), label or joint, quality document (analytical passport).

The raw material data document (vkladish)contains the following props:

- name of raw materials;
- sender;
- signature of the person who checked the authenticity and quality of raw materials;

- The signature of the packaging person and the term of the packaging;

The label (label) includes the following props:

- name of raw materials and its weight
- Receiving address
- Receiver (pharmacy base)
- sent address
- Sender
- Place and duration of preparation of raw materials

Quality document (analytical passport) – All information about the authenticity and quality of raw materials is entered.

Shipping the product on vehicles. Products prepared, dried and placed in containers should be delivered to timely storage places and to customers. If the relevant regulations are not followed when shipping products via a transport vehicle, it may lose its quality due to road wetting, grinding, and other reasons.

Medicinal products are shipped according to GOST 14192-77 and GOST 17768-80 in dry, clean, no smell, top-closed vehicles. Products of medicinal raw materials that have a toxic, powerful effect and contain essential oil will have to be sent in other separate vehicles (some cars, some railway cars, etc.).

Lecture 15. Marking and secondary packaging of finished products. Recycling and neutralizing pharmaceutical production waste

Plan

1. Secondary packaging of finished products.
2. Marking of finished products
3. Recycling and neutralizing pharmaceutical production waste

Base words and phrases: marking and secondary packaging of finished products. Recycling and neutralizing pharmaceutical production waste

The allotted time is 2 hours.

The main purpose of marking is to protect the population from counterfeit drugs, to combat its spread.

International experience shows that the introduction of this mechanism makes it possible not only to manufacture drugs, but also to monitor and control their life cycle, from their import to their arrival in the hands of the end consumer and withdrawal from circulation.

Through the system, the consumer will be able to make sure that the medicine they are buying is not counterfeit, making it safe for life and health.

The use of such digital signs makes it possible for consumers to obtain all information about the drug.

You will find out information such as the name of the manufacturer and the company that imported it to our country, the place of manufacture, the person who is realizing it, the standard number by scanning a special code on the packaging of the drug. This information is stored in the Public Information System.

The finished product should have a clear label. The content and records of the label must comply with the requirements established in the current regulatory and technical documentation for each specific drug. When labeling products, it is advisable to use coding, which facilitates identification in an automated way.

Marking can be in the form of special tabs or directly lowered to the surface of the primary wrapper.

The preparation of labels and other printed materials should be organized in such a way that their intermingling is eliminated.

The necessary labels and other printed materials for the mesh should be stored in special rooms in containers with closures. Labels and medicines of each individual name it marking materials, dosage of medicines should be kept separately. They are issued only if there is an appropriate written order.

The marking of labels from the storage room and taking them to the packaging line should be arranged in such a way that they are guaranteed not to get confused with labels that are intended for counterfeiting or marking other medicines, raw materials or auxiliary materials.

The marking of the secondary packaging must comply with the requirements of the current regulatory and technical documentation. It is also necessary to have information about the number of primary reeds in one box.

The marking of the general packaging must comply with the requirements of the current regulatory and technical documentation and the marking of the secondary packaging.

When the finished product is removed from the premises of the enterprise, the compatibility of the secondary and general packaging marking is once again checked by employees allocated for this purpose.

Medicines in a common taraga trench must be transported on top closed vehicles, in accordance with the requirements of the current regulatory and technical documentation and the rules of Transportation.

The procedure for mandatory digital marking of medicines and medical products is as follows:

- to the realization of drugs and medical products produced by the date of the introduction of the digital marking procedure in no more than three years, until the expiration of their shelf life, without digital identification tools;

- domestic manufacturers are issued a mandatory digital marking procedure for medicines and medical items within 90 days until the date of introduction (the date indicated on the packaging) and undergo certification without digital marking;

- foreign manufacturers are allowed to certify products produced (the date indicated on the packaging) and not digitally marked within 180 days by the date of the introduction of the mandatory digital marking procedure for medicines and medical items, as well as formalize them to the customs regime of "free circulation (import)".

Marking codes for digital marking of medicines and medical items, which are prescribed mandatory digital marking by the Operator, manufacturers of medicines and medical products, orphan drugs and medical products used in the diagnosis and treatment of orphan diseases, as well as the owners of certificates of registration of a foreign manufacturer or its accredited representative office or medicines and medical products — it will be available to foreign manufacturers (next — foreign manufacturers) on an appropriate order;

- digital marking codes are provided free of charge by the Operator in accordance with the list of medicines provided by the pharmaceutical network development agency under the Ministry of health of the Republic of Uzbekistan, when the manufacturer's limited sale price for medicines is not higher than one percent of the amount of the base calculation;

- when the circumstances of the sale of these drugs by the manufacturer at a price higher than the limited selling price established in wholesale or retail trade, these cases are considered a violation of the rules of digital marking, as well as payments for the marking codes provided for these products are fully charged by the Operator;

by the day of the introduction of the procedure for mandatory digital marking of the corresponding group of medicines and medical products, manufacturers have the right to order

marking codes from the operator and produce them using digital identification tools on the primary and secondary packaging of these products;

a) in order to register foreign manufacturers of products whose mandatory digital marking is specified from the "original mark" mat and in order to make it possible to use this system in the future, they are put into account by issuing a taxpayer identification number in the state tax service body for obtaining electronic digital signature key certificates.

In this case, an application for accounting by foreign manufacturers is submitted electronically to the State Tax Service Authority through the official website of the state tax committee of the Republic of Uzbekistan. In order to obtain certificates of electronic digital signature Key, the State Tax Service Authority provides foreign manufacturers with the opportunity to put into account the taxpayer's identification number;

b) opening a representative office of an accredited foreign commercial organization in the Republic of Uzbekistan within twelve months or concluding an agreement with a local legal entity on the issues of introducing a digital marking system (information of this legal entity) on the issue of opening a representative office of a foreign commercial organization accredited in the Republic of Uzbekistan within twelve months in medicine, the obligation is imposed), which is necessarily reflected in the instructions for use. In this case, the representative office or legal entity — to the resident:

order marking codes for the purpose of digital marking of products (only for the representative office of a foreign manufacturer);

implementation of interaction with relevant public administration bodies and economic associations;

informing a foreign manufacturer of changes in rules and requirements in the field of digital marking;

C) when the rules of digital marking by a representative office of a foreign manufacturer or a legal entity — resident are violated three times for a year, the Operator limits interaction with these persons in accordance with the instructions of the state tax committee of the Republic of Uzbekistan.

Requirements for packaging and packaging of medicines

Primary Reaper materials used in the manufacture of medicines must meet the following requirements::

- protection of drugs from the effects of an unfavorable external environment;
- avoid mechanical influences;
- easy to use daily;
- to be tasteful in appearance.

Pharmaceutical enterprises should create directives that cover all aspects of dealing with primary cutting materials (methods of preparation, use and quality control). The implementation of this work guarantees that the cleanliness in terms of Mechanical, Chemical and microbial contamination of the primary cutting materials is at the required level.

In the preparation of primary mowing materials (ampoules, vials, jars, caps. valves, plugs, etc.) it is necessary to use materials that do not affect the irritability of drugs and the properties of pharmacotherapy.

Possible deviations from the shape, size and size of the primary Reaper materials must meet the requirements of the relevant standards.

All primary mowing materials must comply with specially designed and approved network standards or enterprise guidelines and must come from suppliers to the enterprise in a packaging that ensures their entire storage and prevents secondary contamination during the

storage period. The cutting material must be kept in a separate room in conditions that do not mix and do not get dirty. First of all, the cutting material with the appropriate spirit of the quality control department, obtained before the enterprise, should be used. It is necessary to eliminate old or outdated primary cutting materials and formalize this with jujjjat.

When transporting prepared primary mowing materials from one room to another, special devices, containers are used that prevent secondary boron contamination or mixing.

When wrapping medicines intended for children, it is advisable to use disposable packages with heat-insulating plunks. Multi-use wraps containing ingested solutions, syrup and suspensions should be concentrated with dosages, taking into account the age of the child. Aimed at children,- it is forbidden to place drugs that have a strong effect on the packaging, which are used many times. All types of packaging of medicines intended for children should be branded as distinguishable.

Injection drugs (ampoules, vials, rubber stoppers) should be checked for the absence of mechanical particles in the primary winding materials. In the production of non-sterilizing injection drugs in the primary packaging, in addition, their sterility, the state of pyrogenicity at the required points should be controlled.

The sterility and pyrogenicity of the initial sickle materials can be tested on certain occasions if validated during the preparation process.

At the enterprise, it is necessary to have instructions that reflect the rules for the reception and validity of plows and materials, inspection of workplaces and equipment, the procedure for wrapping and labeling.

The finished product should have a clear label. The content and records of the label must comply with the requirements established in the current regulatory and technical documentation for each specific drug. When labeling products, it is advisable to use coding, which facilitates identification in an automated way.

Marking can be in the form of special tabs or directly lowered to the surface of the primary wrapper.

The preparation of labels and other printed materials should be organized in such a way that their intermingling is eliminated.

The necessary labels and other printed materials for the mesh should be stored in special rooms in containers with closures. Labels and medicines of each individual name it marking materials, dosage of medicines should be kept separately. They are issued only if there is an appropriate written order.

The marking of labels from the storage room and taking them to the packaging line should be arranged in such a way that they are guaranteed not to get confused with labels that are intended for counterfeiting or marking other medicines, raw materials or auxiliary materials.

Outdated, defunct tabs, marking and wrapping materials, as well as serial number and other unused informative tabs should be destroyed and formalized with a document.

When transporting ready-made medicines, in order to ensure their integrity, they must be wrapped a second time and placed in a tara group, in addition, in accordance with the current regulatory and technical documentation.

The marking of the secondary packaging must comply with the requirements of the current regulatory and technical documentation. It is also necessary to have information about the number of primary reeds in one box.

The marking of the general packaging must comply with the requirements of the current regulatory and technical documentation and the marking of the secondary packaging.

When the finished product is removed from the premises of the enterprise, the compatibility of the secondary and general packaging marking is once again checked by employees allocated for this purpose.

Medicines in a common taraga trench must be transported on top closed vehicles, in accordance with the requirements of the current regulatory and technical documentation and the rules of Transportation.

In the process of wrapping and marking, measures should be provided that warn against contamination with each other, interference or mistaking another for one type of product instead.

If the range of technological paths is not separated by obstacles, it is impossible to wrap the drugs directly close to each other.

Marking should be carried out immediately after the product is embedded in the primary winding material and sealed. If the Marking (Labeling) is postponed error marking, measures must be taken to prevent confusion and confusion with another product

When the plowing process is complete, all unused plowing and marking materials with a serial number are missing, must be done.

Labeling, transportation and storage of ready-made medicines. All documents that determine the movement of medicines and medical products must be prepared for submission at the request of the relevant responsible organizations. Documents reflecting the reception and shipment of medicines and medical items should include the following information about the product: name of the product, quantity received or delivered, series/batch, name and address of the supplier, manufacturer factory or cargo recipient, license, certificate, date of preparation, shelf life, storage conditions, guaranteed obligations for medical item products, etc. This account must have provided the conditions for all follow-up actions performed with respect to any series/batch of drugs and medical items. The documents must be in the conditions that ensure proper use until the expiration date according to the regulation established by the legislation of the Republic of Uzbekistan. Documents must be stored in a paper or electronic state. The statements should be completed in such a way that at the time of each work process, it is possible to observe all important actions and phenomena in it. Statements should be clear and easy to read.

Waste-free technology is a method of production of products (process, enterprise, industrial complex), in which raw materials and energy are most rationally and comprehensively used in the cycle of raw materials-production - consumption-secondary resources so that any impact on the environment is not disturbed. normal operation. Low waste production is understood as production, the results of which, when exposed to the environment, do not exceed the level allowed by sanitary and hygienic standards, consequently, the term "waste-free technology" refers to such a way of organizing the production and consumption of products, in which all components of raw materials and energy are most rationally and comprehensively applied, and the environmental balance The creation of waste-free technological processes is based on the following necessary conditions: 1. The initial natural reserves should be taken as often as possible, and not for each product2. The products created must have such a shape that allows them to change relatively easily after use for their own purposes. to the raw materials of new production.

It is clear that such a scheme is almost impossible. The complete closure of the system both in matter and in energy is impossible, since each new stage of the raw material cycle - the consumption of production - requires additional energy costs due to the fact that the raw materials attract new natural resources due to environmental losses and imperfections of modern technologies and the inevitable obsolescence of the materials used. Thus, the term "waste-free technology" is idealized. Therefore, in real situations, it is necessary to strive for a similar state. In this case, the level of waste serves as a measure of technology and the perfection of the organization of production and consumption. The coefficient of complexity or the coefficient without waste - the percentage (%) of useful substances obtained from processing raw materials in relation to its entire amount. The low emissions production-free ratio is 75% and higher. More than 95% - waste-free production. In some cases, the level of absence of waste already exceeds 80%. Waste-free technology implies the creation of:

- 1) Waste-Free technological cycles of repeated use of the same substance, closed in the production process;
- 2) technological processes that are ecologically related to the environment and nature in general.

In accordance with the possible directions for solving the issue of interdependence between production and the environment, three types of production can be distinguished:

- 1) without closed waste, when in the technology in which it was carried out, at the same time as the production of the final product, almost complete processing of intermediate waste is carried out;
- 2) natural state by-product or production that returns waste to nature;
- 3) production that returns waste to nature for recycling (with this recycling guaranteed fully provided). The first condition for creating waste-free production is the choice of technology that does not contain or minimize waste and waste. The radical absence of waste and waste is a criterion for improving any technological process.

The second condition for the creation of waste - free technology is the analysis of its relationship with previous and subsequent technological processes: an environmental solution that is successful for a particular technology can be undesirable for the environment and (moreover) makes production significantly environmentally hazardous in general. In other words, you cannot solve your problems at the expense of others and at the expense of others. The third condition is that the optimal technological process should not only be environmentally friendly, but also be distinguished by high productivity, minimum living and past labor costs spent per unit of production. The fourth condition is a critical reaction to decisions that seem simple and easy. At first glance, conventional wastewater and exhaust gas treatment is the simplest solution. It looks the most convenient and solves all the problems. In fact, the use of cleaning interferes with solving the main task - to develop or improve the technological process, when waste does not come out or when they are used. In other words, it is necessary to eliminate the cause of waste and not fight the consequences. The fifth condition for the creation of waste - free technology is the use of technical solutions that ensure the reliable, stable and trouble-free operation of the technological system, which excludes the release of components harmful to the environment even when technological equipment is off-plan. Various cleaning agents and methods allow you to choose the most suitable cleaning method and scheme for a particular production work.

The most important criteria for choosing the final scheme of its organization in order to ensure the futility or low waste of the technological process are:

- 1) unconditional adherence to the norms of the content of substances in air and water bodies;
- 2) effective implementation of the technological process;

- 3) the use of possible cost-effective (taking into account compliance with the first two requirements) technological schemes for cleaning gases and liquids;
- 4) ensure the possibility of obtaining a small amount of concentrated waste, which is easier to neutralize;
- 5) negligible volume of liquefied hazardous waste, which is lowered into water and dispersed in the atmosphere, even less than the maximum allowable concentrations.

Recycling and neutralizing pharmaceutical production waste

Pharmaceutical production waste includes residues from expired drugs, mixtures and tablets, packaging materials, gloves, contaminated waste from food processing units, clothing. All this waste is generated from the activities of research laboratories, forensic institutions, hospitals and veterinary clinics.

In developed countries, this type of waste is destroyed with the help of high temperatures, in Russia, this type of waste is thrown into common urban landfills with garbage, which significantly increases the risk of infection and infection.

Each institution has a special directive with safety regulations for the collection of waste. The legislation requires a license for organizations involved in the elimination of pharmaceutical production waste. Special sanitary and epidemiological departments have the right to issue licenses.

Solving the problem of waste disposal

Pharmaceutical production waste, regardless of its type, can cause great harm to human health, harm the ecosystem and its inhabitants. Redemption is divided into classes:

- A-not dangerous;
- B-potentially dangerous;
- B-very dangerous;
- G-toxic;
- D-radioactive.

Each outlet has its own waste transportation rules. All varieties except Class A are part of the mandatory elimination group. Many institutions ignore the waste disposal rules and take them to the general landfill, which over time can cause epidemics of infectious diseases in unfavorable conditions.

A group of people who live near landfills, as well as a group of people who care for landfills, animals, birds and insects, can also serve as a means of infection.

It is very expensive to use special equipment to eliminate the waste of pharmaceutical production, the state saves on their disposal.

Collection and processing of pharmaceutical production waste

The collection and processing of pharmaceutical production waste is carried out by special organizations that have undergone sanitary examination and have received a license for this type of activity. In such institutions, a special journal is kept in which information about waste processing is entered, each class of waste has its own form of accounting.

The process of using raw materials has the following steps:

- * waste disposal organization organizes waste collection;
- Waste residues are placed in a special storage area, where they wait for the time of disposal;
- all hazardous waste is disinfected;
- after a certain period of time, garbage is removed from the territory of this institution;
- at the final stage, the waste is burned or buried in special landfills.

The state of the ecosystem and its inhabitants will depend on the quality of disposal of pharmaceutical production waste.

Waste collection requirements

The rules for collecting pharmaceutical production waste are established by SanPiN, if they are not met, after further inspection the organization is fined or excluded from this type of

activity. Long-term storage of waste is prohibited, as well as temporary storage without a decontamination procedure. The work area must be properly disinfected. In a bag of any color, except for yellow and red, it is allowed to fill waste substances with expired drugs.

There is a waste collection instruction:

- * Class A waste collection can be carried out using disposable bags placed in reusable boxes;
- Class B litter is pre-disinfected, this method is selected independently in the hospital, but this is a prerequisite, what remains after disinfection is placed in containers with increased moisture resistance, the lid must ensure complete closure;
- * Class B waste is chemically disinfected; their disposal is carried out outside the hospital. For Assembly, special bags or tanks are used, which have a special red mark. Stabbing or cutting waste, Breaking are placed in special sealed containers;
- Radioactive raw materials of Class G are collected in packages, which can be stored in a separate insulated room, in which there should be no heating equipment.

Proper compliance with the instructions will protect workers who collect garbage from contamination.

Waste storage containers

The main requirements for choosing the right equipment and material for collecting waste are:

- * tanks should consist of high-quality moisture-resistant material, the lid is solid, which allows the waste to be completely closed;
- * Containers for waste removal must be marked: a-white, b-yellow, B-Red;
- at the bottom of the tank, there should be special fasteners for convenience when transporting cargo.

The volume of Tanks can vary from 0.5 liters to 6 liters. There are several types of Tanks:

- universal tanks are designed to collect Class B items, they can be: medical devices, organic waste;
- * General containers designed for separate collection of pharmaceutical production waste with a tight lid.

Much depends on the quality of the waste handling equipment used, including the safety of the surrounding people touching trash cans or bags.

Ways to neutralize raw materials and eliminate it

The main requirements for the processing of hazardous pharmaceutical production waste include not allowing the reuse of tools, gloves, spoiled medicines, and high-quality disinfection is also required, with the help of which the possibility of spread of infection is excluded.

The processing of pharmaceutical production waste include:

- mechanical processing, which consists in distorting the appearance of an expired object, which prevents its reuse. Such processing methods may include: pressing, grinding, grinding, or grinding;
- chemical processing is applied to waste that is resistant to high temperatures and tolerates moisture well, such waste cannot be sterilized with steam. This type of waste is affected by a special gas or put into solutions. Waste is pre-crushed, wet oxidation can be used;
- physical therapy, which consists of autoclaving, activating or using radiation sterilization, less electrothermal treatment.

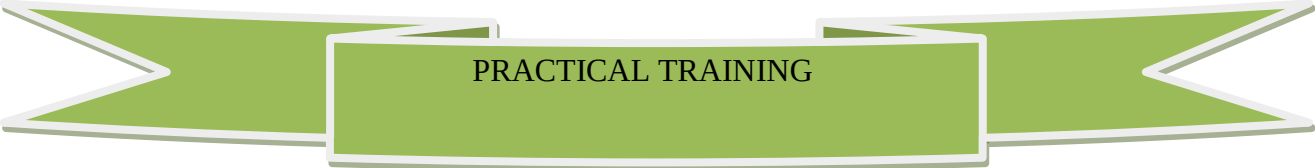
Waste disposal can be carried out by the hospital itself or by an institution that requires medical equipment, or third-party organizations may be involved to dispose of raw materials.

On the territory of the institution, only garbage that does not harm others can be disposed of. Hazardous waste requires a special approach and equipment, so they are removed by special organizations.

Destruction of medical equipment

The SanPiN rules state that third-party organizations licensed for this type of activity are concerned with the destruction of medical equipment. Medical devices and non-hazardous garbage are destroyed in a medical institution, subject to the established safety rules.

SanPiN has developed a way to eliminate pharmaceutical production waste ni for some reason, if you adhere to them, you can prevent the risk of infection of many people and animals, protect the environment from pollution.



PRACTICAL TRAINING

1-Practical Training. The main goals of the development of the pharmaceutical industry. The main concepts and terms of the science” organization of pharmaceutical production”. International requirements in pharmaceutical production. GMP requirements.

The module program covers the prospects for the far future of the science and practice of preparation technology in the production of medicines in the conditions of pharmaceutical production enterprise. The module program covers the prospects for the distant future of pharmaceutical production of the science and practice of Industrial Pharmacy.

The purpose of the training module is: to organize the production of pharmaceuticals in students, to formulate and develop their concepts on the technology of preparation in the conditions of the enterprise, to teach them to clearly state their reasoning and conclusions in a reasonable way, and to form skills and competencies on the acquired knowledge. The prospects for pharmaceutical production and its development, good production practices, materials used in the manufacture of medicines and their requirements, documentation of the production of medicines, training of documents and the formation of skills for their implementation in practice.

requirements for employees in the production of medicines in students, Technical Safety, Fire Safety and production sanitation, ensuring the quality of medicines, ensuring stagnation and determining the expiration date, and drawing up a general Pharmacopoeia article for medicines, regulations consists in teaching the requirements of the present time and generating the skill to implement them in practice.

Tasks of the educational module: Organization of pharmaceutical production faniningnazarian fundamentals, basic concepts, its goals and objectives, methodological approach to preparing and assessing the quality of forms of teaching students step by step from theoretical to the level of implementation of practical skills, introducing modern pedagogical technologies into the course process, increasing the level of thinking and maintaining the student's knowledge, stages of, it consists in the formation of the main directions of scientific investigations in the field of technology of drugs in the conditions of the enterprise. pharmaceutical production requirements for employees in the production of medicines in the conditions of the enterprise, technical safety, fire safety and production sanitation, ensuring the quality of medicines, ensuring stagnation and determining the shelf life, as well as establishing a general Pharmacopoeia article for the types of drugs to be prepared, drawing up regulations, the procedure for controlling the quality of drug types based on, the organization of the workplace in laboratory and enterprise conditions consists in formulating the use of regulatory documents, reference and scientific literature in solving problems in the specialty, making the necessary calculations based on the physicochemical and technological properties of substances. Modul bo'yicha talabalarning bilim, ko'nikma va malakalariga qo'yiladigan talablar:

Student:

- preparation of medicines in the conditions of the enterprise, regulatory documents necessary for this technology, requirements for it,
- materials used in pharmaceutical production and requirements for them,

- equipment and apparatus,
- documentation of the production of medicines in pharmaceutical production,
- study of the requirements for documents in pharmaceutical production in the conditions of the enterprise
- drawing up a general Pharmacopoeia article, regulations for types of drugs,
- to have an idea about the choice of the procedure for controlling the quality of drug types in pharmaceutical production on the basis of MH;
- requirements for employees in pharmaceutical production;
- Technical Safety, Fire Safety and production sanitation;
- to the general and specific preparation technologies for them on the preparation of the type of Medicine;
- the pharmacist can know how to work with the equipment used in production and be able to use them;
- correct Organization of technology and processes in the preparation of medicines in pharmaceutical production;
- correct selection of starting materials used;
- use of equipment and apparatus necessary for the preparation of medicines;
- adjust the appropriate parameters to the operating mode;
- must have skills to improve productivity.

The word "pharmacy" comes from St. Egypt. the words "pharmacies" mean "recovery and safety" or gr. "Pharmacon" is a drug.

Pharmacy is a complex of disciplines that studies issues related to pharmacology (medical technology, pharmaceutical chemistry, pharmacognosy, pharmacy organization and economics, management and marketing):

1. Synthesis and analysis of drugs.
2. Development of new theories and methods of preparation of dosage forms.
3. Study of natural resources of plant, animal, mineral origin and processing them into medicines.
4. Development of new medicines, small-scale mechanization tools and modernization tools for industrial and pharmaceutical production.
5. Quality control, storage and distribution of medicines.
6. Study of pharmaceutical business planning, organization and management, management, marketing issues.
7. Improving the educational and methodological work of pharmaceutical educational institutions and training of highly qualified personnel.

[on measures for the more intensive development of the pharmaceutical network of the republic in 2019 — 2021](#)

in the following years, comprehensive measures were carried out to improve the system of providing the population with medicines, medical supplies and medical equipment (next — pharmaceutical products) in the republic, creating favorable conditions for the development of the local pharmaceutical network.

at the same time, insufficient production capacity, as well as a narrow range of domestic pharmaceuticals, are not meeting the needs of the domestic market and are causing excessive dependence on imports.

the slow organization of work on the implementation of international standards at domestic enterprises is limiting the possibility of producing competitive pharmaceutical products in foreign markets and the export potential of the network.

in order to rapidly develop the pharmaceutical network, attract foreign investments and leading foreign companies to the implementation of investment projects, stimulate the creation of innovative pharmaceutical products, expand the production volumes and export potential of domestic manufacturers

1. ministry of health, ministry of economy and industry of the republic of uzbekistan:

transfer of the state unitary enterprise “uzmedimpeks” of the pharmaceutical network development agency under the ministry of health of the republic of uzbekistan to the structure of the ministry of health of the republic of uzbekistan;

agree to the proposals of the ministry of health to provide the pharmaceutical network development agency under the ministry of health (next — the agency) with the functions of the ministry of health to carry out control over the production, preparation and wholesale trade of medicines and medical products, as well as licensing of pharmaceutical activities.

2. let the following be established as the main tasks of the agency:

development and implementation of a strategy for the sustainable development of the pharmaceutical network, including by introducing modern mechanisms for its state support;

organization of the study of the conjuncture of the pharmaceutical market, systematic analysis of the state of the supply of pharmaceutical products of the population and health institutions and the development of proposals on its basis for further replenishment of the domestic market and localization of production;

assistance to network enterprises in establishing cooperation with leading foreign pharmaceutical enterprises, in mastering the production of competitive, high-quality new types of pharmaceutical products in domestic and foreign markets;

state management of the pharmaceutical network, including pharmaceutical products through state registration, standardization, certification, technical regulation, as well as licensing of pharmaceutical activities (excluding retail sale of medicines and medical products;

coordination of work on the implementation of advanced foreign practices and international standards in the pharmaceutical network;

participation in the implementation of the information system of control and accounting for the movement of pharmaceutical products, which provides for the collection of complete information about pharmaceutical products imported and manufactured on the territory of the republic.

3. let such an order be established, according to which:

the list of medicines and medical products that do not introduce a value-added tax exemption provided for by paragraph 6 of article 211 of the tax code of the republic of uzbekistan when importing is formed by the agency and approved in the manner prescribed by the cabinet of ministers of the republic of uzbekistan. in this case, the names of medicines and medical products included in this list will be introduced both into the finished product and into medicines and medical products imported in the form of “in bulk” products;

as of january 1, 2022:

all laboratories carrying out clinical and pre-clinical research of pharmaceutical products must be subject to mandatory certification in accordance with the national requirements of the necessary laboratory practice (glp);

all clinical bases of the ministry of health of the republic of uzbekistan conducting clinical research shall be subject to mandatory certification in accordance with the national requirements of the necessary clinical practice (gcp);

all domestic enterprises producing pharmaceutical products must be subject to mandatory certification in accordance with the national requirements of the necessary production practice (gmp) ;

all domestic enterprises engaged in the wholesale sale of pharmaceutical products need mandatory certification in accordance with the national requirements of the necessary distribution practice (gdp).

5. in 2019 — 2021, the “road map” for the rapid development of the pharmaceutical network of the republic (next-“road map”) should be approved in accordance with appendix 1.

the heads of the responsible ministries and departments are given personal responsibility for the timely, full and high-quality implementation of the measures provided for by the road map.

6. the following are the sources of financing for the construction and reconstruction of the facilities envisaged in the road map, strengthening the material and technical base of research and testing laboratories:

in 2019 — the balance of available foreign exchange funds as of january 1, 2019 of the fund for the support of innovative development and innovation ideas, which is allocated in agreement with the ministry of finance of the republic of uzbekistan on the basis of the orders submitted to the agency by the executive directorate of the fund for the support of innovative development and innovation ideas;

in 2020-2023-funds allocated from the state budget of the republic of uzbekistan in the implementation of the investment program for the corresponding year, and in the procurement of laboratory and production equipment-unassigned funds from the foundation for the support of innovative development and innovation ideas, in case of lack of them, funds from the state budget of the republic of uzbekistan.

7. in the absence of a legal entity under the agency, the fund for the support and development of the pharmaceutical network (next-the fund) is established.

8. note that the funds are used for the following purposes:

to provide grants to research institutes and domestic manufacturers under the agency to organize scientific developments on the creation of new types of pharmaceutical products; equipment of research institutes and state laboratories carrying out quality control of pharmaceutical products under the agency with the necessary equipment and equipment;

9. the foundation for reconstruction and development of the republic of uzbekistan announced in a month that the president of the republic of uzbekistan on january 6, 2017, " food, to allocate us \$ 25 million to the state fund to support the development of entrepreneurial activity under the cabinet of ministers of the republic of uzbekistan and the fund for the support and development of the pharmaceutical network at the expense of the line of credit opened in accordance with pq-2718”on measures to expand the sources of financing investment projects in the leather and

10. technological and laboratory equipment not produced in the republic of uzbekistan, components and spare parts, “clean rooms” for pharmaceutical production buildings, sandwich-panels and ventilation systems, which are imported by pharmaceutical manufacturers, specialized research institutes and higher education institutions for their own needs, and enterprises engaged in wholesale and retail sales of pharmaceutical products for the purpose of drug preparation within apteka, as well as, let the raw materials and materials, medical products and packaging materials used to feed laboratory animals, produce clinical-pre-research and medicines (including preparation within apteka) be exempt from customs duties (except customs clearance fees) by january 1, 2022, according to the lists approved by the cabinet of ministers of the republic of uzbekistan.

11. in 2019 — 2021, the list of groups of drugs recommended to localize production on the territory of the republic (next-the list) should be approved according to appendix 2.

12. deputy prime ministers of the republic of uzbekistan e.m. ganiyev and a.a. abduhakimov together with interested ministries and departments in two months:

leading pharmaceutical companies with a stable reputation for organizing the production of pharmaceuticals in high demand in the republic;

in order to provide pharmaceutical manufacturers with long-term financial resources, make proposals to attract long-term preferential credit lines from international financial institutions and foreign government financial organizations.

13. cabinet of ministers of the republic of uzbekistan until june 1, 2019:19.

Control over the implementation of this decree is carried out by Deputy Prime Ministers of the Republic of Uzbekistan A.A. Abduhakimov, E.M. Ganiyev and deputy adviser to the president of the Republic of Uzbekistan G.K. It is up to Saidova.

Groups of drugs recommended to localize production on the territory of the Republic in 2019 — 2021

List

T/r	Project naming
1.	Antibiotics
2.	Medicines to treat pathologies of the endocrine system
3.	Anti-inflammatory nosteroid drugs
4.	Antiviral drugs
5.	Medicines for the treatment of pathologies of the gastrointestinal tract
6.	Immunobiological drugs
7.	Medicines to treat pathologies of the respiratory organs
8.	Medicines for the treatment of cardiovascular diseases
9.	Medicines for the treatment of oncology diseases
10.	Diaskin tests for early detection of infection with tuberculosis (tuberculosis) in children

Pharmaceutical network development agency under the Ministry of health of the Republic of Uzbekistan

In order to improve the conditions for the development of pharmaceutical activities, to increase the level of provision of cheap, quality medicines, medical products and medical equipment of the population and health institutions again, to introduce a unified system of coordination of their production, import and sale, in accordance with the decree of the president of the Republic of Uzbekistan dated November 7, 2017, The pharmaceutical Network Development Agency was established under the Ministry of health of the Republic of Uzbekistan. Farmonga asosan, quyidagi davlat muassasalari Farmatsevtika tarmogʻini rivojlantirish

Included in the agency:

— State Center for examination and standardization of medicines, medical supplies and medical techniques of the Ministry of health of the Republic of Uzbekistan;

— Uzbek Chemical-Pharmaceutical Research Institute;

Tashkent Research Institute of vaccines and serums;

— Research Institute “Oriental Medicine” ;

— Innovative R & D pharmaceutical cluster “Tashkent Pharma Park”.

International GMP requirements for pharmaceutical production.

At the present stage of the development of the production of medicines, it is relevant to provide the population with quality products, to control enterprises by organizational, technological, personnel and other indicators. With this in mind, in the Republic of Uzbekistan, as in many other countries, formal requirements have been made to organize control over the production of drugs aimed at preventing errors and shortcomings that can lead to the production of poor-quality products. Such requirements are referred to as "good manufacturing practice (GMP).

GMP:

- this is a single system of requirements for the organization and quality control of the production process from raw materials to finished products
- it is not a production or technology, but a proof system that allows itself and the consumer to prove the quality that produces a quality, quality, efficient product in the factory.
- GMP rules general guide to the organization, it is the proper management and control of the production process.

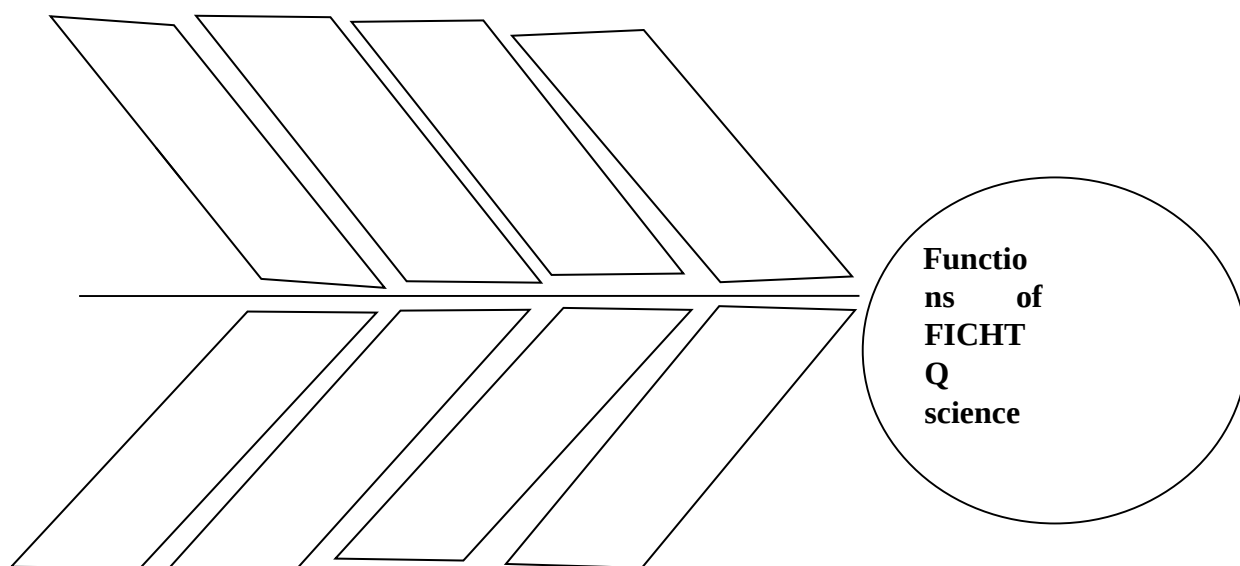
General requirements of GMP:

1. Quality assurance
2. Personnel
3. Buildings and equipment
4. Documents
5. Production
6. Quality control
7. Conditions for the production and quality control of products.
8. Advertising and product reference
9. Check
10. Self-examination

GMP requirements were first adopted in the United States in 1963, and then in Canada in 1966, Italy in 1970, the United Kingdom, Australia in 1971 and another country .

FISH SKELETON GAME

Express the tasks of the fan in the form of a fish skeleton



"BOOMERANG" * TRAINING

Group I Mission

The essence, purpose and objectives of the science of organizing pharmaceutical production.

Group II mission

Making a list of terms used in the study of the science of Organization of pharmaceutical production

Group III mission

Description of the types and content of the necessary regulatory documents in the study of the science of Organization of pharmaceutical production

*** Students are divided into several subgroups and task written material is distributed, with each group outlining their thoughts and a question answer is left between the groups.**

Divide the following given terms into groups:

Packaging materials
Management strategy
Dosage form
Controlled state
Additional substances
Prevention movement
Pharmaceutical Quality System
GMP
Quality certificate
Fillers
Quality policy
Pharmacopoeia of the enterprise
Common Pharmacopoeia
Feedback
State Pharmacopoeia

CONTROL QUESTIONS

1. List the tasks of pharmaceutical manufacturing science.
2. What is the purpose of pharmaceutical manufacturing science?
3. What are the concepts that a student must learn during the study of science?
4. List the cracked documents and their types.
5. List the main terms related to the quality system of the production enterprise.
6. Interpret the auxiliary tools in the production enterprise.
7. What information do you have about the "road map"?
8. 2019-developed on the territory of the Republic in 2021 drugs recommended to localize excretion groups, list the list.
9. How the pharmaceutical network of public institutions was included in the development agency?
10. Are the main tasks of the agency?
- What percentage of the volume of medicines consumed by the pharmaceutical industry on 11th day?
12. What percentage of the volume of medicines consumed by the pharmaceutical industry on 11th day?
13. What does the term technology mean?
14. In the 14th century the science of technology began to take shape?
15. Cite the main tasks of pharmaceutical technology?
- Give an example of 16. Give an example of those that do not belong to the products?
17. Give an example of those that do not belong to the products?
18. Express the general requirements of GMP.
19. The "terminology" part of GMP is the basic concepts
20. Requirements for employees of pharmaceutical enterprises
21. Provide information about the "equipment" section
22. What section is the "registration and reporting" section?

2-practical training. Design of premises for pharmaceutical production. Requirements for buildings and buildings. Sex system in pharmaceutical production. Chemical, technological and hardware scheme of production.

The project (Eng. Project, thrown forward, separator). The project is a pre-structured work plan to do something. Design is said to be the work process of a person or organization in creating a project. Design is the collection of documents intended to ensure the process of its operation and liquidate the creation of a particular object. Engineering design refers to the process of creating a project of this technological object.

The project will show the estimates and the order of the construction stages of the object if necessary for project drawings and project documents. In design, the design process is divided into stages:

a) working project

(B) worker document worker

Project-on new construction and repair. This will bring the project object and transport construction solution, Estimate document, Working Project passport

- . - general explanatory note;
- Master plan and transport
- technological solutions;
- Scientific organization of cocktails (workers and servants);
- construction solutions; - organization of construction;
- Environmental Protection;
- residential-civil engineering;
- estimate documents ;
- passport of the work project

Production buildings

Production rooms must have:

lighting, ventilation, electrical systems, water network and sewerage, production waste removal systems that ensure the cleanliness of rooms, equipment and finished products;

air conditioning devices that provide the necessary temperature and relative humidity for the maintenance of the quality of medicines during the production and storage period, as well as the fulfillment of the hygienic requirement imposed on employees and the accurate operation of the equipment used;

clean and household-sanitary rooms located close to the production rooms.

Rooms (production, storage and household and sanitary rooms) should be integrated into functional-technology blocks, provided with a separate working engineering system if necessary.

The cleanliness class of the room is precisely regulated requirements for the level of various impurities and particles in the air. Purity classes are distinguished by the number of particles per unit volume of a given volume. This parameter, which is one of the most important in the classification of clean rooms, is regulated by standards.

GOST R ISO 14644-1-2002 " cleaning rooms and associated managed environment, Part 1. Classification of air purity"

GOST R 52249-2009"rules for the production and quality control of medicines"

To ensure the best quality of products, there is an international GMP standard - the "rules for the production of medical products". This guarantees the absence of impurities in the composition of the drug, the necessary labels and the quality of the appropriate packaging.

Classes describe the level of air purity in a clean room. The classification of clean rooms has a number of distinctive features in relation to the networks in which they are used.

All production rooms are characterized by the degree of air pollution by microorganisms and mechanical particles. The degree of cleanliness of rooms or zones is determined by the nature of technological processes.

In the production of sterile drugs, "clean" rooms are normalized depending on the amount of mechanical particles in the air. It is carried out in accordance with the requirements presented in the documentation for the detection of mechanical contamination of room air and the nazortation of microbial reproduction.

Some areas of application:

Class 1 (ISO3

Production of integrated circuits.

Class 10 (ISO4

Production of integrated circuits with a distance between conductors of less than 2 microns.

Class 100 (ISO5)

Aseptic production of injection agents that require the absence of microorganisms and particles. Organ implantation or organ transplant surgery. Separation of immunocompromised patients, including after bone marrow transplantation.

Class 1000 (ISO6)

Production of high-end optical elements. Assembly and testing of precision gyroscopes. Assembly of miniature bearings.

Class 10000 (ISO7)

Assembly of precision engineering, hydraulics and pneumatic, precision hydraulic and pneumatic equipment, servo valves, high precision clock mechanism, high quality transmissions.

Class 100,000 (ISO8)

Plastic production, automotive, electronic component assembly, hydraulic and pneumatic Assembly.

In the production of sterile GMP medicinal products:

Class A

Local area (filling, closing) for operations that pose a great risk to product quality.

Class B

Area that immediately surrounds Area A and is intended for the preparation of solutions.



Classes C and D

The following additional requirements are imposed on sterile medicine preparation rooms:

it is forbidden to use wooden surfaces, unpainted surfaces;

the land on which the walls, floors and ceilings are adjacent should be round in shape;

suspended ceilings must be made non-permeable (hermetized) in order to prevent dust from falling from the top;

flexible and hermetic shrinkage materials are used, which do not emit dust to prevent air from entering and close densely from the junctions of the structural parts;

cleaningnng communications (except natural gas) and airways should not be open in rooms belonging to V and S levels (usually, such a state of affairs should not be in rooms belonging to

the Ddaraja of the state of affairs either);



The SINKWEIN method is the purpose of the method: the word "Sinkwein" is derived from the French word, giving a translation of "a poem of five verses". In practice, "Sinkwein": a tool for synthesizing complex ahborot and evaluating the reserve of concepts; very useful as a tool of creative expressiveness. "Sinkwein" is a quick tool in reflexing, synthesizing and embalming basic occupational concepts and ahborot. Sinkwein is a skill that is important to express ideas, feelings and emotions in just a few words. The subject of the sinkwein structuring process, along with helping to comprehend the purest, develops a high level of educational thinking ability.

CONTROL QUESTIONS

1. What documents are included in the design documents?
2. What is a working document?
3. The project is...
4. List the stages of the design process.
5. What are the requirements for production rooms?
6. Count the functional-technology blocks of rooms (production, storage and household-sanitary rooms).
7. What should be the cleanliness class of the room?
8. How will the technical control department and workshops be equipped?
9. What are the requirements for personnel training rooms?
- How to determine the main dimensions of the rooms inside 10Bino?
11. What processes of human activity determine the requirements for residential buildings?
- What components of 12bins are considered closed?

The main function of pharmaceutical technology is to FIND COMPATIBILITY

Ready-made medicines (TDV)

(drug preparations, medikaments) are mixtures obtained by medicinal substances, natural synthetic or biotechnological methods, used for prophylaxis, diagnosis, treatment or

	alteration of the state or physiological function of the body.
Medicines	substation and auxiliary substances, technologically processed, are ready-made tools, including raw materials from oVjnlik, passed the technological process through all stages, quality blinds^tkichs are evaluated, the patient is in an acceptable state.
Parapharniatric products	TDV will be packaged in appropriate containers and intended for human reception. these are drug products that are traded after the expiration of the main and patent Dukes- these are drug products that are traded after the expiration of the main and patent Dukes
Cosmetic drugs	(substance, acting substances, biological substances) natural (from people, animals, microorganisms, plants, minerals) synthetic substances or biotechnological means enter, have a pharmacological or, immunobiological effect, are used in the production of fDV
Excipients	this is what is put into the technological process it will be necessary to develop a product that determines the demand, lists the sequence of the technological process, and meets the school
Medicinal raahsulotes late in production	ma'lum bir shaklga keltirildi ;bu abiiium yoki sintetik moddalar aralashmasi, tarkibida moddalarni yoki ularning aralashmasini saqlaydi, teri kasalliklarini davolashda, profilaktika maqsadida, shuningdek sochlar, kirpiklar, og'iz shilliq qavati, burun bcr shilimshiqlarining tashqi tomoniga surtish uchun isbotlangan va CMSI organlari.
Technological regulatory documents	these are penetrated by natural synthetic substances and do not have a healing effect, they are used in the production of TDV, to ensure storage and reception in a favorable state. Recycled drugs (generic drugs) - they come on sale after the expiration of their shelf life. It is possible to extend their stagnation by changing their composition and technology.
Active ingredients	Biological active ingredients, cosmetic, disinfectant and insecticidal preparations, the drug does not enter the product. They include materials used in laboratory diagnosis, medical products, mineral waters, parchees

and baby baits, optical glazing, upa latitude products, and the like. They are used in measures to treat and prevent the disease, in adjuvant therapy, as a food rich in mjddas, to increase the body's flziological activity.

3-practical training.

Documents. Internal and external documents. State standards and enterprise standards.

Regulations and their types. Drawing up regulations.

There are the following types of regulatory documents that determine the demand for the quality of medicines:

State Pharmacopoeia-DF (GF).

General Pharmacopoeia article-UFM (OFS).

Provisional Pharmacopoeia article-VFM (VFS).

Pharmacopoeia article-FM (FS).

Network standard-TS (OS

Regulation(limitation) is the Basic Laws of the production of drugs, which is divided into the following types:

Laboratory regulation (LR;

Experimental industrial regulation (TSR;

Industrial regulations (SR;

LR-includes the safety of methods, conditions and equipment for the preparation of the product, ensuring the stagnation of technological processes of production in laboratory conditions.

Experimental-industrial regulation-the drug is developed into a new product at the same time as the pharmacopoeia article, for the purpose of preparing experimental samples of a new type of product and entering the initial data when designing a new industrial production.

Industrial regulation is a document in the serial production of medicines containing the stages of the process, tasks to be performed, requirements for equipment, methods of quality control, in which each technological process is described in detail.

Standard, this is a normative document approved by the recognized office, developed on the basis of the consent of the majority of interested parties and established for the purpose of general and multiple use of rules, general principles, descriptions, requirements and methods related to various types of activities aimed at the dissolution of regulation in a particular area to a moderate level.

State standards of the former USSR (GOST) - state aro standards of the states of the Commonwealth of independent states - are allowed to use without modification on the basis of the decree of the National Standards authorities adopted by Russia and other states.

State standards of the Republic of Uzbekistan (Qz Dst) – defined for popular products, are obliged to be used on the territory of the Republic of Uzbekistan, that is, by state management agencies, economic entities.

Network standards are mandatory for all enterprises of this industry, as well as enterprises using industry products and organizations belonging to other industries.

Enterprise standard-prepared and accepted by the enterprise. It is a document that reflects the specifics of the process of production of goods, and in itself embodies the requirements for its quality.

Technical conditions-a document that defines the technical requirements approved by a specialist on specific products.

The State Register of medicines and medical products is an official document consisting of a list of medicines and medical products allowed for use in medical practice.

The following regulatory documents are needed for the production of drugs in an enterprise setting: Pharmacopoeia, organization Pharmacopoeia articles (TFM), Pharmacopoeia articles (FM), temporary Pharmacopoeia article (VFM), industrial regulation (SR) and other related documents.

These standards are drawn up with the participation of the authors of the proposed drug, employees of the laboratory and the technical department of the enterprise. The standards will list the appearance, validity, purity, method of quantitative estimation, packaging, preservation and pharmacological effects of the drug from the dietary and quantitative indicators. The composition and technology of the drug is not written. VFM is approved by the General Directorate for quality control of medicines and medical equipment.

The document must be carefully designed, drawn up, checked, approved and distributed. It must comply with the relevant rules for the production and sale of finished products.

All documents must be signed and approved by authorized persons with an indication of the date. The responsible person must put a Signature (Visa) on any amendment to the entry in the document.

The content of the document is unambiguous and should not have a second explanation. They should be hamabop and easily verifiable. The nusha of documents should be clear and clear.

It is necessary to constantly revise certain documents related to the production of each product, indicating the date of its revision. If the document is revised, it is necessary to eliminate its old errors.

Documents should not be handwritten. However, if it is necessary to include some kind of information in them, they can only be written manually, provided that an employee with legal rights is issued a visa. The Notes should be unambiguous, clear, clear and non-volatile.

The work result data can be recorded using an electronic system (computers), with a photo or another reliable technique. The manuals related to the writing system used are understandable, and their correct writing should be checked by the responsible persons. If documents are carried out using a computer, it is possible to enter the data into a computer or change them only by an employee with competent ownership.

The alteration or destruction of records must be made official by the document. Access to information on a computer is protected by a password (code) or another way, while entering basic information should be checked independently. Records stored in computer memory can additionally be recorded on electronic carriers (SD, USB storage) and paper.

All stages of the production process or the corresponding records for conducting inspection tests must be performed simultaneously with the production process or conducting inspection. All records must be kept for a certain period of time, but at least 1 year after the period of storage of the drug.

The main documents used in the production process include:

industrial regulations;

production record sheets;

analytical methods, quality details and other enterprise standards.

According to the approved industrial regulation, the production process of each drug should be covered in special instructions. These instructions should contain at least the following information:

appearance, name and dosage of the drug form;

the authenticity and quantity of raw materials at all stages of production;

description of operations for the production and storage of semi-finished products and ready-made medicines;

the theoretical amount of the output of the finished product at different stages of production and the amount of the product being extracted from the truth, given in spirit;

description of methods for wrapping and labeling the drug;

a description of the name of the control analyzes and control departments, which must be carried out at each stage of production.

Production recording records (Series reports, route charts, writing logs), should contain the following information on all stages of production and control of each series of drugs and indicate that the series is prepared in accordance with industrial regulations and written instructions:

name of pharmaceutical enterprise;

name and dosage of the drug;

date of preparation of the series;

full chemical formula of the active substance;

the serial number (or control number of the analysis) of each ingredient used in the preparation of the drug;

the amount of actual output compared to the theoretical output of the finished product at different stages of production;

production sequence compiled and signed records, precautions and special measures taken in preparation of the drug series;

records of all analyzes and results obtained during the production of the drug;

an example of the labels used in this series;

primary Reagent material serial number;

signature of a specialist who monitors the conduct of technological operations and the date of signing;

passport (quality certificate) testifying to the compliance of drugs in the series with current regulatory documents;

indication for the processing or elimination of the released series of the drug to the unfit.

Normative havolas

GOST 12.1.005-88 “general sanitary and hygienic requirements for air in the working zone”

Gost R 50766-95 "clean rooms. Classification. Attestation style. Basic requirements " M.Gosstandart Rossii. 1995.

TST 19-02:2003 "product of the medical and microbiology industry. Production technological regulations. Content, creation, Agreement and approval procedure"

AST 42-505-96. "Natural industrial products. Production technological regulations. Content, creation procedure, agreement, approval"

AST 42-506-96. "Procedure for the development, agreement and approval of a regulatory document for medicines and medicinal plant raw materials".

AST 42-507-96. "The procedure for organizing work on the creation and application of new drugs in the industry. Basic Rules"

Gost 2874-82 " Consumer water. Hygiene requirements and quality control".

AST 42-504-96. "Quality control of medicines in industrial enterprises and organizations. Basic Rules".

Technological regulation

The industrial regulation is a document in the serial production of medicines, which includes the stages of the process, the tasks to be performed, the requirements for equipment, quality control methods, etc., each technological process is described in detail.

In terms of application, technological regulations are divided into the following types:

- Laboratory regulation (LR;
- Experimental industrial regulation (TSR;
- Commissioning regulation (ITR;
- Industrial regulations (SR;
- Model industry regulation (NSR).



- ✓ **O'zbekiston Respublikasi dori vositalari, tibbiy texnika va tibbiy ashyolar Davlat reestrini har yili nashr etadi.**
- ✓ **O'zbekiston Respublikasi Davlat reestrining elektron versiyasini tayyorlaydi.**
- ✓ **Dori vositalarini Davlat reestri №23, 2019 yilda 1 noyabrgacha bo'lgan ma'lumotlar bazasini o'z ichiga oladi.**

In mastering this topic, students were used the method of pedagogical technology in the VVV - method.

Control questions.

1. Documentation of the production of medicines.
2. Decree and decisions of the president in order to implement the program of comprehensive development of the pharmaceutical industry in the Republic.
3. Regulatory documents that determine the demand for the quality of medicines.
4. All types of domestic enterprises producing pharmaceutical products.
5. All domestic enterprises engaged in the wholesale sale of pharmaceutical products.
6. How is the organizational structure of a pharmaceutical agency structured?
7. Functions of a pharmaceutical agency?
8. State-Stock Company "medicines" of the Republic of Uzbekistan, their structure and functions?
9. What is the enterprise standard?
10. What is the standard operating procedure (SOP) document?
11. Types of Pharmacopoeia article.
12. State Pharmacopoeia kandai is a document with a status.
13. Differences of the state standard from the network standard.
14. Regulation and its types .
15. How to document the state register.
16. Requirements for quality and its essence.
17. Types of foreign state standards.
18. Count the quality control methods of tire product.

In mastering this topic, students were used the method of pedagogical technology ""Carpenter" training.

<i>Nº</i>	What regulatory documents will be needed to produce the finished drug	Regulatory documents
1	SM	
2	TSM	
3	SF	
4	SST	
5	TU	
6	TST	
7	Regulation	
8	Decision of the Social Institute	
9	KST	
10	License	
11	Pension	

4-practical training.

Compilation of a pharmacopoeia article for substance and drug forms. 1. Preparatning name in Latin, state and Russian languages.

International nonpatent name.

Chemical name on IYUPAK students.

Structure and empirical formulas, as well as molecular mass.

The amount of the acting substance. (in percentage or unit of effect).

Description.

Solubility.

Integrity.

Melting (decay), hardening or boiling temperature.

Density.

Light breaking indicator.

Comparative absorption indicator.

Comparative angle of inclination.

Clarity of the solution.

Solution color.

pH environment, acidic or alkaline.

Mechanical attachments.

Foreign substances (similar compounds).

Purity (chlorides, sulfates, etc.

Sulfate ash and heavy metals.

Mass or water lost when dried. K. Determined by the Fisher method.

Residual organic solvents (if used in the final technological process).

Pyrogenicity or presence of bacterial endotoxins (LAL-test).

Toxicity.

Acting compounds similar to histamine.

Microbiological purity (sterility).

Quantitative analysis.

Packaging.

Label.

Transportation (transportation).

Preservation.

Shelf life.

Main pharmacological effects.

* Due to the development of new drug forms, the introduction of modern methods of quality control, the use of new materials for packaging, new sections can be included in this list.

Additional: 1,3-8, 18, 20, 21, 26-33 the sections are divided into sections. In the rest of thebusdigiritylidorimoddasi (substance) to ningtabiati, gettechnologiesabusubstantiadanolinadigandorishaclarition.

Structure rules of drug quality standards

The title of the standard gives the naming of the drug. The text should be short, without the return of the expression of thoughts, clearly written, and the reduction of words is not allowed. The terms, concepts and magnitudes used should correspond to those adopted by the state pharmacopoeia and other standards.

An indication (indication) is brought to the relevant regulatory document on the substance (substance) of the drug, which is part of the drug.

The name of the drug substance (substance) is written in Latin, state language and Russian, and the chemical name based on IUPAC standards is given. In the empirical formula of the drug substance, first carbon, then hydrogen are written in order.

For example: $C_{18}H_{21}NO_6$. When the relative molecular mass of a drug substance is less than 400, two figures are written in accuracy after the whole, and one figure is written in accuracy after the whole "description" section provides information on the appearance (physical condition, color, smell) of the drug, whether it can change under the influence of air and light during the storage process, hygroscopicity. It is not recommended to determine the smell for toxic and strongly acting drugs. Currently, a reversible spectrophotometric method is also used to determine the degree of whiteness and glare of a drug substance (discoloration).

In the "determination of authenticity" section, 2-3 chemical quality reactions specific to the drug substance are cited, as well as ultraviolet and infrared absorption spectra and other data. In the "solubility" section, the relative solubility of the drug substance in water, 95% alcohol, chloroform and ether can be indicated, and other solvents can be indicated in the required manner. When assessing solubility, the terms solubility, which are presented in the state Pharmacopoeia, are used.

The elimination, dilution and hardening of the drug substance, as well as the density, the angle of comparative deflection, the index of light refraction, the index of specific light absorption and other physical constants are given in the case of certain sections, and the lower and higher values of medicinal indicators are given.

The clarity and discoloration of the solution of the drug substance are determined for a certain concentration of the solution, and for colored and turbid solutions, the degree of turbidity or number of degrees of colouring or the corresponding absorption spectra of these solutions are given.

When the acidity or alkalinity of a solution of a drug substance is determined using indicators, the pH Potentiometric method of the solution is measured using solutions of acid or alkalis at a concentration of 0.01 mol/L to 0.1 mol/L.

- "Determination of foreign private mixtures" section should indicate the normative Etalons or other modern methods, such as chromatographic, in which the compounds formed during the process of preservation of a technological mixture or substance can be allowed.

If the chromatographic method is used for this purpose, the sorbent type, the porous phase composition, the amount of chromatographic substance and the standard sample (witness), the time of chromatography, the type of reagent and all the conditions that determine the process are cited. The "organic solvent residue" section is injected into the MH if toxic solvents are used in the drug preparation technology or if an organic solvent is used at the final stage of obtaining the drug substance.

In the sections "chlorides", "sulfates" and others, the permissible regulatory limits of these mixtures are indicated.

In the sections "reduced mass when dried" and "water", the amount of the drug substance, the norm of drying conditions or the amount of moisture and K. In the case of Fisher, the titration method is shown.

In the section "sulfate ash and heavy metals", quantitative norms of the drug substance, sulfate ash and heavy metals are presented.

In the "arsenic" section, the allowable quantitative ranges of arsenic in the form of a foreign mixture or the requirements for its absence in the drug substance are indicated.

The sections "toxicity", "pyrogenicity", "substances with histamine action" indicate the type of animal being experimented on, the test dose, the method of sending the substance to the animal, and the duration of the experiment.

The "sterility" section is introduced when the drug form cannot be sterilized.

In the section "microbiological purity", methods for detecting microorganisms and their permissible quantitative limits are indicated.

In the "quantification" section, the method of quantitative analysis of the main substance in the drug is presented and the unit of action of its percentage amount or activity in milligrams is indicated.

In the "packaging" section, the initial packaging (jar, ampoule, vial, package, etc.) with the indication of a regulatory document is indicated.), information about the amount of the product in the primary packaging (e.g.: the amount of the tablet in the container), the secondary packaging (with the indication of the main document, the amount of the primary packaging and the hermetic routes, etc.) are cited when the transport packaging (tara) is indicated, a reference is given to the corresponding regulatory document. The packaging must ensure the preservation of the drug during the specified shelf life.

The "labeling" section is formalized under the requirements of NN 19-11 for graphic equipment of medicines, and RD 42-28-36 for microbiological and immunobiological preparations. In the "transportation" section, a reference is given to the current standard and, if necessary, the conditions for loading and unloading the product for transportation and the requirements for the treatment after transportation are indicated. In the "storage" section, the storage conditions that ensure the quality and commodity condition of the product are indicated, and when necessary, the requirements for the care of the product from the influence of external factors (humidity, sunlight, temperature) are indicated. For drugs that are toxic, strongly acting, psychotropic, narcotic agents and belong to the group of precursors, specific aspects of their storage are cited (according to the current list, List A or B).

In the "shelf life" section, the period of time during which the drug can be used is indicated.

The section "basic pharmacological effects" outlines the pharmacological effects of a drug substance.

Drawing up a pharmacopoeia article for drug forms.

Compilation of a pharmacopoeia article for tablets, capsules and dragees

The title gives the name of the drug in Latin, state and Russian, in which the name of the substance of the drug acting is written (in general agreement), then the name of the type of drug (in general agreement), dosage (concentration), volume.

For example: Analgin tablets 0.5 g or analgin solution for injection 25% 1 ml.

Some sections are combined, and when necessary, other sections are introduced (Acid Number, Number of soaps, iodine number, ether number, toxicity, pyrogenicity, bacterial endotoxins, histamine-like irritants, sterility, etc.).

In the introduction of the standard, the chemical name of the acting substance (for one-component preparations), the Latin, Uzbek, Russian name of the medicinal plant raw materials, the name and family of the plant (for nastoyka and extracts) are indicated.

When the composition of the drug is given, the amount of the acting and additional substances is written in the list style, giving an indication of the corresponding MH.

In the "description" section, organoleptic indicators of the appearance of the finished drug are given, and the color of the drug is brought at the end of the sentence.

For example: blue-green color.

In the "fragility" section, the time of full decomposition of a tablet or capsule in a liquid medium is indicated.

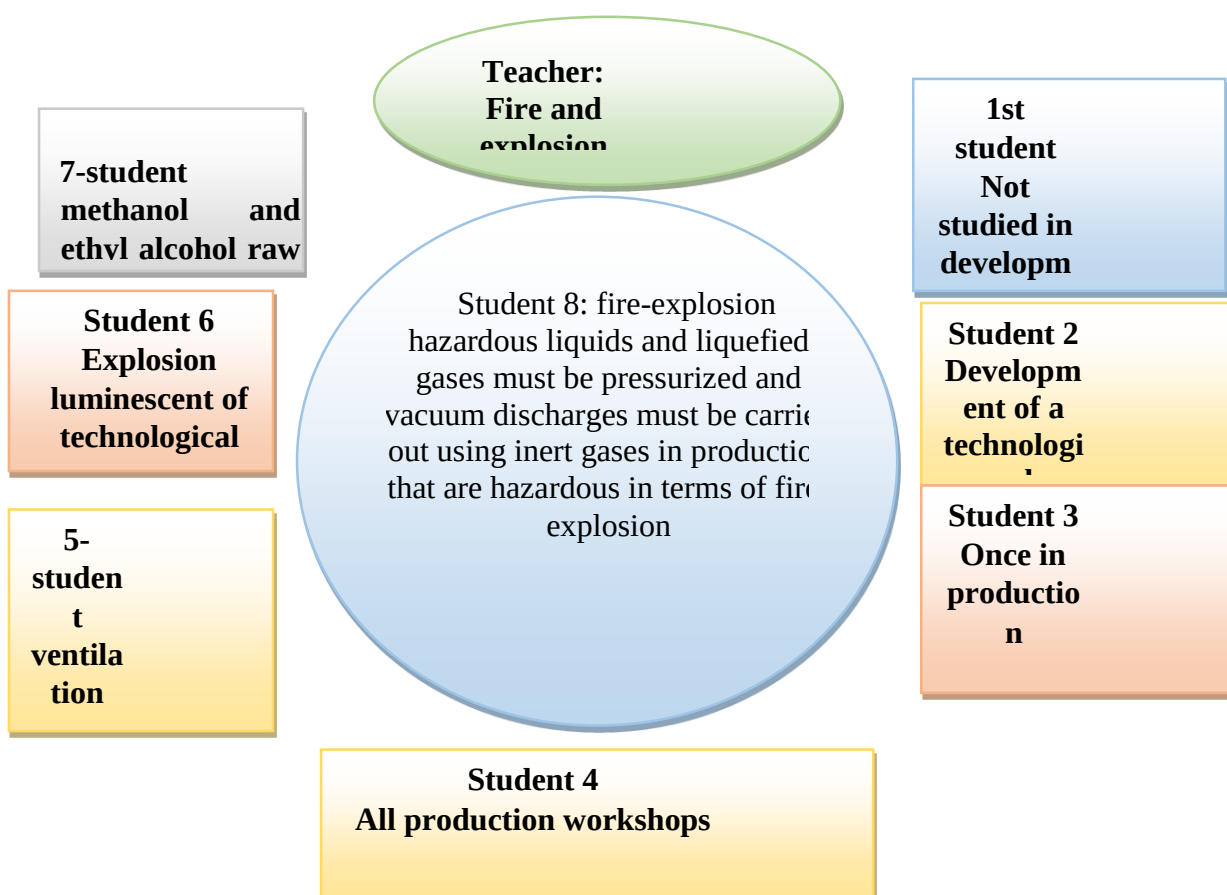
When the validity of drugs with complex composition is determined, after the statement of the method of analysis

the parenthesis brings the identifying ingredient.

In the sections" dry residue"," amount of alcohol"," boiling temperature"," density"," light refractive index"," turning angle"," viscosity", the lower and higher values of these regulatory indicators are indicated in the corresponding units of measurement.

In the" solubility " section, the percentage of the acting substance that must pass into the solution at a certain time interval under the given conditions is indicated.

The method of pedagogical technology” snowdrop " is used to illuminate the practical training.



KWK METHOD

KNAW	WANT TO KNAW	KNEW

Assignment.

Students in a split position

Group 1: provide information about Zone C,D based on GMP requirements.

Group 2: provide information about Zone A, B based on GMP requirements

In this case, 1 group played 2 groups in a situation where they listened to each other baholashadi.

5-practical training.

Qualification of the ventilation system. Pharmaceutical production heating, air conditioning and lighting system Ventilyatsiya tizimini loyihalash.

Local ventilation

Use specially designed local ventilation systems that absorb dust, steam and gases and return their effect to workers.

An extraction system can be effective if:

When it is useful for workers;

If the work processes are completed to the maximum possible;

If you have the right level of facilities for storing and using hazardous substances;;

If you have the opportunity to separate toxic gases into the filter and in a safe place;

If you are as grueling and resilient as you need to withstand working conditions and dangers;

If you have practical tests to determine the ability of recruiters to work.

The most common errors when applying an extraction system are:

The effectiveness of working with small hoods is not high;

The indicator of the use of headgear in the work process is low;

Headdresses do not always completely surround;

Insufficient air currents;

Failure to regularly inspect certain equipment for continued operation;

As a result of workers ' lack of information about substances, these substances become unusable .

General ventilation

A stream of fresh air should circulate all over the work area.

General ventilation is understood to be the presence of special air conditioners that supply fresh air flow throughout the entire area of the workplace.

The Universal ventilation system is an integral part of some manufacturing enterprises, for example, manufacturing enterprises where welding processes go

Personal protective clothing and equipment

In demanding workplaces, the effects of harmful substances are not observed, since, along with other measures, workers are provided with personal protective clothing and equipment. Do not

start the plan directly from personal protective items when planning the work process, as this may not always be reliable. Chapter 24 provides the necessary information about this.

Protective measures

It is essential that you review all your protective measures, make sure they are effective and check regularly. These measures must be drawn up at a sufficient level and include:

It is necessary to have all the equipment necessary for the operation of the ventilation system and appoint the supervising, inspecting personnel. Each part of the ventilation system must be checked every fourteen months;

Make sure the ventilation system is controlled, which should be revised if it has stopped working;

Make sure that the ventilation system is placed in suitable places that do not interfere with work activities.

In some cases, you will need to organize points of monitoring the health of workers.

In the case of problem situations, serious risks, management practices and other similar issues, tips may remain necessary for you, in case of such problems, you can contact the British hygienic Labor society through the following site:

The simplest ways to check dust and sponges

It is a complex matter to see dust and sponges that are too small under normal lighting conditions. Only with the help of a "dust lamp" will you be able to observe them. Any bright flashlight will create this opportunity. You can see small dust particles flying if you pay close attention to the rays radiating light.

Prevent dust from accumulating on the surfaces.

Take control of the cleaning measuring instruments and indicators in the extraction system.

Control damage and overlooked phenomena in the process.

Keep in touch with the Operator and explain that he must report any defects.

Asbestos substances are used on a large scale, for example, in factories when wrapping around internal qims of pipes, fire protection equipment, insulated noise and special fireproof rooms, in addition to asbestos cements.

Nevertheless, all types of asbestos substances can be life-threatening. Fibers separated from asbestos substances into the air can pose risks in breathing. The asbestos substance dropped through the breath can cause lung cancer.

If you are a poor person in terms of technical services and repair work at your workplace, you should identify the places where asbestos substances were used or used at your workplace. If you can't find the places where the asbestos substance was used, you should roughly mark the places where the asbestos substances were used. You will need to anticipate and prevent any risks that an asbestos substance can cause. You can leave hermetically asbestos-free, Well-condition areas intact, but it will be advisable to check regularly

It is imperative that you regularly check the condition of the asbestos-containing materials. If their condition has deteriorated, it begins to distinguish dust particles from itself, in this case they are required to be replaced.

If you work with asbestos substances, then:

You should assess the range of effects of asbestos substance on workers and the risks it poses;

When working with asbestos substances, carry out practical work processes on the basis of approved codes for working with hazardous substances.

Materials that contain asbestos substances must be marked with special labels*.

Heating devices serve to maintain the temperature of the working zone in the prescribed amount, in order to ensure the normative working conditions based on the requirements of State Standards.

The main requirements for heating devices are to maintain the air temperature in the production rooms on the basis of sanitary and hygienic requirements in the normative amount and ensure healthy working conditions for workers. In production, mainly domestic and central heating systems are used.

.Lighting of production buildings and workplaces. General information about lighting.

Illumination is one of the main indicators that determine the connection of a person with the external environment and represent the quality of information about the external world that comes to the human brain. The correct and normal amount of illumination allows you to quickly determine the color, size of work tools and equipment, and increases labor safety, creating conditions for the employee's ability to work to be preserved for a long time, increased labor productivity, quality of the produced product.

Based on the lighting of working rooms and places, the following requirements are established:

- it is necessary to give the opportunity to quickly and lightly distinguish work objects;
- the illumination should be uniform, not give any sharp shade;
- there must be a certain degree of difference (“contrast”) between the color of the object and the place where it is located (background);
- the light source should not produce any light return (flashes) on the object to be seen;
- the light source should not lock the working eye;
- it is necessary that the degree of refraction of working surfaces does not change over time.

These requirements for coverage have proven themselves not only in research, but also in practice. Normative illumination is determined not only by the flow of light, but also by the return of light from the ceiling and wall of the room, the contrast (color difference) between the background and the object. For example, to see a black thread on a black background requires at least a thousand times greater illumination than a background in white.

The main light-technical indicators of illumination. Light-technical indicators of illumination include light, light flux (F, lumen), light intensity (I, Candela), luminosity (E, Lux), clarity (l, kd/m²), and light return coefficient (%). In the quality indicators, however, it is possible to include the background, the contrast of distinguishing the object with the background, the pulsation coefficient.

The light-electromagnetic spectrum is part of the visible sphere. As its main characteristic, the wavelength (e.g.) and the frequency of oscillation (e.g.) were adopted. The correlation between these indicators is expressed as follows: $\lambda = s / \nu$,

where s is the speed of propagation of light.

The visual field of view of the eye is different in different parts of the visible sphere of the spectrum, and in the green region of the spectrum, the wavelength is maximum in the case of a cell = 554 nm.

The main light–technical indicators of illumination include the strength of light, illumination, the coefficient of absorption, conduction and return of light, the clarity of light, the contrast of the object with the background (a sharp difference between the object and the main color), the pulsation coefficient of illumination and the non-uniformity coefficient of illumination.

The light Force (J) is expressed by the ratio of the light flux to the angle at which the light propagates::

$$J = dF / d\omega,$$

Candela (Kd) was adopted as the unit of measurement of light intensity.

Light flux (F) is characterized by light power and measured in Lumen (lm).

Luminance (E) is the density of the luminous flux along the surface, measured in Lux (lk).

Coefficients of return, absorption, transfer of illumination. The quality of illumination will depend on the amount of illumination and the characteristics of the illuminating surface. The properties of the luminous flux return, absorption and conduction of the illuminating surface are estimated by the coefficients of the luminance return of the light c , absorption C and conduction C . These coefficients are defined as follows:

$$\alpha_s = F_\alpha / F; \quad \beta_s = F_\beta / F; \quad \gamma_s = F_\gamma / F,$$

where F is the flux of light falling on the surface to be illuminated; F_α Is The Flux Of Light returning from the illuminated surface, F_β Is The Flux Of Light, F_γ Is The Flux Of Light returned from the illuminated surface, LM.

Clarity, contrast and background. One of the main characteristics of the illuminated surface is the property of returning light, and this will depend on the clarity ("yarkost") of the surface. NIT (Nt) was adopted as the unit of measure of clarity. The sharp difference between clarity on the surface (surface) of the object and the general ambient background (color) is called contrast. An object that is differentiated as a background is told the color of the corresponding surface, that is, the surface on which this object (Object) is located. The background is characterized by the property of returning the stream of light, and the light is black when s is 0.4, the sound is medium when s IS $s=0.2...0.4$, and the sound is black when s is 0.2.

Depending on the background, the contrast is higher if K_0 is 0.5, on average if $K_0=0.2...0.5$, and small if K_0 is 0.2.

The pulsation coefficient of luminance (K_n) is estimated through the relative depth of the luminance oscillation caused by the change in light in gaseous lamps operating with alternating current, and it is determined as follows:

$$K_{PK} = \frac{E_{max} - E_{min}}{2E_{or}} \cdot 100\%,$$

here E_{max} , E_{min} , E_{OR} – maximum, minimum and average illumination during the oscillation period.

The luminance pulsation coefficient (CPC) should be 10...20%.

The unevenness coefficient of illumination (K_{NK}) is expressed through the ratio of minimum and maximum illumination on the working surface:

$$K_{NK} = E_{min} / E_{max},$$

Lighting will be in natural and artificial ways. The most favorable working conditions for a person are created if natural lighting is properly designed and at the standard level.

Natural lighting. Natural lighting can be side-sided, high-sided and combined, that is, both side- and high-sided, depending on the ways in which light is transmitted.

The change in the level of natural lighting during working hours, depending on the time of day and climatic conditions, is calculated, normalized not by the illumination of the workplace, but by the coefficient of natural illumination.

The coefficient of natural illumination is said to be the percentage expression of the ratio of the illumination of a point in the room to the illumination of the external environment at this time:

$$e_{\min} = \frac{E_{\text{ichki}}}{E_{\text{tashqi}}} \cdot 100\%,$$

here E_{ichki} – illumination at some point inside the room, lk; E_{tashqi} – illumination in the open field in the external environment, lk.

The coefficient of natural illumination (e) In N-sided illumination is considered good if the e -direction is 80% e_n ; in high-sided and combined illumination, the e -direction is 60% e_n . The coefficient of natural illumination will depend on the climatic coefficient of light. Its amount is selected from special tables, depending on the discharge of work, the smallest size of the object of differentiation and the light base of the climate, and on this basis is the number of windows and flashlights (in high-sided lighting) that must be installed in buildings. To ensure natural lighting at the norm level, light transitions (the area and number of windows) are determined by calculation based on the established lighting norm, depending on the type of work.

Artificial lighting. Artificial lighting can be general or combined. In combined lighting, general and local lighting are used together. In general lighting, the interior of the room is illuminated using common lights, while in local lighting, the lights are installed directly in the workplace or in front of the workpiece, for example, portable lights installed above the desktop, lights installed in stanzas or other work devices, etc.

In order to facilitate the normalization of illumination, all works are divided into 6 discharges according to the degree of accuracy: ultra – high – precision works – I razryad; very high - precision works – II razryad; high –precision works-III razryad; super-precision works-IV razryad; low-precision works-v razryad; rough works-VI razryad.

The highest luminance I is set for works in razryad 5000 lk. constitutes, while the minor illumination is defined as -75 lk for works in the IV discharge.

In the work performed in the external environment, the illumination depending on the work discharge is from 2 to 50 lk. up to.

Light is considered one of the important conditions of human existence. General information about lighting. The main units of measurement of lighting. Basic description of light and units of measurement. Methods of lighting industrial enterprises. The main requirements for the rupture of industrial enterprises. Lamps and their placement. Providing information on ways to ensure safety. To check the artificial lighting of the workplace, learn to evaluate it and master the methods of assessing the effectiveness of lighting devices. Lighting devices. You need to provide: use good lighting tools, but not too eye-catching; it is imperative that there are good level lighting devices; that the lighting must be in demand. Some mixing equipment must be provided with light-emitting equipment, as the worker must notice that the mixing apparatus has stopped; special installation work or special ognetshtellar, for fire safety; be well-lit rooms and corridors. Issues to consider: having the walls painted in different colors to be bright.

Moving around plant or Enterprise facilities

You must have:

- corridors that are safe for passengers and cars-they must be separated from each other;
- the presence of corridors with high amenities and no recesses;

- the presence of handles on the stairs and, if necessary, in the sloping areas of the work area;
- the presence of safe, touch-opening-closing doors; the presence of non-slip surfaces. Problems to consider:

- to place markers in special black and yellow colors in the places where construction work is being carried out. Lighting is natural (directly using the sun through the diffusion of its rays in space) and artificial (carried out using electric lamps). Light is the visible radiation of the electromagnetic spectrum. The wavelengths of electromagnetic spectra are 10 n.m from 340000 n.the range up to m is called the optical process of spectra, from 10 to 380 n.M I infrared rays, 380 to 770 n.M I visible rays and 770 to 340,000 n.m. those up to are said to be ultra-violet Rays. We perceive light rays from purple to red with our eyes.

The main light-technical sizes used in assessing the quality of lighting include light strength, illumination, return coefficient, brightness of light, luminance pulsation coefficient, luminance unevenness coefficient, etc.

Light power (I). Natural lighting is the illumination of a room from external blocking devices by sunlight falling through transparent barriers (straight or reflection).

The coefficient of natural illumination (TEK) e is the ratio of natural illumination generated by sunlight at some point (straight or reflection) of a given surface inside a room to the ratio of sky light falling horizontally outside at that time.

$$e = E_{\text{ichk}} / E_{\text{tash}} \cdot 100\%$$

here :

e -coefficient of natural illumination, %

E_{ichk} -indoor lighting, lk;

E_{tash} -lighting outside the building, lk;

The difference of the background with the object of observation is said to be (K)- contrast to the difference between their brightness.

$$K = V_o - V_f / V_f, ,$$

here:

V_o -object clarity, kd/m²

V_f -background clarity, kd/m²

The optimal size of the difference is taken 0.6-0.9.

The area under study is called the background, in contrast to the part that touches the object.

The light return coefficient is called a light background if it is more than 0.4, an average background if it is 0.2 to 0.4, and a black background if it is less than 0.2.

In order to produce even light in rooms inside the building, the ceiling and Wall return coefficient should be around 0.8, and those of the floor and equipment should be equal to 0.3.

It uses a combined lighting method when natural light is not available, that is, it uses artificial light. Natural lighting is designed for rooms where people will be constant. Natural light is rich in ultraviolet light, which is necessary for the course of human organs of vision and other physiological processes, and working in rooms illuminated by this light is very useful for the eye. Natural light spreads evenly throughout the illumination zone.

Control questions:

How many gours are divided according to the size of the powders, that is, their dispersion?
General ventilation is....
What protective measures do you know?
Give an example of steam heating systems.
How should air heating systems be installed?
By what formula is the amount of heat spent on technological purposes determined?
What are the general requirements for lighting?
What is said to be the natural lighting coefficient ?
Bring the formula for illumination and comment on the parameters in it.
How many discharges is the degree of accuracy of work divided to ease the normalization of illumination?
What is the unit of measurement of the flow of light?
What is the unit of measurement of clarity?
What is the pulsation coefficient?
What types of natural lighting do you know?
What types of artificial lighting do you know?
What types of luminaires do you know?
Which main parameters represent the quality indicators of the luminaires?
How does productivity depend on lighting conditions in workplaces?
What are the norms of natural and artificial lighting?
The effect of ultraviolet and infrared rays on the human body.

7-Practical Training.**Clean rooms in pharmaceutical production, their classification and requirements for them.**

The duties of employees of "clean" rooms include:

- a sharp reduction in penetration into "clean" rooms, for which it is necessary to develop appropriate instructions;
- production processes must be carried out with the minimum amount of employees. Inspection and control activities are necessary to be carried out mainly outside the "clean" zones;
- reduce the level of cleanliness in rooms of Level V and S than the need of employees and refrain from sharp disturbances in the work zone;
- not to be located between the airway and the work zone source so that the airflow does not change the yunalishi;
- top open capacity or not to bend and touch the product;
- not to raise and use items that fell on the floor during working hours;
- before entering the "clean" rooms (staff training room), it is necessary to remove all jewelry, clean from perfumery, including nail polish, take a shower (in the necessary cases), treat the hand with a disinfectant and wear sterile technological clothing-head and shoes;

- not to conduct conversations on unnecessary topics, to carry out oral communication with people outside the production rooms at a special talking point;
- to convey to the head about all errors, as well as unpleasant changes in the sanitary and hygienic mode or changes in climatic parameters.

Classification of "clean rooms" under GMP (2004)

Room	1 M3 the number of particles allowed in air			
	In the production process		In the process of exploitation	
	0,5 mkm	5,0 mkm	0,5 mkm	5,0 mkm
A	3500	1	3500	1
V	3500	1	350000	2000
S	350000	2000	3500000	20000
D	3500000	20000	Belgilanmagan	Belgilanmagan

Classification of "clean rooms" under GMP (proposed)

Xona	1 m ³ the number of particles allowed in air			
	In the production process		In the process of exploitation	
	0,5 mkm	5,0 mkm	0,5 mkm	5,0 mkm
A	3520	20	3520	20
V	3520	29	352000	2900
S	352000	2900	3520000	29000
D	3520000	29000	Unspecified	Unspecified

“Toza xona”larni ISO va FED STD 209 (AQSH) bo'yicha tasnifi

GOST ISO 14644-1	FED STD 209 D	FED STD 209 E
1 ISO		
2 ISO		
3 ISO	1	M 1,5
4 ISO	10	M 2,5
5 ISO	100	M 3,5
6 ISO	1000	M 4,5
7 ISO	10000	M 5,5
8 ISO	100000	M 6,5
9 ISO		M 7,5

The heating, ventilation and air conditioning system in production buildings must be designed in accordance with the current building standards and regulations with the requirements of guidelines for the design and construction of industrial enterprises and with this document.

Production rooms must have an efficient working airflow controller, flow - creating and absorbing ventilation system, temperature, humidity, filtration efficiency and pressure change measuring instruments in the filter, and an OOP-test (Hermeticism and flow testing).

The efficiency of the flow supply system in ventilation and air conditioning should be determined based on the conditions for ensuring the required parameters of the air supply in the working zone, taking into account the scheme of Organization of the intake-killing air exchange.

The blower device of the blower ventilation is installed in the clean place of the roof, as far as possible, taking into account the dampness of the wind. The air flow, which is given to rooms belonging to the V and S levels of cleanliness, is cleaned in three stages.

The air flow supplied to the rooms belonging to the Ddaraja of cleanliness can be cleaned in two stages.

The ventilation air preparation system must ensure the cleanliness of the air in the "clean" rooms in accordance with the schedule and a positive change in pressure compared to the surrounding rooms with a much lower level of cleanliness. In adjacent rooms with different levels of cleanliness, the pressure change rule should be 10-15 Pa.

The filter chambers of ventilation devices in "clean" rooms and the inner and outer surfaces of the airway must have a coating that allows them to be treated with a disinfectant. With the help of air pollution control devices, it is necessary to regularly assess the effectiveness of the work of filters. The replacement or hermetization of the filtering equipment means that the replacement period has come when the air flow rate relative to the normative indicator increases by two careers, as indicated by the instruments. Increased resistance indicates a decrease in filter efficiency or its damage.

The air supply system for the production rooms of antibiotics of the penicillin group should be completely separate from the air system in the production rooms of other medicines in medical need.

The generating capacity of the suction ventilation system must be equal to 80-90% of the production capacity of the discharge ventilation system so that it does not completely absorb the air in the "clean" rooms.

The sucking air in the production rooms is passed through an elegant filter in order to prevent poisoning of the environment.

In the production of sterile medicines, depending on the need, in order to protect the most responsible plot or operations, it is possible to create a horizontal or vertical laminar flow in the entire land or in a separate small zone of the room, using special dryers.

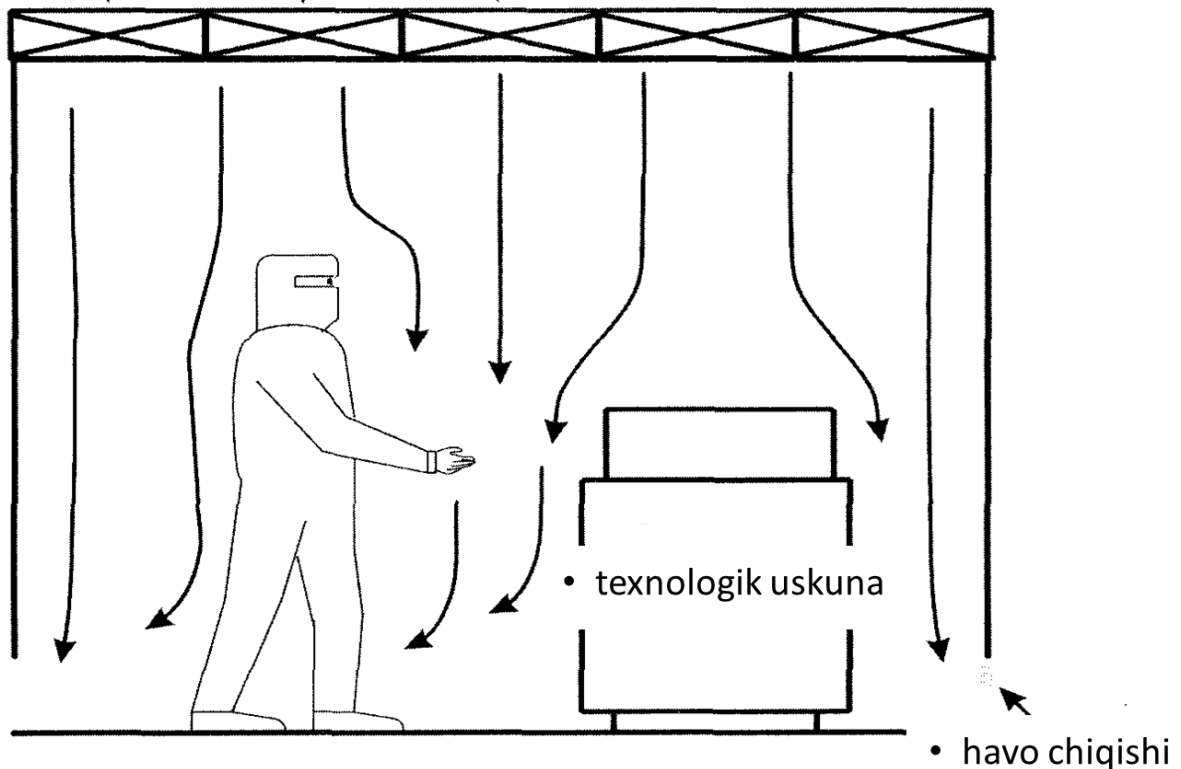
In a "clean" plot or "clean" room, where vertical laminar flow is created, a flow-giving ventilation filter should be placed inside, and a suction ventilation hole should be placed on the floor or at the bottom of the wall. In "clean" rooms or "clean" plots with horizontal laminar flow, flow-giving filters and suction ventilation holes are placed along opposite walls.

"Clean" cameras must meet the following requirements:

- the lining flow, cover and surface of the panel should be made of smooth and durable material;
- pre-cleaning filters must be made of material that can be used once or cleaned thoroughly and used again;
- final air filtration, pre-tested and hermetized, is treated through elegant filters;
- laminar flow rate should be around $0.45 \text{ m / s} \pm 20\%$;

The activity of laminar flow devices of sterile air should be constantly monitored in accordance with the relevant directories and the inspection schedule.

- Yuqori samaradorlikka ega havo filtri



Clean room recess with vertical air flow on one side

- At the required points, the production rooms can be equipped with a air conditioning system that provides airflow, and it must provide
 - clean the air from microorganisms to the appropriate extent;
 - automatic control of climatic parameters (temperature and relative humidity of the basin) on the way to creating the most favorable conditions for the operation of technological processes and personnel;
 - to have high aerodynamic stability to maintain optimal air distribution and other parameters in the building and its individual rooms;
 - elimination of the appearance of static electricity and associated dust accumulation;
 - low noise during Operation,
 - build against disinfectants using stationary and dust-free material as well as corrosion-resistant coatings.

Each building must have a system for supplying compressed air, nitrogen if necessary, as well as a technological system for distributing them to all necessary rooms.

The absence of impurities or oil vapors in the air being supplied from non-lubricated compressors is darcor.

Sanitation

Production rooms must be kept clean and in the appropriate order in accordance with the rules of sanitary order. It is not allowed to grow flowers, accumulate ahlal, the appearance of insects.

The fact that each enterprise has a program for conducting sanitary events, which sets out the following::

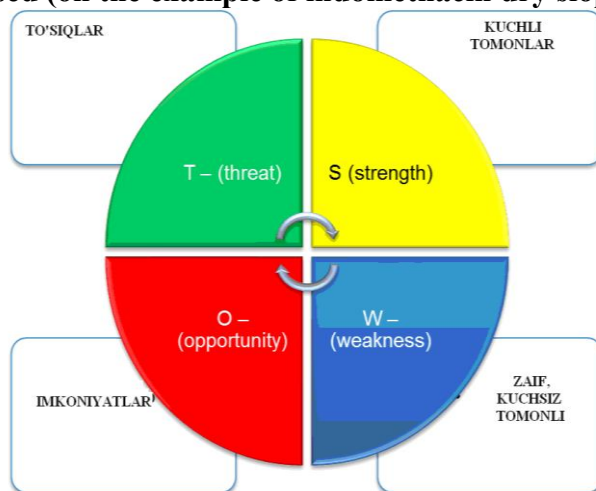
- list of rooms and equipment subject to regulation and processing, style and their periodicity;
- list of inventory, material, washers and disinfectants used in room arrangement and equipment processing;
- list of employees and managers assigned the tasks of assembling rooms, processing equipment.

From these instructions, the relevant personnel are constantly kept in an alert and are included in the program for training and professional development of personnel.

It is necessary to allocate a room for the storage of detergents and disinfectants, inventory and materials, which are used in the assembly of rooms and equipment processing. To prevent the appearance of microorganisms in a stable form, it is necessary to replace disinfectants. Disinfectants should be sterile. In order to prevent the growth of microorganisms, the prepared solutions must be briefly yellowed in pre-washed containers. It is forbidden to pour freshly prepared solutions into partially filled containers

The amount of mechanical particles and microorganisms in the air in the production rooms, as well as the level of microbial contamination of johos according to the relevant instructions, should be regularly monitored.

When covering the topic of practical training, the method of pedagogical technology “SWOT analysis” is used (on the example of indomethacin dry slope).



Questions to check student knowledge.

- 1.What is a clean room?
- 2.Areas used in clean rooms
- 3.Types of clean rooms
- 4.What is clean room technology?
- 5.What are the basics of standardization of clean rooms?
- 6.Classification of clean rooms in the pharmaceutical industry.
- 7.Societies for the control of impurities-Confederation of Chalcaro (ICCCS)?
- 8.Say ISO 14644 standards group?
- 9.What is the procedure for validation?
- 10.What is the production stage?

8-practical training.

Requirements for employees in pharmaceutical production.

Organization of work on the provision of instructions to employees, training and verification of their knowledge

All employees of enterprises, including their heads, must study in the prescribed manner in their professions and types of work, receive instructions, check their knowledge, and undergo re-certification.

Testing of labor protection knowledge of workers, managers, engineering and technical personnel directly related to the organization and performance of work in production should be carried out in accordance with the "Model regulations on the organization of studies in labor protection and testing of knowledge" (August 14, 1996, registration number 272).

List of hazardous and harmful production factors

In each enterprise producing pharmaceutical products, a list of dangerous and harmful production factors and measures to reduce or completely eliminate the influence of these factors is compiled, taking into account the specific conditions of production.

Each enterprise producing pharmaceutical products GOST 17.2.3.02-78

it should be fully and objectively informed about dangerous and harmful production and technological processes, factors of production, their classification, sources of occurrence, features of exposure to workers and the level of health hazard, as well as the future consequences.

Employees of pharmaceutical production OST 64-031-87 SSBT "technological processes for the production of ready-made medicines. Production of tablet-type doridarmon forms. Safety requirements", OST 64-7-472-83 SSBT "technological processes for the production of ready-made doridarmon tools. Production of injection solutions in the ampoule. In accordance with the "safety requirements", the following groups of hazardous and harmful production factors can be affected:

group of physically dangerous and harmful production factors:

moving machines and mechanisms; walking objects and materials; dust and gas with a high amount of air in the working zone; surface with a high temperature of equipment and materials; air with a high temperature of the working zone; noise with a high level in the workplace; high level of vibration; air with a high humidity level;

the voltage at which the level in the electrical circuit, the connection of which can occur through the human body, is dangerous;

light lipylation (pulsation); high-level static electricity; non-availability of natural light; high-level ultraviolet radiation; high atmospheric pressure.

group of chemical hazardous and harmful production factors: harmful liquid, solid, vapor-containing substances and aerosols acting through the respiratory tract and skin lining;

corrosive liquid, solid and vapor-containing substances that affect the respiratory tract, skin lining and eye.

C) group of psychophysiological harmful and dangerous factors of production: excessive tension of the sensory organs; monotony of Labor.

In changes in technological processes that lead to the appearance of New harmful substances or the loss of hazardous and harmful factors, or when introducing new production equipment, appropriate changes should be made to the lists.

Extremely dangerous professions and jobs in labor security

Each enterprise must have a list of works performed in extremely dangerous conditions.

The list should take into account the risks associated with a specific technological process, production equipment, raw materials used and the features of carrying out work.

In the event of the emergence of new types of hazardous work in connection with technology, modification of the equipment being used, the creation of new productions, the list should be revised at the request of the supervisory and supervisory authorities.

Team and individual protective equipment of employees

Basic at all enterprises in the field of pharmaceutical production to reduce or eliminate the impact of harmful production factors on employees of production and auxiliary services, gost 12.4.011-89 and OST 64-7-473-83 SSBT "individual protective equipment in the production of ready-made medicines. Classification. In accordance with the "field of application", collective and individual protective equipment should be used.

Team protection tools include: tools for normalizing the air environment of production rooms and workplaces

(ventilation and air purification, heating, maintaining air temperature, humidity in the same norm, etc.);

means for normalizing the light of production rooms and workplaces (lighting instruments, light places, light protection devices, etc.); noise, vibration, electric shock, static electricity, high level of equipment surface

temperature protection tools;

means of protection against the influence of mechanical and chemical factors.

Employees of pharmaceutical production should be provided with individual protective equipment in accordance with the "standard standards for free issuance of special clothing, special shoes and other individual protective equipment for employees of pharmaceutical production enterprises"(September 24, 2008, registration number 1861 — collection of legislation of the Republic of Uzbekistan, 2008, Number 39, article 402).

A critical aspect in the clean room system is employees, if such rooms employ employees who do not have proper training and do not fit into such goals, the use of a clean room, even if the project is developed at the highest level, does not give the intended goal, the funds spent on its organization waste.

Insufficient consideration of critical factors in the use of clean rooms leads to contamination of the clean room and a decrease in the quality of the product. In the planned procedure, it is necessary to establish control over Risk Factors and determine actions for the detection of impurities.



Picture 13.2

Requirements for employees

Persons placed in clean rooms: compliance with personal hygiene requirements; compliance with the rules of behavior in clean rooms; lack of contraindications for working in clean rooms for Health; Study in a training course before starting work and subsequent regular

retraining; strict adherence to all instructions and rules of work. An important factor is the positive attitude of employees to maintaining cleanliness, their order, order, tendency to strictly follow the rules, reliability. The readiness of employees to record and analyze mistakes and shortcomings of themselves and others, to inform about all violations at work serves as the basis for the analysis and implementation of risks in the technological process and allows you to maintain the established level of cleanliness. But it is their implementation that creates certain difficulties for individual individuals. At the same time, cleanliness and unconditional adherence to the agenda are mandatory conditions for effective work, and it is also impossible to approach a clean room without fulfilling them!

The area of the body surface is on average 1.75 sq.m. the outer skin coating is renewed in a few days, when a person separates several hundreds and millions of particles from 0.5 and millions of particles in each reality. The total mass of dividing particles per day is 10 g. microorganisms pose a special danger. Three conditions are necessary for their reproduction: heat, humidity and nutrient medium. In most parts of the body, these conditions are present in harmony, these are, first of all, the head, hairstyle, nose, mouth, ears, nails and the space around them, places where a person hides under clothes. Particular attention should be paid to the cleanliness of such places.

Anyone who enters a clean room: thoroughly infects their hands before entering the room, wash your hands to the wrist before entering sterile zones; wash your hands after leaving the bedroom; do not wipe their noses with their hands; keep the oral cavity tidy and brush their teeth regularly; should dress nicely. When an employee leaves the house, he finds out what he did the day before (working in the field, fixing a car, caring for pets, sports games, etc.k.) must remember and put itself in order.

When hiring an employee, it is advisable to include a special section in the employment contract and establish in it the obligations and obligations of the employee for personal hygiene. For example, in rooms with a cleanliness class of 5 people, workers come to work without makeup, do not drink alcohol before the working day, do not smoke on the territory of the enterprise, and two hours before coming to work. The last requirement is that the concentration of particles in the air emitted by Chestnut breath is very high, decreasing very slowly after the end of smoking. These particles are often small in size and do not fall into the mask. Sometimes the question arises: Do you need to take a bath before entering a clean room? Practice shows that if a person is washed to work, there is no need to take a shower at work. In addition, bathing in warm or hot water under the shower leads to the opening of skin pores, the separation of sweat and microorganisms. Without this, microorganisms do not protrude over the surface of the skin coating. There is no strict information about the need to take a shower directly before work. At the same time, in special cases, it may be required to take a shower after work. Shower networks can be designed for accidents. It is necessary to take a shower at home every day (not a bath), after all, it is considered more effective than a bath. Pardož anjomlari va zeb-ziynat bezaklari

Makeup tools (dream for eyelashes, upa, lipstick, nail polish, rumyana, etc.k.) provides a favorable environment for the proliferation of microorganisms. Expensive jewelry decorations tend to have many places where impurities accumulate, so they are required to be removed before entering a clean room. The following useful rule should not be forgotten: not to bring items into a clean room that are not needed for work or to ensure the activities of employees.

Hand washing

Proper hand transmission and handling are an important component of preparing employees to enter a clean room. At the same time, when working, a person grabs various surfaces with his hands. Hands should be infected every time you enter a clean room. There are various hand washing schemes: before changing clothes and/or before entering a clean room. In most cases, the hands are washed before changing clothes. For clean rooms and sterile

Productions belonging to high purity classes, this is a strict rule. Otherwise, moisture can get on clean clothing, especially its sleeve.

Hand washing scheme: solving rings and other decorations. Holing the hand before soapy. Soap the entire surface of the skin of the hands (bactericidal soap). It is advisable to use liquid soap with a dosing agent that does not form drops. Hard soap leaves a damp mark and flows. The surface of the hand is rubbed and washed, special attention is paid to the nails, the zones around them, between the fingers, the parts of the skin that are under the ring. Lint-free brushes made of plastic can be used. When using brushes, it is necessary not to damage the skin. The hands are rinsed under a stream of water until the foam of dirt and soap is completely gone. Hands are dried with a hairdryer or disposable vors are used non-separating towels. In cases of special responsibility, Nera filters can be used to dry the hands. It is not allowed to wipe the hands with ordinary towels of general use. If a towel wrap is used, the hands are wiped only with a clean part of them that no one has touched. Further actions (changing clothes, entering a clean room) are performed only with dry hands. There are additional rules for sterile production: the hands are washed up to the wrist; the hands are treated with disinfectants, which must be kept for 1.2-2 minutes after application to the hand, at which time the wrists must stand so above the wrists that no liquid flows to the critical surfaces (fingers). Special gloves can be used to change clothes so that the hands do not touch sterile clothing. These gloves are removed after changing clothes and sterile gloves are worn to work or working gloves are worn over them. Every clean room should have a hand washing guide. In sterile production, it is advisable to use rakovinas with a rounded bottom to prevent moisture from accumulating.

Actions in clean rooms

It is necessary to establish control over compliance with the rules established by employees. In this case, it should be remembered that there is nothing worthwhile for clean rooms. It is the small ones that pose the greatest danger. The main criterion that determines the rules of behavior is to avoid anything that can contaminate a clean room.

How to move in a clean room? It is necessary not to rush, not to act sharply. This is determined by two reasons: when moving quickly, the separation of particles from a person accelerates; rapid movements disrupt the movement of air currents and lead to the spread of impurities. Unnecessary actions should be excluded at all. It is only necessary to perform the actions prescribed by the regulation. Some people have a habit of shaving, rubbing hands, face and other body parts, repeating gestures a lot. Such actions are not allowed. People who cannot get rid of harmful habits should not be included in clean rooms. In the clean zone, it is forbidden to eat, drink liquids, smoke, read newspapers and magazines. Respectively, the room will receive food products (including drinks), chewing gum, medicines, matches, lighters, cigarettes, papers and other utensils not provided for in the technological process, printing products, etc.k.import of S is prohibited.

The wristwatch is a source of pollution. It is necessary to remove the clock before entering a clean room. It is impossible to speak out loud in a clean room. Loud speech and screams sharply increase the intensity of the separation of impurities from the mouth. Bending over the

workplace, leaning on walls and equipment, moving items from place to place or pressing them on the body is prohibited. It is necessary to observe special caution when working in unidirectional airflow. It should be remembered that if the hand or other body part falls between the filter and the work zone, the working zone will definitely get dirty. Impurities separate from the person's mouth, nose, wherever he is looking. Therefore, when there is a need to contact the operator, it is necessary to approach him so close that he is forced to turn and look, so that when talking, the particles that separate from the mouth separate from the working zone to the other side. If the need to hit the aksa or cough occurs, it is necessary to turn from the side of the working zone, cover the mouth with gloved hands, and then replace the glove. If hitting or coughing the accent continues to repeat, it is necessary to leave a clean room and inform the management about it.

It is necessary not to leave items that are not necessary for work in a clean room. Any failures in the work of equipment and any deviations from the requirements established in the instructions should be reported to the head.

Health status

The criteria for assessing the state of health are quite simple: Individuals with acute and chronic diseases are not allowed to clean rooms. In the first gal, this applies to acute respiratory diseases. Coughing, hitting the buttocks, runny nose and tears have a negative effect on the level of cleanliness. It is also worth counting diseases such as conjunctivitis and other eye diseases; diseases of the upper respiratory tract; skin diseases, including herpes, boils, seborrhea (Thrush). Some people sweat a lot, which also makes it worthwhile to work in clean rooms. Injuries also lead to the separation of impurities.

kwk method

I know	I want to know	I knew

9-practical training.

Production, storage, transportation and acceptance of material and raw materials in pharmaceutical production. Requirements for the warehouse.

Reception and issuance of medicines and medical items in the warehouse

The reception of medicines and medical items in the warehouse is carried out by the reception Department of the warehouse. When carrying out loading and unloading work, Protection of medicines and medical items from precipitation-hairpins, direct effects of sunlight, high or low temperatures should be provided.

The places of reception and storage of medicines and medical items must be separated from each other.

In case of detection of poor-quality, counterfeit, unregistered medicines and medical items, illegal copies of medicines registered in the Republic of Uzbekistan, as well as medicines and medical items in circulation, facts confirming their harmful effects on human health, they must be removed from circulation in the prescribed manner and an act is drawn up and disposed of in the manner prescribed by the Cabinet of Ministers of the Republic of Uzbekistan. In doing so, they must be kept on the basis of identification or an act in a specially isolated place separate from other medicines and medical items until they are disposed of in the prescribed manner.

Medicines and medical items returned to the warehouse must be identified and stored in a separate place until a decision is made on them in the prescribed manner.

In cases where it does not comply with the requirements of regulatory documents and other documents in the field of technical regulation, according to the results of analyzes, medicines and medical items returned to the warehouse can be transferred to the main storage room.

In cases where it does not comply with the requirements of regulatory documents and other documents in the field of technical regulation, according to the results of the analysis, medicines and medical items returned to the warehouse are formalized on the basis of the act and destroyed in the prescribed manner.

. Organization of storage of medicines and medical items

. In the warehouse, all medicines and medical items should be placed in stelages and diapers. It is not allowed to place medicines and medical items on the floor without diapers. Diapers are placed in a row on the floor or several floors on the stelages, taking into account the height of the stelages.

The storage rooms for medicines and medical items and the equipment, equipment in them should be kept in a clean state.

Manufacturers and wholesale realization organizations should take appropriate measures to prevent the breakdown of medicines and medical products (spills, splashes, fractures), damage by microorganisms and contamination of drug crossovers.

In the warehouse, it is required to create conditions that are kept from insects, rodents and other types of animals and provide them with the means used against them. It is forbidden to use powerful influencing agents in this.

The storage of medicines and medical items can be systematized as follows:

by pharmacological group;

by methods of application.

The labeling of all medicines and medical items on the wrappers must be laid out and placed with an outward focus.

In manufacturers and wholesale realization organizations, the accounting of drugs is carried out in electronic or paper form by expiration dates.

Medicines should be stored in warehouses separately, depending on their physicochemical nature, subject to temperature, humidity and light regimes under conditions specified by manufacturers.

Temperature and humidity in the warehouse should be recorded in a special electronic program every day or in a journal whose pages are numbered, sewn and sealed (business entities are not required to confirm with a seal).

Medicines that require light protection should be stored in a dark room or in black-painted cabinets with tightly closed doors, or in crates with a tightly closed lid.

When storing thermolabile drugs, they must be branded or adhere to the temperature regime indicated in the instructions for use.

Medicinal plant raw materials (pre-dried) should be stored in dry rooms, closed (glass, metal, wood) containers, where air circulates well.

The following requirements are imposed on the storage of medical items consisting of binding materials:

binder materials are stored in rooms that are dry, air circulates well, protected from dust and rodents. Unsterilized materials are allowed to be stored in unheated rooms. It is allowed to store sterile materials in a room where the temperature level does not change rapidly so that they do not affect the quality of the packaging at temperature changes;

when storing sterilized binding materials in a warehouse, it is necessary to plan them according to the production times.

Requirements for the storage of medical items consisting of rubber items:

the room should be protected from sunlight. Light should only be artificial, electric;

boxes and cabinets with items should be placed no less than 1 meter from the central heating battery, as well as no less than 5 meters from the Ovens.

Requirements for the warehouse.

Warehouse areas. they must have a wide enough capacity to ensure the orderly storage of materials and products of various categories: raw materials and packaging materials, intermediate, unpacked and finished products, as well as quarantine, allowed for release, non-ferrous (brak), returned or recalled preparations.

Warehouse areas should be designed or adapted to provide better storage (GSP) conditions. In particular, they should be clean and dry, and the required temperature should be ensured in them. If special storage conditions (for example, temperature, humidity) are required, then they must be provided, checked and controlled.

Protection of materials and products from the influence of weather conditions should be ensured in the reception and shipment zone areas. Reception areas must be designed and equipped to allow cleaning before the Tar loaded with the products being taken into storage.

If quarantine is provided with the storage of products only in separate areas, then such areas must be clearly labeled, and access to it is allowed only to the authorized employee. Any quarantine system that applies to a separate God instead of being quarantined should provide security equivalent to it.

To select samples of raw materials, it is usually necessary to have a separate territory. If the selection of the sample is carried out in the storage area, contamination or collision should be carried out in a removable manner of contamination.

There should be areas with defects (braces), separately allocated for the storage of materials or products that have been returned or harvested back.

It is necessary to store strong-acting raw materials or strong-acting products in safe and protected areas.

Since packaging materials are considered critical for the quality of medicines, special attention should be paid to the safe and guaranteed storage of these materials.

Buildings and equipment

1. Necessary measures must be taken to prevent unauthorized persons from entering the storage space.
2. Storage areas should be large enough to allow orderly storage of materials of different

categories.

3. The receiving and sending areas must be protected from the effects of the weather.
4. Quarantine places should be clearly defined and only authorized employees should be allowed to enter them.
5. There must be a separate area for sampling with the appropriate control conditions.
6. There must be a separately allocated area for the storage of rejected, expired, withdrawn, returned products.
7. Very active and radioactive materials, harmful, hazardous materials, fire and Explosives must be stored in specially designated places equipped with appropriate additional safety and safety tools.
8. Drugs, Psychotropic Substances and precursors should be stored in accordance with international conventions and national legislation of the Republic of Uzbekistan.
9. Lighting the premises for storing products should ensure that all operations are carried out accurately and safely.
10. Materials and medicinal items must be stored in conditions that ensure that their quality is maintained.
11. The principle of shelf life should be applied first, from the standard Özdst 2763: 2018 to Section 4.

Equipment:

- the equipment must be suitable and sufficient to ensure the correct preservation of medicinal products;
- measuring instruments designed for monitoring must be checked in the prescribed manner;

Storage conditions:

- the conditions for storing medicinal products must meet the requirements specified on the drug label.

Monitoring storage conditions-monitoring temperature data and, if necessary, relative humidity. The temperature map should display the same temperature regime in all storage areas; it is recommended that the temperature sensor be placed in areas with a high probability of temperature changes.

Control questions.

1. Provide information on the main points of storage conditions.
2. What areas are warehouse areas considered?
3. Requirements for warehouse areas.
4. Requirements for buildings and equipment.
5. What is GSP?

10-Practical Training.

Preparation, storage and distribution of water in pharmaceutical production storage and distribution of treated water

The main task in the design of the system for storing and distributing purified water is to ensure the constant movement of water in the pipes, the absence of stagnant zones that contribute to the growth of microorganisms and the formation of biofilms on the surfaces. Modern storage and distribution systems refer to a recirculation system that flows in one direction and has the ability to completely extract water from the pipe.

Important parameters when storing and distributing treated water include:

- temperature;
- movement of water and its speed;
- pressure;
- pipeline materials and storage containers.

Distribution and storage of purified water according to GMP regulations should be carried out at temperatures that prevent the proliferation of microorganisms - above 800 C or below 150 C.

Systems that use cold water must be equipped with UB systems to lower the level of microorganisms in the water.

The movement of water inside the pipe should be turbulent at a speed of 1.5 to 3 m / s. In hydrodynamics, the degree of turbulence in a fluid flow is described by the Reynolds number (Re).

One of the main problems is the correct choice of materials for storing and distributing purified water. The material of the structures should not worsen the quality of water and meet the requirements and conditions of pharmaceutical production. Purified water according to the requirements of FS 42-26 (9-97 "purified water" and GMP rules) is stored in closed containers with a very smooth surface, which does not change the properties of water and protects it from foreign particles and microbiological contaminants. Above 0.8 Ra) and should be protected from bacteria, dust with a reliable filter. The storage tank must be optimally selected to ensure that the water circulates through the circulation system 1 to 5 times an hour, if necessary, the water in the tank must be completely drained. s if there is any place, the container must be installed vertically, and the height of the container should be equal to 2 diameters.

Main materials used:

- Polymer materials such as PP and PVDF (polypropylene, polyvinylidene fluoride), etc., are often used in the design of cold distribution schemes of purified water;
- stainless steel 316 L, surface roughness no more than 0.8 Ra.

Distillation method and preparation of water for injection.

Water requirement for injection

The main difference between the requirements of Pharmacopoeia (Russia, USA, Europe) for the preparation of water for injection is as follows:

* According to the European Pharmacopoeia, distillation is a mandatory way to prepare water for injection;

Us pharmacopoeia and FS 42-2620-97 (Russia) allow distillation and reverse osmosis.

Distillation. There are three types of distillation processes:

- single column,
- * thermocompression,
- multi-column.

Single column distillation has long been used and is widely used. Its significant drawback is its simple design and high energy consumption, despite the low cost of distilleries.

The essence of the distillation of thermocompression is as follows. Forced compression of steam by the compressor leads to an increase in steam pressure and its temperature. The increased amount of heat (enthalpy) of steam is used to heat water and convert it into steam. The disadvantages of this method are the ingress of foreign particles into clean water, high noise levels and the need for constant maintenance.

The best combination of different properties is multi - column distillation, in which the energy of heated water is fully and efficiently used Steris / Fin-Aqua concern is the world leader in the production of multi-column distillations. In 1971, Finn-Aqua was the first to use the principle of multi-distillation to inject water.

Checking water from a sanitary point of view

When checking water from the point of view of sanitation, attention is paid to:

- A). Organoleptic and physical properties of water;
- B). Chemical composition of water;
- V). Bacteriological indicators of water quality;
- G). Presence of radioactive compounds in water;

Organoleptic and physical properties of water. Water with good organoleptic properties is highly valued. This is a natural state of course, such water is characterized by a clear, colorless, odorless, clean, thirst-quenching.

Chemical composition of water. Water sources are contaminated with chemicals due to the untreated discharge of wastewater into bodies of water in industrial sectors. Hygienists have developed an acceptable amount of lead, margimush, zinc, copper and other substances in water, the amount of which is also specified in the drinking water quality standard. The continued contamination of open water sources with the remains of all kinds of pesticides and fertilizers also changes flora and fauna activities in soil and waters. Especially in this regard, pesticides resistant to external environmental influences are dangerous.

Bacteriological indicators of water quality. From an epidemiological point of view of water, checking whether there are pathogenic microorganisms from a hygienic assessment is a complex and long-lasting work. Indirect bacteriological indicators are used in this. The less water is contaminated with saprophytic microbes, the less epidemiologically hazardous it is. The presence of an intestinal wand in the water means that the water is contaminated with feces. This means that such water can also contain pathogenic microorganisms.

The presence of saprophyte microflora in water is a sign of pollution, the level of which is expressed by the concept of "microbial number".

"Microbial number" is said to be-1.0 ml of the number of microbes in the water being examined. To do this, 1.0 ml of the water being examined for meat peptone Agar is planted and left on the thermostat for 37 0c24 hours. In time, the number of microbes that are considered a microbial colony is determined. The number of germs indicates that the water is contaminated with common germs.

The quality of the water is determined by the number of colonies. The colony content in non – polluted, well – equipped artesian wells reaches 10-30, in the water of an uncontaminated mine well – 300-400, in slightly clean, open water sources – 1000-1500, in water of vodoprovod, where good antimicrobial measures are taken.

Again, in a bacteriological assessment of water, it is determined whether it has an intestinal wand. Whether the intestinal wand is present in the water is represented by the size of the coli-titre or coli-index.

Coli-titr deb-one intestinal wand holder is said to have the least amount of water. The lower the coli titer, the more contaminated the water is with the intestinal wand in the human population. Coli-index deb-is said to be the number of intestinal sticks in 1.0 liters of water. Studies show that if the coli-index is reduced to three after water neutralization (in which the colititr is higher than 300 ml), then the pathogens of pathogenic microbes, leptospirosis and tularemia, which belong to the group of typhoid, paratyphs, completely die. The quality of tap water is expressed in standard indicators developed on the basis of the above estimates. The number of saprophytic bacteria in 1.0 ml of water should be at most 100, the coli-titer should not be less than 300 ml or the coli-index should not be higher than

kwk method

I know	I want to know	I knew

11-practical training.

Buildings and equipment for the production of sterile drugs. Cleaning equipment.

Tool used in pharmaceutical production equipment, devices and requirements for them.

Equipment structures and technical and production issues

Technical constructions and characteristic of pharmaceutical device and production tool equipment

ri affects the health and safety of workers. Dust separation and volatile vapors are controlled in reducing the concentration of harmful substances and in the production of maxillary tightening ventilation systems. Fire and explosion prevention safety requirements (fire extinguishers, dust vapor-proof equipment, fire and smoke detectors, emergency alarms) when quick-ignition fluids and pars are used. Safety measures in the transportation of liquids (containers for storage, pumps, pipes), ensuring the Hermeticism of containers when working with solids, isolating production hazardous tools and materials, providing barrier tools to machine rotating parts prevent danger through mechanical means.

Control over the means and equipment of production is carried out through manual and automatic means. In the first method, operators receive control equipment instructions next to the production equipment. Remote control of process control on automated lines will be set up. Written instructions for all operational processes, working measures must be fully described, as well as technical safety measures must be prepared for workers and for supervision.

The pharmaceutical industry, as a branch of the medical system, carries out such works as the production, preparation of medicines, conducting scientific verification work.

Safety conditions when placing production equipment .Equipment should be placed with the following goals in mind: optimizing the flow of starting raw materials, materials, as much as possible reducing the need for employees to move from one place to another; the possibility of their contamination during the production of medicines

elimination;

mixing of different products or non-conduction of production stages

elimination of risk;

equipment washing, operation, use and service work

facilitate; ensure the rational use of the space;

the fact that the established workplaces comply with the requirements of labor protection norms and rules.

When installing equipment:

the main corridors along the service at the Hamda control area in the permanent stands of workers — 2 meters; the main corridors along the service of machines, dish apparatus, local measuring instruments-1.5 meters;

if it is necessary to show the apparatus to the service circuit, the width of the corridors between the apparatus and between the apparatus and the walls of the room-at least 1 m; the width of the corridors for inspection and adjustment of apparatus and instruments on a periodic basis-at least 0.8 meters;

the width of the corridors between the separate standing pumps — at least 0.8 meters; squares located at an altitude of 0.6 meters or more above the floor level, crossing bridges, stairs, trenches, holes in the trestles should be blocked by a continuous covered fence with a height of — 0.9 meters, from below — 0.14 meters.

Equipment included in the range of objects at high risk should be placed in accordance with the requirements for the construction of pressure-operated containers, heat-operated devices, compressors, load-bearing machines and other equipment, as well as the safety of their use.

Aseptic rooms designed for the production of sterile products should only be equipped with basic technological equipment that directly provides the technological process. It is necessary to place auxiliary equipment in aseptic rooms in adjacent rooms.

Pipes passed over the floor should be laid in a ditch on the land of intersection with crossings or covered with crossing bridges (ramps).

All flange attachments of pipes that have passed over the top of the passages (where aggressive liquids and hot solutions and steam pass) must have protective devices.

Pipes should be in accordance with GOST 14202 "pipes of industrial enterprises, special paint colors, warning signs and packing shutoffs", depending on their intended purpose.

Fire-fighting pipes should be painted red in the lock-in-place iron parts and where hoses and other devices for extinguishing fires are connected, no matter what happens inside them.

Signs indicating final (open-closed) States in disconnection devices must be.

For automatic adjusting caps and valves usually such marks are required not done. If it is not possible to specify the position of the cranes and locking devices in the way indicated above, it is necessary to mark with a directional arrow or inscriptions.

As a result of dangerous bending and deformation of pipes passed over the ground in order to avoid the risk of an accident and the passing of products, control over the condition of the hooks and stems of the pipes must be ensured. Any malfunctions detected on the hooks and stems of the pipes must be eliminated immediately.

When conducting pipes for crystallizing and gluing liquids, the possibility of cleaning them using Steam, washing them, and if necessary — disassembling them. Places that are convenient to disassemble should be connected by flange tool.

After overhaul, all locking devices for apparatus and pipes and iron are required to be tested for mechanical durability and Hermeticism using compressed air or inert gas pressure. These tests are performed after fitting and chilling-mechanical processing.

Transit technological pipelines with aggressive, harmful and potentially hazardous substances are prohibited from passing over or under buildings, structures and devices.

It is forbidden to leave sliding valves open on non-working apparatus or pipes are.

Temporary non-working apparatus and pipes must be disconnected from working apparatus or pipes.

Frozen pipes cannot be heated using open grass.

The method of placement and transfer of pipes should ensure that the pipes themselves, the locking and adjusting iron and the installation, repair and maintenance of equipment that is connected or located directly on the ground near the pipes can be safely and conveniently carried out.

In the production of injection solutions in the ampoule, material pipes must be equipped with sterilizing devices and locking devices that do not allow products to get into the production rooms and into the drain. On the site of preparation of injection solutions should be a drawing of steaming equipment and communications.

Requirements for workplace safety

Permanent workplaces in pharmaceutical production should be equipped with appropriate furniture (comfortable desk for records, chairs, wardrobe for work and accident instruments),

the necessary individual protective equipment, medical aptechka, a set of production instructions and a fire safety guide.

In workshops, it is impossible to block workplaces, corridors and passages for transport with raw materials, semi-finished and finished products, as well as various items.

It is necessary that the windows intended for internal inspection and cleaning of technological equipment are not blocked.

Metal corrosion-inducing containers are subject to internal inspection every 12 months and must be tested.

Shutters must be provided for the connection of water, steam or inert gas networks for washing and air-assisted cleaning of apparatus with explosive hazardous and toxic substances before repair, internal inspection and testing.

There should be no locking device between the container and the storage valve.

Activated activated ignition faucet can be installed between storage devices and stationary containers designed to operate under pressure of toxic, flammable or explosion-hazardous gases, whereby the switch-on faucet must be mounted in a nozzle that connects the container with the two storage devices, and in any case of the tap probe, one or two of the storage devices must be connected to the container.

The way to calculate the total number of storage valves in the prescribed order determined by.

Storage valves should be placed in places convenient for inspection.

Measures should be taken to ensure that when the storage valves are installed on apparatus (pipes) with a flammable and toxic product, they start in as Little position as possible.

Emissions from the valves installed in the apparatus on the basis of toxic vapors and gases and heavy from the air should be sent to a special closed system, which allows you to return waste products to production. The debris can be thrown into the atmosphere after being decontaminated in a special suction device.

The Storage Plate (membrane) can only be installed before the storage valve, when there is a device between them that allows control of the plate setting.

All storage plates must have a factory stamp and have a plate opener on it the pressure must be indicated.

There are signs of corrosion, bending, scraping areas and other mechanical damage installation of storage planters is prohibited.

In the installation of explosive plates (membranes), it is necessary to take measures to exclude the possibility of separation of harmful and explosion-hazardous gases into the room and the emission of a spark in the event of membrane development, as well as injury from its fragments and parts.

The installation of rupture membranes must be recorded in the appropriate notebook and certified by the signature of the person in charge.

All pressure vessels are required to have sath pointers and storage tubes that do not allow the rods to overflow.

In the flow method of freely pouring bottles with quick-firing liquids filling is prohibited.

Special purpose compressors should be used to compress gases.

The installation and use of autoclaves and the design and use of a special room (autoclave) where an autoclave is being installed are carried out in the manner prescribed by law.

When using autoclaves: safe temperature regime (increase and decrease in the temperature of the autoclaves wall is permissible

speed); ensure the possibility of change in the heat space during the start and stop of autoclaves and control the absence of places where the excitable poles are pinched; continuous supply of condensate from autoclaves when the autoclaves are started and during Operation;

At least once every four years, a complete examination of all welded seams and the metal next to the seam zone (by magnetic-powder defectoscopy or other non-damaging method) is required; the condition of autoclaves must be monitored daily by persons responsible for the safe use of autoclaves and records related to a special notebook intended for this purpose must be noted.

Moving and rotating parts of the apparatus, with straps and studs

there should be removable barriers at the protruding ends of the switches, electrical contacts and shafts.

The work of solving obstacles for the repair of hardware is carried out after the hardware has been turned off and the mechanisms have completely stopped.

After repair, inspection and cleaning work, the operation of the mechanisms is allowed once the fences are installed in the place and all its parts are hardened.

Height at least 0.9 in all passages and mounting places on the beams m.ni the height of the board from below is 0.14 m.ni the barriers that make up must be installed.

204. Fences for cleaning and repair of machines and hardware mechanisms
easy to take or open is necessary.

Regardless of the voltage being used, all electroscopes, electroscopes and fences must be equipped with a cable connected to the ground.

In order to control the presence of porosity of vapors and gases in the air in the production rooms, where flammable gases and vapors can be separated, it is necessary that the automatic signaling instruments produced in the industry are installed.

In the rooms where vapors and gases of sulfur, chlorine, cyanide and phosphorus compounds can be separated, gazanalizers of permissible highest concentrations should be installed instead of signaling signalizers, which indicate the presence of a dangerous amount in terms of explosion.

In terms of porting, the hazard of available quantity alarms can be found in the following

it is necessary to install in order: in the compressor rooms — after taking air samples around the salnik carbines, a single sensor is installed on each compressor;

in pump rooms-after air samples are taken, depending on the placement of pumps, one sensor is installed on the group of pumps conducting one-body products.

All workshops and devices of fire and explosion hazardous production should be provided with telephone communication, and interconnected workshops — if necessary-with signaling about the operation of interconnected units.

All hardware and machines must be provided with the ability to start and stop them while standing in front of the hardware or machine directly from the workplace.

12-practical training.

Equipment for the production of solid drug forms in pharmaceutical production.

Equipment used in the production of solid drug forms in pharmaceutical enterprises and the requirements imposed on them.

Equipment structures and technical and production issues

Technical structures and characteristics of pharmaceutical device and production tool equipment affect the health and safety of workers. Dust separation and volatile vapors are controlled in reducing the concentration of harmful substances and in the production of maxillary tightening ventilation systems. Fire and explosion prevention safety requirements (fire extinguishers, dust vapor-proof equipment, fire and smoke detectors, emergency alarms)

when quick-ignition fluids and pars are used. Safety measures in the transportation of liquids (containers for storage, pumps, pipes), ensuring the Hermeticism of containers when working with solids, isolating production hazardous tools and materials, providing barrier tools to machine rotating parts prevent danger through mechanical means.

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Safety conditions when placing production equipment .Equipment should be placed with the following goals in mind: optimizing the flow of starting raw materials, materials, as much as possible reducing the need for employees to move from one place to another; the possibility of their contamination during the production of medicines

- elimination;

- mixing of different products or non-conduction of production stages

- elimination of risk;

- equipment washing, operation, use and service work

- facilitate; ensure the rational use of the space;

- the fact that the established workplaces comply with the requirements of labor protection norms and rules.

When installing equipment:

- the main corridors along the service at the Hamda control area in the permanent stands of workers — 2 meters; the main corridors along the service of machines, dish apparatus, local measuring instruments-1.5 meters;

- if it is necessary to show the apparatus to the service circuit, the width of the corridors between the apparatus and between the apparatus and the walls of the room-at least 1 m; the width of the corridors for inspection and adjustment of apparatus and instruments on a periodic basis-at least 0.8 meters;

- the width of the corridors between the separate standing pumps — at least 0.8 meters; squares located at an altitude of 0.6 meters or more above the floor level, crossing bridges, stairs, trenches, holes in the trestles should be blocked by a continuous covered fence with a height of — 0.9 meters, from below — 0.14 meters.

Measures to reduce the level of exposure of hazardous and harmful production factors

Equipment of finished medicines manufacturers

it should be hermetic, resistant to chemical influences and not contaminate raw materials, semi-finished and finished products with oxides, metal salts and other impurities.

The apparatus, designed to carry out technological processes in which strong-acting and toxic substances (chlorine, bromine, cyanide acid, cyanide salts, arsenic, etc.) are applied, should be placed in boxing, closures or insulated rooms equipped with local pullers and necessary devices that prevent the spread of harmful substances.

Control questions:

- 1.What are the safety conditions for the placement of production equipment for ?
2. What are Pump Rooms for?
3. What are the requirements for the safety of workplaces?
4. What is the accelerated obsolescence method?
5. How should compressor rooms be designed ?

13-practical training.

Equipment for the production of soft and liquid drug forms in pharmaceutical production.

Equipment used in the production of soft drug forms in pharmaceutical enterprises and the requirements for them.

General requirements for equipment

Equipment used in pharmaceutical production GOST 12.2.003-91 " production equipment. General security requirements" and are required to meet other network documentation requirements.

In order to control the production and quality of medicines, it is necessary to build and place the equipment used to prepare them for use, with the goal of making use and service work as easy as possible.

Equipment and control-the Type, Dimensions and descriptions of measuring instruments should be in accordance with the technological processes being carried out.

The placed equipment should not block natural light and air access to the room through the window from the outside.

Control and measuring instruments must be installed to monitor the continuation of the technological process, ensuring that their serviced parts are illuminated.

The scales and measuring instruments used to prepare medicines and control their quality must be calibrated and examined in generally accepted methods on a periodic basis.

In the production, packaging, storage and transportation of the product, its quality control work, it is advisable to use computer technology.

The equipment in the workshop must be installed with the possibility of freely approaching them. When installing equipment, it is necessary not to leave difficult and uncomfortable places for cleaning, since such places can be a source of waste and dust accumulation.

The following requirements are imposed on the construction of the equipment:

a) it is necessary that the starting raw materials, semi-product or finished product contact surfaces of the equipment are made of a smooth and non-toxic, corrosion-resistant material that is resistant to treatment with disinfectants;

b) all parts of equipment that come into contact with production products must be removable and detachable to make them easier to wash, work with disinfectants or sterilize;

C) in order to prevent contamination of finished products and their quality from changing in a negative way, the equipment should not be contaminated with the materials used for their use (for example, lubricants;

g) all transmission devices (transporters, valuable transmissions, transmission privods) must be closed or blocked;

d) bunkers, containers and other similar equipment must be closed;

e) tables for cleaning, washing and disinfection of all technological dishes, apparatus and other equipment on a periodic basis should be drawn up and they should indicate washers and disinfectants. The tables are developed by the head of the workshop and approved by the chief engineer of the enterprise.

According to the schedule approved by the chief engineer of the enterprise in accordance with the current technological equipment, repair system and legislative acts of the installed equipment for proper use, it is necessary to carry out preventive examination of equipment and take all measures for their repair.

Preparation of the equipment for work should be carried out according to the instructions for working with disinfectants or sterilizing it.

The quality of the equipment's readiness for operation should be monitored according to the established procedure when the equipment is treated with disinfectants or after its working parts have been sterilized.

The equipment used for the production of a single type of medicinal product must be cleaned in a way that does not allow different categories of the product to mix.

The equipment used for the production of several names of medicines must be diligently cleaned from the contents of the washing water, until the medicinal substances contained in the prepared medicine are completely eliminated.

Before producing the next designation of medicines, the equipment must be washed, treated with disinfectants or sterilized according to the specified requirements.

The equipment used for the production of antibiotics is not used for the production of other medicines in order to prevent opposite (reverse) contamination.

Production of soft medicines

In order to prevent thermal burns, it is necessary to carry out work with solutions of Vaseline, lanolin, other substances applied to the preparation of spermacete in appropriate special clothing, subject to the temperature and time regime in accordance with a separately carefully prescribed procedure using protective equipment.

It is necessary to grind, sift and mix the powdery substances that are part of the flavors into boxing with as high a compaction or aspiration as possible.

In the process of processing the concentrate in colloidal Mills, shesterenkal pumps and uving machines, it is necessary to control that the equipment is equipped with a wire connected to the ground from static electricity, the rotating and moving parts are protected by cojuses and fences.

Packaging and packaging of flavors and pastes should be carried out in automatic networks.

The process of using automatic networks for the preparation, packaging and packaging of soft forms of the drug should be carried out in strict compliance with safety rules.

It is forbidden to carry out cleaning, troubleshooting until the networks are completely stopped.

During the conduct of the technological process in order to avoid accidents, oils that have fallen on the floor should be regularly washed and cleaned with soapy water and other detergents.

It is forbidden to use paraffin, gasoline and other organic solutions for washing.

It is necessary to collect oil-soaked wiping materials into a special metal container and remove them from the production rooms in time.

Features of equipment for the production of sterile products

The main requirements for such equipment come from its purpose - the production of sterile products. It requires compatibility with cleaning rooms, adaptation to the sterilization process, guaranteed implementation of their functions.

GOST R 52249-2009 (Annex I, paragraphs 56-60) imposes specific requirements on equipment working in the production of sterile drugs, specifically:

if the conveyor belts are not constantly sterilized (for example, in a sterilization tunnel), they should not pass through the separation barrier between zones A or B and production zones with low air purity;

The structure of the equipment should have the opportunity to place the front part in a clean room and the possibility of maintenance from a non-clean place;

In the process of designing water treatment and distribution systems, selecting equipment, installation and maintenance, the necessary water quality must be ensured. It is not allowed to exceed the design capacity of water treatment equipment. Preparation, storage and distribution of water for Injection should be carried out in such a way as to prevent the proliferation of microorganisms, for example, due to the constant circulation of water at temperatures above 70 ° C.;

The weight of critical equipment (sterilizers, air preparation and filtration systems, air and gas filters, water preparation, storage and distribution systems, etc.) must be tested (certified) and scheduled service provided.

Below are examples of equipment not meeting GMP requirements:

Technological equipment:

Does not comply with GMP and is not certified;

purchased before the start of the design and does not correspond to the project and design assignment;

elements of single complexes are purchased from different suppliers, which makes it difficult to configure and certify;

the equipment is outdated;

foreign companies, under GMP equipment, supply of unsuitable products;

the manufacturer does not have a representative, and if the user is deprived of assistance in working, it is difficult or impossible to return to a foreign factory due to the customs procedure;

according to the documents and records on the front panel, the equipment was produced in a country known for its high quality; when the equipment failed and the cabinet panel was dismantled, it was found that everything was done badly and in a completely different place in the world.

There are many types of equipment for the production of medicines. This is the result of different dosage forms and the requirements for them. At the same time, there are basic requirements that must be met for any processes and types of equipment. Examples include the characteristics of equipment for the manufacture of rigid forms, requirements for water and compressed air.

Technological equipment must perform the functions required by this process and meet GMP requirements. These requirements are constantly improved, detailed and to some extent tightened, but the general logic of the requirements remains unchanged. The requirements of GOST R 52249-2009 (EU GMP) and the requirements of the US cGMP regulations are listed below.

Such requirements are true for any production, but for the pharmaceutical and medical fields they are strictly mandatory.

General requirements. GMP regulations (GOST R 52249) define the following requirements for technological equipment:

- equipment must be purposeful;
- the equipment must be suitable for cleaning and maintenance;
- cleaning products, inventory and materials should not be a source of pollution and collect pollution;
- it is necessary to design and place equipment, eliminate as much pollution or improper behavior as possible;
- the equipment should not compromise the quality of the product and pose no risk;

- the accuracy of the instruments and the measurement scale must meet the requirements for the parameters they control;
- parts of technological equipment that come into contact with the product should not react with it, release (or adsorb) substances that affect the quality of the product.

Control questions.

1. GMP regulations (GOST R 52249) specify the following requirements for technological equipment
2. Equipment design, its dimensions and location
3. GMP regulations specify the following requirements for automatic, mechanical and electronic equipment, cleaning and servicing equipment and filters
4. Measuring instruments used for general purposes are
5. What should the design of the equipment provide
6. Will measuring instruments installed on technological equipment be dismantled
7. Technological equipment must ensure the compliance of the product with the specified requirements, including which parameters
8. Does the work area and materials (products) come into contact with the environment in open processes
9. Indicate the causes of contamination when preparing for production and during its use
10. How many groups are the surfaces of technological equipment divided into

14 practical training.

Primary packaging materials and requirements for them. Primary and intermediate packaging materials and requirements for them.

The preparation of medicines from medicinal substances is the main goal of the pharmaceutical enterprise. In this case, the first raw materials and auxiliary, cutting and labeling materials are used.

A well-structured package of documents as necessary is an integral part of the quality assurance system of finished products. It must be associated with all sections of this rule and reflect its basic requirements.

The production process must be carried out in strict compliance with the technological regulation, in which the requirements of the rule are reflected. This ensures that the finished product of the desired quality is obtained.

Primary raw materials

Pharmaceutical enterprises must have a regulatory and technical document approved in the prescribed manner for primary raw materials.

The production enterprise must have an approved enterprise standard and include;

- raw material statement containing name, conditional mark and code;
- links to existing regulatory documents;
- to indicate those who are likely to supply raw materials, to agree with them regulatory documents, to indicate the size and duration of the raw materials to deliver;
- guidelines for sampling and access control;
- requirements for quality, taking into account the production classification;
- precautions when using raw materials and storage in appropriate conditions;
- term or date of use of raw materials. Further quality inspection is required after this;

When receiving raw material series, the presence of documents indicating the information on the supplier's Whirlpool blank, the analytical passport, the correctness of the shipping letter

and labels, the non-damage and cleanliness of the packaging, the quality of the raw materials is checked. Each series of raw materials being obtained is registered.

If at once the same raw materials from several different series were obtained, the sampling should consider each series separately, carry out access control on the basis of a regulatory document, and provide an indication for use in production.

The resulting raw materials are subject to access control based on the current documents, for which the average naamuna from all series of raw materials is selected.

Samples are selected in specially equipped rooms, subject to conditions that prevent additional contamination of raw materials. As far as possible, the sampling should be taken under the supervision of another employee, only an authorized employee of the quality control department. Controlled samples should be kept under appropriate conditions for another year after the expiration date.

Deviations from the requirements of the regulatory document, as well as damage to the packaging, which can affect the quality of the initial raw materials, must be registered.

The raw materials obtained must be provided with a label and the following information:

- product name, conditional mark and or code;

- serial number;

- shelf life or date. Further quality inspection should be required after this. In this case, it is advisable to use a color label. In the process of passing the control stages, labels are replaced (for example, raw materials were given or deemed unsuitable for use).

Raw materials should be stored in rooms separated from the main production. In order to prevent the mixing and contamination of raw materials, separate rooms or places should be allocated for the purpose of making, storing and giving the bark. Employees who are competent in storage should have easy access to the room where the raw materials are stored.

At the time of working with raw materials, it is required to strictly adhere to the applicable sanitary, hygienic and technical safety standards.

If the raw materials comply with the requirements of regulatory and technical documents, the technical control department is transferred to production with the spirit. It is necessary to register raw materials that are being transferred and reserved.

It is necessary to leave a sufficient number of samples from each series of raw materials for repeated analytical control.

First of all, the series that fell before the enterprise, with the spirit of belonging to the quality control department, should be used.

A competent sex worker must carry out weighing and measuring raw materials used in production on the scales on the basis of a written instruction. Before weighing and measuring on the scales, it is necessary to make sure that the raw material can be used and the capacity is branded. Weighing on the scales should be carried out under the supervision of one employee 2

In order to prevent secondary contamination, it is necessary to attach special importance to the conditions of delivery of primary raw materials to the production site.

All components that are part of sterile drugs must be subjected to regular microbial contamination testing.

All components that are part of the sterile drug should be examined for regular sterility or microbial contamination, and, if necessary, pyrogenicity. The expressed amount of microorganisms must be specified in the enterprise standard separately for each type of raw

material. It is necessary to determine the amount of mechanical particles in primary raw materials at the required points.

The re-labeling of raw materials deemed unsuitable must be returned to the supplier or disposed of. It must be formalized with relevant documents.

Raw materials should be obtained only from suppliers registered by the main Department of quality control of medicines and medical equipment of the Ministry of health of the Republic of Uzbekistan.

Intermediate products, if necessary, must be tested in accordance with the requirements of the industrial regulation.

It is necessary to enter and verify in the minutes that the amount of the intermediate product deviates significantly compared to that of the approved or project (including the Unpacked product).

Medicinal substances and their classification.

Any classification is made conditionally. It can be straightened, filled or developed later.

To date, two main types of the following classification of medicinal substances are distinguished:

1. According to the origin of the drug substances.
2. According to the pharmacological activity of medicinal substances.

Classification of medicinal substances by Origin. It is divided into two main large groups:

1. Passed the primary processing process (cleaning from impurities, drying, sorting, etc.), substances of mineral, plant and animal nature of origin:

- mineral medicinal substances (drinking soda, activated charcoal, medicinal Honeysuckle, etc.);

- medicinal plant raw materials (assemblages, leaves, herbs (ground tops), flowers, fruits, seeds, roots, rhizomes, bark, etc.);

- medicinal substances obtained from animals (medicinal substances obtained from the internal secretion glands of domestic animals).

2. Synthetic or semi-synthetic drug substances obtained through targeted synthesis or through the processing of Tabby raw materials.

These are divided into the following subgroups:

1. Chemicals. This type of medicinal substance is an individual chemical substance by nature, obtained by synthesizing or refining natural raw materials in terms of origin (sodium chloride, sodium sulfate, silver nitrate, hydrochloric and sulfuric acids, sodium bicarbonate, calypermanganate, sodium thiosulfate, etc.);

2. Chemical-pharmaceutical drug substances. These are chemically individual substances in nature and are obtained through complex synthesis pathways. For example, sulfonamides (streptocide, norsulfazole), anti-tuberculosis drug substances (ftivazide), sleeping and pain medication substances, anti-malaria drug substances (bigumal), etc. This group also includes substances that are obtained cleanly from plants and animals of biologically active substances origin. For example, alkaloids and glycosides can also be cited as a separate group, again with different radioactive isotopes (radioactive iodine).

3. Antibiotics. They are obtained by biological synthesis, by growing microorganisms in a nutrient medium, being considered products formed as a result of the life activity of various microorganisms. Examples include penicillin from microorganisms, streptomycin, biomycin,

gramicidin, etc. Antibiotics obtained synthetically are considered methicillin, Oxacillin, as well as antibiotics belonging to the cephalosporin group, which have a wide range of action.

4. Vitamins. These include individual synthetic chemicals (ascorbic acid, thiamine, nicotinic acid, cyanocobalamin, etc.) as well as complex substances with a macromolecular structure (concentrates, extracts and syrups).

5. Organopreparations. They are substances obtained mainly from animal organs, and are obtained mainly from tissues and fluids of animal organs. Organopreparations as a biological substance are complex substances that retain substances of a hormone nature in their composition. There is an icon to take some of them clean (adrenaline), and there is a chance to get some of them synthetically (sex hormones). Organopreparations also include enzymes (pepsin).

6. Vaccines and serums. These are immunobiological medicinal substances produced by vaccine and serum, immunological, epidemiological, microbiological and hygiene institutes and sanitary and epidemiological stations.

7. Substances obtained as a result of the primary processing of medicinal raw materials (essential oils, oil and oil products obtained from plants and animals)

Classification according to the scope of pharmacological action. This is divided into three main large groups:

1. Toxic substances.
2. Strongly acting substances.
3. Weakly acting substances.

Toxic and strongly acting substances - are divided into therapeutic, toxic and lethal (lethal) doses. Therapeutic influences are divided into single dose (minimum, average, single peak, percussive, supportive, and preventative), daily dose (therapeutic, maximum absorption, toxic), and treatment doses (prescribed during the course of treatment).

Medicines and drug forms, their classification.

The effectiveness of drugs depends on their drug form. That is why the following individual students are put in drug forms:

- to be mutually proportional to the form of the drug with the treatment method;
- to have the drug substance in the form of the same drug has a high bioavailability;
- manifestation of targeted pharmacokinetics;
- equal distribution of drug substances in the composition of auxiliary substances;
- division into exact doses;
- the fact that the upper in the storage process manifests stagnation;
- microbial contamination and compliance with their standards;
- availability of conservation options as needed;
- to be comfortable in receiving;
- be able to eliminate the unpleasant taste and smell of the drug substance;
- it is necessary to be compact and comfortable.

Today, the following classification of drugs based on various homogeneous laws by drug forms exists in practice:

1. By aggregate state of drug forms
2. According to the ways of sending

In the packaging of ready-made medicines, the types of packaging can be primary or

secondary. Primary packaging types will be 3 different:

1. Solid packaging: — metal packaging (balloons, greases, creams, pastes, liniments and tubas for gels) for aerosol drug types; — glass packaging: cans (powders, granules, tablets, dragees, capsules, pharmaceutical solutions, greases, creams, pastes, liniments, gels and infusion solutions) and ampoules (injection solutions); — cans made of polymers (powders, granules, dragees, capsules, pharmaceutical solutions, greases, creams, pastes, liniments, gels and infusion solutions). 2. Semi-finished packaging: — packaging made of cardboard paper (medicinal plant raw materials and assemblies made from them);-packaging made of polyethylene: syringe-tubes (for injection solutions), tubes for drops (m for ingested solutions for the eye), contour — slots (for suppositories); - combined cans: blisters (for capsules, capsules and suppositories). 3. Soft packaging: - Polymer Packages (for powders, granules and plastics); — paper packages (for tablets, dragees, plant raw materials and assemblies made from them; - convolutions (for tablets, dragees and capsules). The operations of the technological process should be carried out in previously clearly defined styles. In order to obtain a quality product, they must obey the Basic Rules of good production practice, have the appropriate license for production and a full set of recording documents. The technological process should be carried out and monitored by employees who have the authority to it. Actions such as obtaining substances, materials and products and quarantining, sampling, labeling, preparation and distribution, processing, packaging and distribution should be carried out on the basis of written methods or instructions, and, if necessary, formalized in the form of a statement. All incoming substances and materializing must undergo inspection to guarantee compliance with the order. When necessary, the packaging container must be cleaned and labeled with the necessary information provided. All sorts of reasons that may indicate an unpleasant effect on the quality of a substance or material, or a violation of the packaging container, formalized as a statement, information about which should be communicated to the quality control department. Incoming materials and finished products must be quarantined separately or through appropriate administrative measures from the time they are obtained or processed until their use is allowed. In cases where intermediate or unpackaged products are purchased, they must be treated as raw materials.



All substances, materials and products must be made in the appropriate order for the series created by the manufacturer and the Reserve turnover in the warehouse to be kept separate. To make sure that there are no deviations from the permissible norms, it is necessary to check the outputs and compare the amounts. Except in cases where there is no risk of intermingling and cross contamination, work related to different products cannot be carried out at the same time or at the same place. Products, substances and materials must be protected from microbes and other contaminants at each stage of processing. In the case of dry matter and

products, precautions should be taken to prevent dust formation. This is especially important in work involving sensitizing and strongly acting substances. All materials used, unpacked product comb, basic equipment and, if necessary, rooms must be labeled with the name of the product or substance being processed throughout the process and its activity (if necessary) and serial number. In possible situations, such tabs should also indicate the stage of the technological process. Labels glued to Tara, equipment or rooms should be understandable, represent a single m organ, and their shape should be in the form adopted at the enterprise. In many cases, in addition to the information presented on the label, it is very useful to have them in different colors (for example: in quarantine, accepted, unsuitable, clean, etc.).k.). Inspections should be carried out that assess the correct connection of the pipes and other parts of the equipment used in the transportation of products from one zone to another. It is necessary not to deviate from guides and styles as much as possible. If deviations from them are observed, this should be recorded in writing by a competent boigan employee, with the participation of the quality control department when it is found. Access to production rooms should only be allowed to employees who are authorized to do so. As a rule, non-medical products should not be prepared in zones and equipment intended for the production of medicines.

Starting raw materials and specifications of primary or printed mower materials, if permissible, must maintain the following:

- a) classification of raw materials or materials, including: - a link to the given name and internal code; - a link to the pharmacopoeia monograph, if any; - the name of the approved suppliers, if possible, the manufacturer of the product; - a sample of rolling materials;
- b) links to guidelines or styles for sample selection and testing;
- d) requirements for qualitative and quantitative determination with the indication of permissible limits;
- e) storage conditions and precautions; maximum shelf life up to re-Control.

Intermediate and non-packaged products must be purchased, sold or intermediate product m advantages to assess the quality of the finished product, to which there are specifications. the same specifications should be compatible with raw materials or finished product specification i series. Finished product specifications may include: a name given to the product and a reference to the code in the case of need; content or reference to it; exhaustive information on the classification and packaging and label of the drug form; instructions for sampling and analysis reference to this method; requirements for qualitative and quantitative clarifications with the indication of permissible limits; storage conditions and, if necessary, what special precautions in drug circulation; shelf life. Packaging materials and requirements for them should be instructions on the packaging, which is officially approved for the size and type of packaging of a drug. As a rule, they contain the following information or links to them: the name of the drug; classification of the drug form and, in cases of need, the mechanism of its action (activity, concentration or mass of the drug substance); quantity of preparation expressed in number, mass, or volume in the last wrapper; full list of all the Reaper materials you will need for a standard size series, each Reaper material specification with size, including quantity, code, or number, given size and type; appropriate printed Reaper materials luiuunas or copies and samples of them with product serial number and shelf life; special precautions subject to compliance, which include inspection of the zone and equipment, to make sure that the line is cleaned before starting work;-classification of the winding process along with all the main

auxiliary operations and the equipment used in this; —complete classification of control in the production process with sample selection instructions and permissible limit indicators. The minutes of each prepared Series or the series of scrolls on its part should be kept. It should be based on the relevant parts of the instructions on the scroll, and the method of preparing the statements in question should not cause errors in copying. The statement must indicate the serial number and quantity of the unpackaged product, as well as the planned quantity and series of the finished product to be obtained. Before starting any trench operations, the tool equipment and work zones must be checked and stated that the previous products, documents and materials that are not required for the planned process are exempt, and the tool equipment is clean and ready for use. The information on the actions that each will do must be stated; when the operations are completed, the statement must be agreed, the date must be indicated and signed by the person in charge of the packaging operation and include the following information: - product name; - the date and time of the packaging operation; - the signature of the responsible person who carried out the packaging operation; - the surnames of the operators of various important stages; — the details of the verification of exactly the same and compliance with the instructions for the packaging, including the results of production control;- detailed information on the operations carried out on the packaging, including; - displays serial numbering, shelf life and other additional printed records, including samples of used, printed scroll materials, in cases where possible; complete information on particular problems and unusual circumstances;

Talabalar bilimini tekshirish uchun savollar.

1. Konteynerlarning maqsadiga ko'ra tasnifi.
2. Idishlar qattiqligiga tasnifi
3. Yordamchi qadoqlash materiallariga nimalar kiradi.
4. Birlamchi qadoqlash uchun maxsus talablar.
5. Konteynerlarning dizayni bo'yicha tasnifi.
6. Aerosol ballonlari qanday qadoq turiga kiradi?
7. Mahsulotlarni atrof-muhit ta'siridan, buzilish va yo'qotilishdan himoya qilishni ta'minlaydigan qadoq vositalar to'plami qanday nomlanadi?
8. Qadoqlash sifati darajasi qanday ko'rsatkichlarning kombinatsiyasi bilan baholanadi?
9. "Quruq joyda saqlash" daqanday namlik nazarda tutiladi?
- 10 To'g'ridan-to'g'ri mahsulotga yoki uning qadog'iga qo'llaniladigan va iste'molchi uchun zarur bo'lgan ma'lumotlarga ega yozuvlar, belgilar qanday nomlanadi?

15-Practical Training.

Marking and secondary packaging of finished products. Recycling and neutralizing pharmaceutical production waste

Requirements for packaging and packaging of medicines

Primary Reagent materials used in the manufacture of medicines must meet the following requirements::

- protection of drugs from the effects of an unfavorable external environment;
- avoid mechanical influences;
- easy to use daily;

- to be tasteful in appearance.

Pharmaceutical enterprises should create directives that cover all aspects of dealing with primary cutting materials (methods of preparation, use and quality control). The implementation of this work guarantees that the cleanliness in terms of Mechanical, Chemical and microbial contamination of the primary cutting materials is at the required level.

In the preparation of primary mowing materials (ampoules, vials, jars, caps. valves, plugs, etc.) it is necessary to use materials that do not affect the irritability of drugs and the properties of pharmacotherapy.

Possible deviations from the shape, size and size of the primary Reaper materials must meet the requirements of the relevant standards.

All primary mowing materials must comply with specially designed and approved network standards or enterprise guidelines and must come from suppliers to the enterprise in a packaging that ensures their entire storage and prevents secondary contamination during the storage period.

The cutting material must be kept in a separate room in conditions that do not mix and do not get dirty. First of all, the cutting material with the appropriate spirit of the quality control department, obtained before the enterprise, should be used. It is necessary to eliminate old or outdated primary cutting materials and formalize this with jujjat.

When transporting prepared primary mowing materials from one room to another, special devices, containers are used that prevent secondary boron contamination or mixing.

When wrapping medicines intended for children, it is advisable to use disposable packages with heat-insulating plenks. Multi-use wraps containing ingested solutions, syrup and suspensions should be concentrated with dosages, taking into account the age of the child. Aimed at children,- it is forbidden to place drugs that have a strong effect on the packaging, which are used many times. All types of packaging of medicines intended for children should be branded as distinguishable.

Injection drugs (ampoules, vials, rubber stoppers) should be checked for the absence of mechanical particles in the primary winding materials. In the production of non-sterilizing injection drugs in the primary packaging, in addition, their sterility, the state of pyrogenicity at the required points should be controlled.

The sterility and pyrogenicity of the initial sickle materials can be tested on certain occasions if validated during the preparation process.

At the enterprise, it is necessary to have instructions that reflect the rules for the reception and validity of plows and materials, inspection of workplaces and equipment, the procedure for wrapping and labeling.

The finished product should have a clear label. The content and records of the label must comply with the requirements established in the current regulatory and technical documentation for each specific drug. When labeling products, it is advisable to use coding, which facilitates identification in an automated way.

Marking can be in the form of special tabs or directly lowered to the surface of the primary wrapper.

The preparation of labels and other printed materials should be organized in such a way that their intermingling is eliminated.

The necessary labels and other printed materials for the mesh should be stored in special rooms in containers with closures. Labels and medicines of each individual name it marking materials, dosage of medicines should be kept separately. They are issued only if there is an appropriate written order.

The marking of labels from the storage room and taking them to the packaging line should be arranged in such a way that they are guaranteed not to get confused with labels that are intended for counterfeiting or marking other medicines, raw materials or auxiliary materials.

Outdated, defunct tabs, marking and wrapping materials, as well as serial number and other unused informative tabs should be destroyed and formalized with a document.

When transporting ready-made medicines, in order to ensure their integrity, they must be wrapped a second time and placed in a tara group, in addition, in accordance with the current regulatory and technical documentation.

The marking of the secondary packaging must comply with the requirements of the current regulatory and technical documentation. It is also necessary to have information about the number of primary reeds in one box.

The marking of the general packaging must comply with the requirements of the current regulatory and technical documentation and the marking of the secondary packaging.

When the finished product is removed from the premises of the enterprise, the compatibility of the secondary and general packaging marking is once again checked by employees allocated for this purpose.

Medicines in a common taraga trench must be transported on top closed vehicles, in accordance with the requirements of the current regulatory and technical documentation and the rules of Transportation.

In the process of wrapping and marking, measures should be provided that warn against contamination with each other, interference or mistaking another for one type of product instead.

If the range of technological paths is not separated by obstacles, it is impossible to wrap the drugs directly close to each other.

Marking should be carried out immediately after the product is embedded in the primary winding material and sealed. If Marking (Labeling) is postponed error marking, measures must be taken to prevent confusion and confusion with another product.

When the plowing process is complete, all unused plowing and marking materials with a serial number are missing, must be done.

Labeling, transportation and storage of ready-made medicines. All documents that determine the movement of medicines and medical products must be prepared for submission at the request of the relevant responsible organizations. Documents reflecting the reception and shipment of medicines and medical items should include the following information about the product: name of the product, quantity received or delivered, series/batch, name and address of the supplier, manufacturer factory or cargo recipient, license, certificate, date of preparation, shelf life, storage conditions, guaranteed obligations for medical item products, etc. This account must have provided the conditions for all follow-up actions performed with respect to any series/batch of drugs and medical items. The documents must be in the conditions that ensure proper use until the expiration date according to the regulation established by the legislation of the Republic of Uzbekistan. Documents must be stored in a paper or electronic state. The statements should be completed in such a way that at the time of each work process, it is possible to observe all important actions and phenomena in it. Statements should be clear and easy to read. Recycling and neutralizing pharmaceutical production waste

The second condition for the creation of waste - free technology is the analysis of its relationship with previous and subsequent technological processes: an environmental solution that is successful for a particular technology can be undesirable for the environment and (moreover) makes production significantly environmentally hazardous in general. In other words, you cannot solve your problems at the expense of others and at the expense of others.

The third condition is that the optimal technological process should not only be environmentally friendly, but also be distinguished by high productivity, minimum living and past labor costs spent per unit of production. The fourth condition is a critical reaction to decisions that seem simple and easy. At first glance, conventional wastewater and exhaust gas treatment is the simplest solution. It looks the most convenient and solves all the problems. In fact, the use of cleaning interferes with solving the main task - to develop or improve the technological process, when waste does not come out or when they are used. In other words, it is necessary to eliminate the cause of waste and not fight the consequences. The fifth condition for the creation of waste - free technology is the use of technical solutions that ensure the reliable, stable and trouble-free operation of the technological system, which excludes the release of components harmful to the environment even when technological equipment is off-plan. Various cleaning agents and methods allow you to choose the most suitable cleaning method and scheme for a particular production work.

The most important criteria for choosing the final scheme of its organization in order to ensure the futility or low waste of the technological process are:

- 1) unconditional adherence to the norms of the content of substances in air and water bodies;
- 2) effective implementation of the technological process;
- 3) the use of possible cost-effective (taking into account compliance with the first two requirements) technological schemes for cleaning gases and liquids;
- 4) ensure the possibility of obtaining a small amount of concentrated waste, which is easier to neutralize;
- 5) negligible volume of liquefied hazardous waste, which is lowered into water and dispersed in the atmosphere, even less than the maximum allowable concentrations.

The following directions will be the basis for the organization and development of safe industrial production: 1) complex processing of raw materials; 2) development of new technologies that can significantly reduce or completely eliminate the harmful effects of industrial waste on the environment; 3) development of effective methods for cleaning gas, liquid and solid industrial waste; 4) introduction of closed technological cycles, water circulation cycles and; 5) cooperation of different industries to use some waste as raw materials for others; 6) create without problems

Production waste is raw materials, materials, semi-finished products, chemical compounds that are formed during the production of products or the performance of works (services) and have completely or partially lost their initial consumer properties. Consumer waste-products and materials that have lost their consumer properties as a result of physical or spiritual deterioration. Emissions from production and consumption are secondary material resources (SMRS) that can currently be reused in the national economy. Waste can be toxic and dangerous. Toxic and hazardous waste is contained in or in concentrations that are contaminated with materials of this type or where they pose a potential threat to human health or the environment. In the Russian Federation, about 7 billion tons of waste are generated every year, only 2 billion tons are reused, i.e. about 28%. About 80% of the total volume of used waste - hardened and enriched waste - is sent to replenish the processed area of Mines and open-pit mines; 2% is used as fuel and mineral fertilizer, and only 18% (360 million tons) is used as secondary raw materials, of which 200 million tons are used in the construction industry. On the territory of the country, about 80 billion tons of solid waste are collected in landfills and warehouses, hundreds of thousands of hectares of land are removed from economic circulation; waste collected in landfills, landfills and landfills is a source of pollution of surface and groundwater, atmospheric air, soil and plants. The accumulation of toxic and environmentally hazardous waste in landfills and landfills, the total amount of which reaches

1.6 billion tons, can lead to irreversible pollution of the individual environment. Almost 75 billion tons of highly toxic waste are produced in Russia every year, of which only 18% is processed and neutralized. The total area of organized warehouses for toxic waste is 11 thousand hectares, unorganized warehouses and waste are not taken into account, according to some data, about 4 million tons of extremely toxic waste are disposed of. It should also highlight the problems associated with the formation of solid waste and sewage sludge. In the Russian Federation, 140 million m³ of solid waste is produced annually. The small number of 10,000 hectares of land around the city were alienated to eliminate solid waste landfills, excluding solid "waste" waste. The problem of solid waste processing in Russia is practically unresolved, the total capacity of waste processing and incineration plants is 5 million m³ per year, i.e. activated carbon dioxide. the solid waste produced is only 3.5% of the total volume. The total annual amount of sewage sludge is 30-35 million m³, or by dry matter - 3-3.5 million tons; they are diverse in quality composition and properties, and contain a large amount of ions of heavy metals, toxic organic and mineral compounds and petroleum products. Most of the problems are the removal and processing of unresolved formed sediments in treatment facilities, which leads to uncontrolled disposal of liquid toxic waste into water bodies. A large part of the environmental pollution is unorganized landfills around garden cooperatives and summer cottages. In many cities, in each courtyard, huge "deposits" of household waste were formed around each house, which were not removed and rotted for several months. In a number of cities, lakes under oils and diesel fuel were accidentally found. Near the Kursk oil base, at a depth of 7 m, a "field" of diesel fuel and gasoline with a volume of about 100 thousand tons was found, covering an area of up to 10 hectares. Similar "deposits" were found in Tula, Orel, Rostov and Kamchatka. Small rivers die from unaccounted flows, in particular, in the regions of Kalmykia, Bashkortostan, Belgorod, Voronezh, Saratov, Chelyabinsk, Vologda. All of these examples may be related to unaccounted environmental pollution-chronic environmental mismanagement. If we conditionally perceive the general environmental disorder as 100%, then an important part of it - 30-40% - corresponds to the consequences of local management. This is a huge reserve for improving the habitat of people. In modern conditions, the problem of recycling accumulated waste is becoming one of the priority problems that must be solved immediately in order to maintain the environment and its own health.

In mastering this topic, students were used the method of pedagogical technology of the "case-stadi" method.

The purpose of the method: "Keys-stadi" is an English word, ("case" - Clear situation, phenomenon, "stadi" – learn, analyze) is a method aimed at carrying out training based on the study, analysis of specific situations. Stages of implementation of the Keys method

Work stages	Form of activity and content
Stage 1: Introduction of Keys and its information support	• individual audio-visual work; • * acquaintance with the situation; • * generalization of information; • • information analysis; • * problem detection

Stage 2: identifying a problem situation-setting a traction and problem assignment	• individual and group work; • * determination of the relevance hierarchy of problems; • * setting the main problem situation
Stage 3: search for a problem assignment solution, solve road-rini development	• individual and group work; • development of alternative solution paths; • * analysis of the capabilities and obstacles of each solution; • * selection of alternative solutions
Stage 4: formulation and justification of a problem assignment solution	• work alone and in a group; • * justification of the possibilities of putting alternative options into practice; • * preparation of creative-project presentation; • * coverage of the final conclusion and practical aspects of the situation solution

Questions to check student knowledge.

1. Requirements for the labels of Veterinary Medicines and medicines for medical use.
2. General requirements for labels.
3. Requirements for tag text.
4. List of auxiliary substances indicated on the secondary packaging of medicines (veterinary products).
5. . Features of the finished product.
6. What represents the value of commercial products?
7. In what case is the shelf life on the packaging of drugs written?
8. What does the date on the packaging of the tablets mean?
9. Classification of industrial waste.
10. Features of industrial waste and pollution.
11. Regulation of industrial waste collection.
12. Collection, accounting, storage and transportation of waste.
13. Features of industrial waste and pollution.
14. Activate solid waste incineration.
15. Activate liquid waste incineration. Activating methods.
- 16 pyrolysis and gasification of production and consumption waste.
17. Plasma-chemical method of neutralization and disposal of waste.
18. Plastic waste disposal and recycling technolog

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№	Independent educational topics	Clock size	Competencies
Semester 3			
1	Enterprises operating in pharmaceutical	5	Research, Learning,

	production and their types		Development
2	Production control and technological process control	5	Research, Learning, Development
3	Lightning protection of the production water supply system, buildings and structures	5	Research, Learning, Development
4	Technical preparation of production, Planning technical preparation	5	Research, Learning, Development
5	General description of production, Types of production.	5	Research, Learning, Development
6	Basic concepts and terms of pharmaceutical production.	5	Research, Learning, Development
7	Organizational structure of quality departments of pharmaceutical production enterprises	5	Research, Learning, Development
8	Mudflat system of pharmaceutical development, good production practice (GMP).	5	Research, Learning, Development
9	Materials used in pharmaceutical production. Material balance	5	Research, Learning, Development
10	The main elements of structural schemes of industrial buildings, criteria for the placement of auxiliary buildings and	5	Research, Learning, Development

	rooms		
11	Pharmaceutical production organizational structure of the process.(On the example of types of solid and liquid drugs)	5	Research, Learning, Development
12	Providing clean air to buildings and rooms in the production of farmsteads	5	Research, Learning, Development
13	Definition of GXP concepts, national, regional GMP rules	5	Research, Learning, Development
14	Documentation of pharmaceutical production enterprises	5	Research, Learning, Development
15	Modern evaporators and their technical characteristics.	5	Research, Learning, Development
16	Chemical and technological systems of production. General concepts	5	Research, Learning, Development
17	Modern filters.Placement of equipment in pharmaceutical Productions	5	Research, Learning, Development
18	Documentation, control of the production process.	5	Research, Learning, Development
18	Equipment used in the chemical-pharmaceutical and biotechnology industries	5	Research, Learning, Development
19	Pharmaceutical production technological classification of equipment	5	Research, Learning, Development
20	Pharmaceutical production requirements for	5	Research, Learning, Development

	equipment and their productivity indicators		
21	Pharmaceutical production equipment maintenance and cleaning.	5	Research, Learning, Development
22	Pharmaceutical production equipment used to store substances in warehouses	5	Research, Learning, Development
23	Pharmaceutical production equipment used to store raw materials in the workshop	5	Research, Learning, Development
24	Apparatus scheme of production. General concepts	5	Research, Learning, Development
Total:		120	

GLOSSARIY

	O'zbekcha	Ruscha	Inglizcha	Ma'nosi	
				O'zbekcha	Ruscha
1.	Aseptik sharoitlar	Асептические условия	Aseptic conditions	tayyor mahsulotga mikroorganizmlar yoki mexanik zarrachalar tushib qolishini istisno qiluvchi steril dori moddalari yoki tayyor dori vositalari ishlab chiqarish sharoiti.	это комплекс технологических и гигиенических мероприятий обеспечивает защиту продукта от попадания в него микроорганизмов на всех этапах технологического процесса.

2.	Tayyor dori vositasi	Готовые лекарственные средства	Finished medicinal product	davolash hususiyatiga ega bo'lgan dori shakli xususiy iste'molchiga davolash uchun qulay bo'lgan shaklda sotishga tayyorlangan dori vositasi.	лекарственное средство, предназначенное для отпуска индивидуальному потребителю в удобной для применения (дозированной) форме.
3.	Validatsiya	Валидация	Validation	ishlab chiqarish sharoiti, texnologik jarayoni, jihozlar, yarim tayyor mahsulot va tayyor mahsulot sifatini belgilangan talablarga mosligini hujjatlar asosida tasdiqlash.	действия, которые в соответствии с принципами надлежащей производственной практики, доказывают, что определенная методика, процесс, оборудование, система, деятельность или система действительно приводят к ожидаемым результатам.
4.	Ventilyatsiya yalangan havo	Вентиляционный воздух	Ventilation air	ventilyatordan ventilyasion tizimga kelayotgan va ishlab chiqarish xonasining tegishli darajadagi tozaligini ta'minlovchi tozalangan havo.	воздух соответствующей степени очистки, поступающий с помещения через вентилятор или вентиляционную систему и обеспечивающий соответствующий чистоту производственного помещения.
5.	Havo shlyuzi	Воздушный шлюз	The airlock	tozalikning turli darajalariga mansub xonalar orasidagi tutash joyga —tozal xonaga mexanik zarrachalar va mikroorganizmlar kirishini oldini olish maqsadida	Установленное в замкнутом пространстве устройство, предотвращающее проникновение механических частей или микроорганизмов, или

6.	Karantin	Карантин	Quarantine	xom ashyo, yordamchi, o'rov, markalash materiallarining, yarim tayyor mahsulotning alohida joyda saqlanayotgan yoki ularni ishlatishga qaror chiqarilguncha sotilish va foydalanishni ta'qiqlaydigan huquqiy xolatlardir: sotilish, yaroqsizlarni ajratish yoki qayta tiklash.	статус исходного сырья, вспомогательный, упаковочный, маркировочный, промейточной, нерасфасованной или готовой продукции, изолированной физически или другим эффективным способом, после того, как производство продукции производится решение
7.	Sifat	Качество	Quality	tayyor mahsulot xususiyati va undan foydalanish uchun belgilangan standartlarga ya'ni ro'yhatga kiritilgan texnologik jarayonni asosiy parametrlariga mosligini aniqlab beruvchi belgilar yig'indisidir.	совокупность свойств и характерные продукты или услуги, которые придают им возможность удовлетворять обусловленные или предполагаемые потребности потребителя
8.	Xonaning tozalik darajasi	Класс чистоты помещений	Class of cleanliness of premises	xonaning —tozal yoki —tozalik darajasi 1 m ³ havoda ma'lum kattalikdagi mexanik zarrachalar va mikroorganizm miqdoriga qarab belgilanadi.	статус "чистой" зоны или "чистого" помещения, устанавливающий границы содержания механических частей определенного размера и / или
9	Ishlab chiqarish jarayoni nazorati	Контроль процесса	Control of the production process	tayyor mahsulot sifatini me'yoriy hujjat talablariga mosligini ta'minlash uchun chiqarilayotgan mahsulotni ishlab chiqarish jarayonini kuzatish maqsadida tegishli texnologik parametrlarga korrektirovka kiritishni bosqichma-bosqich nazorat qilish turlarini amalga oshirish. Atrof muhit va jihozlar tozaligi nazorati ishlab chiqarish jarayoni nazoratining bir qismi hisoblanadi	виды контроля, включаемая постадийный контроль, выполняемые во время производства с целью наблюдения за производственным процессом и при необходимости корректировки технологического соответствия требований к качеству нормативная документация. Контроль окружающей среды и чистоты оборудования является частью контроля процесса производства
10	Dori moddalar i yalar	лекарственные вещества (субстанции)	Medicinal substance	ishlatishga ruhsat berilgan tabiiy va sun'iy biologik faol moddalar.	разрешенное к применению уполномоченным на органу соответствующей страны вещества природного, синтетического происхождения, обладающее биологической активностью.

11	Dori vositalari	Лекарственные средства	Medicinal products	profilaktika, diagnostika va davolash uchun foydalanishga ruxsat berilgan bir yoki bir necha dori moddalari (substansiyasi), tabiiy va sun'iy ravishda olingan qo'shimcha moddalardir. Bular qatoriga immunobiologik, radiofarmatsevtik preparatlar, gomeopatik, diagnostika va sterilizatsiya vositalari kiradi.	Это вещества или смеси веществ, разрешенное к применению для профилактики, диагностики, лечения заболеваний, полученные методами синтеза или с применением биологических технологий. К лекарственным средствам относятся иммунобиологические, радиофармацевтические, гомеопатические препараты, средства диагностики и стерилизации.
12	Material balans	Материальный баланс	Material balance	nazariy olinishi mumkin bo'lgan va amaliy olingan tayyor mahsulotni	сравнение теоретически возможного и практически полученного
	Seriya raqami	Номер серии	Series number	seriyaning bir xilligini taqqoslash va shu seriyani olishdagi ishlab chiqarish hamda nazorat qilish operatsiyalarining bajarilish ketma-ketligini aniqlashga yordam beruvchi raqamli harfli yoki harf-raqamli belgilar.	цифровое, буквенное или буквенно-цифровое обозначение, которое специфически идентифицирует серию и позволяет определить всю последовательность производственных и контрольных операций, ведущих к получению данной серии.
	Ishlab chiqarish chiqindilari	Отходы производства	Waste	tayyor mahsulot ishlab chiqarish jarayonida olinadigan qo'shimcha mahsulot.	Остатки сырья, материалов, гирь, образовавшиеся в процессе производства, и утратившие полную или частично исходные потребительские свойства.
	Bir tomonlama havo oqimi (laminar oqim)	Однонаправленный у поток воздуха (ламинарный поток воздуха)	Unidirectional air flow (laminar air flow)	bir xil tezlikdagi ko'ndaloang kesim bo'ylab bir tomonlama o'tadigan parallel havo oqimi (chiziqli oqim).	воздушный поток с параллельными, как правило, струями (линиями тока), протекающими в одном направлении с одиночной в поперечном сечении скорости.

	Ishlab chiqarish (ishlab chiqarish jarayoni)	Производство (производственный процесс)	The production process	tayyor dori vositalarini ishlab chiqarish operatsiyalarini ya'ni xom ashyo, birlamchi o'rov, markalash materiallari va qo'shimcha, yarim tayyor mahsulotlarni sotib olishda ularni tayyorlash, o'rash, sotishga ruhsatnomalar olish, saqlash, transportirovkalash va tayyor mahsulot sifatini nazorat qilish kabi ishlarni o'z ichiga olgan tamoillardir.	это совокупность действий работников и средств труда, в результате чего из сырья, материалов, полуфабрикатов комплектующих изделий, поступающих на предприятие, превращаются в готовую продукцию или услуг в заданном количестве, качества и ассортимента в определенные сроки. Производственный процесс состоит из основных, вспомогательных и обслуживающих процессов.
	Yarim tayyor mahsulot	Полупродукт	Intermediate product	dori vositasi bo'lishdan avval ishlab chiqarish jarayonining keyingi bosqichlarini o'tishi lozim bo'lgan qisman ishlov berilgan xom ashyo yoki dori moddasi.	Частично обработанное сырье или лекарственное вещество, которое должно быть дальше дальнейшие стадии производственного процесса, прежде чем на станет готовым лекарственным средством.
	Seriya	Серия	Series	muttasil sharoitda bir ishlab	определенное количество

MODUL DASTURI

MINISTRY OF HEALTH OF THE REPUBLIC OF UZBEKISTAN

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ORGANIZATION OF PHARMACEUTICAL PRODUCTION MODULAR PROGRAM

Field of knowledge:	900 000	- Health and Social Security
Education sector:	910 000	- Health
Direction education:	60910800	-Industrial Pharmacy (by type)

TOSHKENT –2023

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The modular program was developed at the Tashkent Pharmaceutical Institute.

The module program was reviewed and recommended at the Board of the Tashkent Pharmaceutical Institute (2023 "30" 08 statement in "9").

Relevance of training modulinig and its role in higher education

President of the Republic of Uzbekistan on April 20, 2017 PQ-2909 "measures for the further development of the higher education system", on May 5, 2017 PQ-2956 "measures for the further reform of the medical education system in the Republic of Uzbekistan", on July 27, 2017 PQ-3151 "measures for the further expansion of the participation of sectors and sectors of the economy in the, PQ-3775 of June 5, 2018 "on measures to improve the quality of education in higher educational institutions and ensure their active participation in the comprehensive reforms carried out in mamalakat", PQ-4310 "on measures for the further development of the system of medical and Pharmaceutical Education and Science module".

The module program covers the prospects for the far future of the science and practice of preparation technology in the production of medicines in the conditions of pharmaceutical production enterprise.

2. Purpose and objectives of the training module

2.1. Purpose of the module:

It consists in the organization of pharmaceutical production in students, the formation and development of their concepts on the technology of preparation in the conditions of the enterprise, teaching them to clearly state their reasoning and conclusions in a reasonable way, and the formation of skills and competencies in the acquired knowledge. The prospects for pharmaceutical production and its development, good production practices, materials used in the manufacture of medicines and their requirements, documentation of the production of medicines, training of documents and the formation of skills for their implementation in practice.

Requirements for employees in the production of medicines in students, Technical Safety, Fire Safety and production sanitation, ensuring the quality of medicines, ensuring stagnation and determining the expiration date, and drawing up a general Pharmacopoeia article for medicines, regulations consists in teaching the requirements of the present time and generating the skill to implement them in practice.

2.2. Module functions:

Theoretical foundations, basic concepts of the science of Organization of pharmaceutical production, its goals and objectives, methodological approach to preparing and assessing the quality of forms of step-by-step teaching students to the level of implementation of practical skills from theoretical education, introducing modern pedagogical technologies into the course process, increasing the level of thinking and maintaining the student's knowledge, stages, it consists in the formation of the main directions of scientific investigations in the field of technology of drugs in the conditions of the enterprise.

Pharmaceutical production requirements for employees in the production of medicines in the conditions of the enterprise, technical safety, fire safety and production sanitation, ensuring the quality of medicines, ensuring stagnation and determining the shelf life, as well as establishing a general Pharmacopoeia article for the types of drugs to be prepared, drawing up regulations, the procedure for controlling the quality of drug types based on, the organization of the workplace in laboratory and enterprise conditions consists in formulating the use of regulatory documents, reference and scientific literature in solving problems in the specialty, making the necessary calculations based on the physicochemical and technological properties of substances.

2.3. Requirements for knowledge, skills and qualifications of students by module:

4 at the end of the semester

4 credit

Students:

- preparation of medicines in the conditions of the enterprise, regulatory documents necessary for this technology, requirements for it,
- materials used in pharmaceutical production and requirements for them,
- equipment and apparatus,
- documentation of the production of medicines in pharmaceutical production,
- study of the requirements for documents in pharmaceutical production in the conditions of the enterprise
- drawing up a general Pharmacopoeia article, regulations for types of drugs,
- to have an idea about the choice of the procedure for controlling the quality of drug types in pharmaceutical production on the basis of MH;
- requirements for employees in pharmaceutical production;
- Technical Safety, Fire Safety and production sanitation;
- to the general and specific preparation technologies for them on the preparation of the type of Medicine;
- the pharmacist can know how to work with the equipment used in production and be able to use them;
- correct Organization of technology and processes in the preparation of medicines in pharmaceutical production;
- correct selection of starting materials used;
- use of equipment and apparatus necessary for the preparation of medicines;
- adjust the appropriate parameters to the operating mode;
- must have skills to improve productivity.

3. Main part

3.1. Topics and content of lecture sessions in the module, general instructions and recommendations for organization

semestr 4

Theme 1. The main goals of the development of the pharmaceutical industry.

The main concepts and terms of the science” organization of pharmaceutical production”. International requirements in pharmaceutical production. GMP requirements.

Introduction to the science of organizing pharmaceutical production. The main concepts and terms of the science of organizing pharmaceutical production. Organization of the pharmaceutical network development agency and its tasks.

What is GMP itself? In the modern world, the rules of GMP - the rules for the production of medicines are mandatory. Struggle for quality: facts of history, determination of GMP rules, GMP history, regulatory documents on GMP, principles of work on GMP, equipment and apparatus used in the preparation of medicines

Theme 2. Design of premises for pharmaceutical production. Requirements for buildings and buildings. Sex system in pharmaceutical production. Chemical, technological and hardware scheme of production.

Master Plan of the enterprise. General plan and regulatory rules of construction. Production zone. Classification of production by explosion, fire-explosion and fire hazard. Personnel discharge. Fire hazard levels of external devices. Transport communications.

Categories of industrial buildings. Requirements for industrial buildings. Main production buildings. Auxiliary-production buildings. Service buildings.

Sex system in the production of solid, liquid and soft drugs in pharmaceutical production. General concepts about the chemical, technological and hardware scheme of production.

Theme 3. Documents. Internal and external documents. State standards and enterprise standards. Regulations and their types. Drawing up regulations.

Purpose and requirements for documents, language and style of the document, procedure for developing documents, basic types of documents, information about the company. Industrial regulations, technological instructions and packaging instructions, documents and modifications, acceptance and control of materials, certification of processes and equipment, execution of technological processes, procedure for the use of buildings and equipment, internal production control, control of finished products. Analysis of deviations from technical characteristics, complaints analysis.

Regulations and their types. Laboratory regulation, experimental industry regulation, technological regulation. Regulation drafting guidelines.

Technological regulations of production. Laboratory regulation. Production regulation. Provisional regulation. Principles of regulation. Production basis of the

project. Development stage and composition of the project. Technological department-the basis of the project. Certification and examination of the project. The cost of the project and the cost of the object. Simple design errors. Selection of equipment. Construction and installation.

Theme 4. Drawing up a pharmacopoeia article for substance and drug forms.

The name of the drug in Latin, state and Russian languages. International nonpatent name. Chemical name on IYUPAK students. Structure and empirical formulas, as well as molecular mass. The amount of the acting substance. Description. Solubility. Integrity. Melting, hardening or boiling temperature. Light breaking indicator. Comparative absorption indicator. Comparative angle of inclination. Clarity of the solution. Solution color.

Theme 5. Technique and fire safety. Pharmaceutical production sanitation.

Labor protection and security at the enterprise is a set of activities necessary to protect workers when performing the task of the employer. Industrial safety. General requirements for industrial safety. Special safety requirements. Instructions for preparing an evacuation plan. Protection of workers from injuries. Rules for working on the territory of the enterprise and basic safety rules. To prevent safety regulations on workers, dangerous places in workplaces and accidents.

Theme 6. Qualification of the ventilation system. Heating, air conditioning and lighting system in pharmaceutical production.

Ventilation system in the production of farmastevtic. Requirements for the air of a clean room. Modern filters. Types of filters. Requirements for a clean room. Principles of operation of the filter. Requirements for filters.

Particles in the air of cleaning rooms, filtration with an Air Fiber filter, mechanisms for holding fragments. Filtration with Air Fiber filters. General condition. Specific requirements for employees engaged in the production, control and processing of medicines in the rules of GMP.

Theme 7. Clean rooms in pharmaceutical production, their classification and requirements for them.

Particles in the air of cleaning rooms, filtering with an Air Fiber filter, mechanisms for holding fragments. Water treatment, water used for pharmaceutical purposes. Preparation of purified water. Storage and distribution of purified water. Storage and distribution of water for injection. Filtration with Air Fiber filters. General condition. Specific requirements for employees engaged in the production, control and processing of medicines in GMP regulations

Theme 8. Requirements for employees in pharmaceutical production.

Recruitment. Attitude to work. Employee movement. Cleanliness and hygiene. Technological clothing. State of Health. Executive discipline and responsibility. Selection of personnel. Order. Cleanliness and hygiene. Preparation for work.

Theme 9. Production, storage, transportation and acceptance of material and raw materials in pharmaceutical production. Requirements for the warehouse.

Production, storage, transportation and acceptance of material and raw materials in pharmaceutical production. Requirements for the warehouse. Temperature control in the warehouse.

Theme 10. Preparation, storage and distribution of water in pharmaceutical production.

Water treatment, water used for pharmaceutical purposes. Preparation of purified water. Storage and distribution of purified water. Storage and distribution of water for injection.

Theme 11. Buildings and equipment for the production of sterile drugs.

Buildings and production site in the production of sterile drugs, technological requirements, technological process, cleaning rooms. Ventilation and air conditioning systems, what and how much should be produced, nomenclature and volume of production, all buildings and rooms necessary for production. The specific composition of buildings, buildings and networks depends on the task. The main thing is not to miss important elements and ensure the balance of power throughout the production chain.

Theme 12. Equipment for the production of solid drug forms in pharmaceutical production. Equipment for the production of solid drug forms in pharmaceutical production. Their structure and principle of operation.

Theme 13. Equipment for the production of soft and liquid drug forms in pharmaceutical production. Equipment for the production of soft and liquid drug forms in pharmaceutical production. Their structure and principle of operation.

Theme 14. Primary raw materials, primary and intermediate packaging materials. Requirements for them. Primary raw materials, primary and intermediate packaging materials. Requirements for them. Packaging materials used in primary hom ash packaging. The packaging tools stood. Requirements for drug instructions.

Theme 15. Marking and secondary packaging of finished products.

Recycling and neutralizing waste from pharmaceutical production.

Pharmaceutical production in pharmaceutical manufacturing enterprises in the processes of preparation of medicines eliminate waste. Methods of waste processing at the stages of waste processing, the equipment used. Their structure and principle of operation.

semestr 4 (4 credit)

Theme 1. The main goals of the development of the pharmaceutical industry. The main concepts and terms of the science" organization of pharmaceutical production". International requirements in pharmaceutical production. GMP requirements.

Theme 2. Design of premises for pharmaceutical production. Requirements for buildings and buildings. Sex system in pharmaceutical production. Chemical, technological and hardware scheme of production.

Theme 3. Documents. Internal and external documents. State standards and enterprise standards. Regulations and their types. Drawing up regulations

4- subject. Compilation of a pharmacopoeia article for substance and drug forms.

Theme 5. Technique and fire safety. Pharmaceutical production sanitation.

Theme 6. Qualification of the ventilation system. Heating, air conditioning and lighting system in pharmaceutical production.

Theme 7. Clean rooms in pharmaceutical production, their classification and requirements for them.

Theme 8. Requirements for employees in pharmaceutical production.

Theme 9. Production, storage, transportation and acceptance of material and raw materials in pharmaceutical production. Requirements for the warehouse.

Theme 10. Preparation, storage and distribution of water in pharmaceutical production.

Theme 11. Buildings and equipment for the production of sterile drugs.

Theme 12. Equipment for the production of solid drug forms in pharmaceutical production.

Theme 13. Equipment for the production of soft and liquid drug forms in pharmaceutical production.

Theme 14. Primary raw materials, primary and intermediate packaging materials. Requirements for them

Theme 15. Marking and secondary packaging of finished products. Recycling and neutralizing waste from pharmaceutical production.

3.2.2. General instructions and recommendations for organizing practical training in the module:

Laboratory classes on this teaching module are conducted by one teacher to one academic group in an auditorium equipped with multimedia structures.

When conducting practical exercises, the following didactic principles are followed:

- to clearly define the purpose of practical training;
- to arouse interest in students in the possibilities of deepening knowledge of innovative pedagogical activity of the teacher;
- ensuring the opportunity for the student to independently achieve the result;
- the formation of the skills of students to be able to put into practice the knowledge gained in theory and draw conclusions.

3.2.3. Practical skills and competencies that are acquired during the

training of the module.

The list of practical skills acquired during the module:

It is envisaged that during the transition period of educational practical exercises, students will master the following practical skills:

1. Correct Organization of technological processes in pharmaceutical production;
2. The correct choice of starting materials used in the production of Farmastevtik;
3. The use of equipment and apparatus necessary for the production of farmastevtics;
4. Adaptation of the appropriate parameters of the equipment to the operating mode;
5. Increase the productivity of equipment.

List of competencies (name, code) that are occupied during the module:

UK 1. Ability to abstract thinking, analyze, synthesize;

UK 2. Self-development, self-awareness, self-education, the ability to use creative potential;

UK 3. Willingness to work in a team, tolerant acceptance of social, ethnic, confessional and cultural differences;

UK 4. Readiness to apply first aid techniques, protection methods in emergency situations;

UKG 1. Readiness to solve the standard tasks of professional activity using information, bibliographic resources, medical terminology, information and communication technologies and taking into account the basic requirements of Information Security;

UKG 2. Readiness for communication in Russian and foreign languages in oral and written forms to solve problems of professional activity;

UKG 3. Ability and willingness to analyze the results of their activities to prevent professional mistakes;

UKG 4. Readiness to use basic physical, chemical, mathematical and other natural science concepts and methods in solving professional problems;

UKG 5. Ability to participate in scientific research;

UKG 6. Willingness to participate in the implementation of new methods and techniques aimed at protecting the health of citizens.

General instructions and recommendations for organizing practical training during the module:

In practical training, the process of training in practical skills is planned in detail and involves several stages:

1. The first stage – the motivational basis for studying the learned practical skill, based on the purpose and tasks of the training, is determined, the theoretical

aspects of which are discussed. To implement practical skills, students are introduced to the mechanism of working with the necessary equipment, the rules of operation. For the implementation of the first stage, the department has all the equipment and must be in working condition.

2. The second stage is to demonstrate practical skills and perform practical work. The step-by-step algorithm of practical skills for the implementation of this stage is prescribed by the teacher and through videos, with a special emphasis on the correct implementation of practical work on the basis of the algorithm in stages. The student performs the practical skill independently, but under the supervision of a teacher.

Practical skills developed by the Department for the implementation of the second stage are the step-by-step algorithm and video, educational-methodological manual, execution scheme or technique, etc.k., evaluation criteria must be developed. Equipment, reagents and necessary conditions must be created. At this stage, the teacher controls and corrects errors in the work of students when necessary. In this process, student actions can be video-recorded and self-addressed, critically discussed. The student will explain to the teacher and other students what his mistake is. Interactivity is manifested in the fact that other students participate in this as experts and assess whether the student being taught has mastered the practical skill correctly.

3. For the implementation of the third stage, a set of educational and methodological manuals, situational tables and tests developed by the Department, Keys, should be used. Interfaith is manifested in the fact that other students participate in this not only in the performance as experts and in assessing the correct mastery of the practical skill of the student being taught, but also in the work in the team.

4. The fourth stage is the conclusion. At this stage, the teacher must make sure that he is able to correctly and fully apply the knowledge and acquired skills acquired by the student in various homogeneous situations, in the process of activity, and then the practical skill is considered mastered.

At the end of the training, the teacher confirms that each student has mastered the practical skill. In situations where the student is not able to master practical skills, it is recommended to master independently at extracurricular times and re-entrust it to the teacher. The student is considered to have mastered the module, having mastered all practical skills.

Types of control of student knowledge on the module and evaluation criteria.

The degree of student mastery by module is determined through the following types of control:

- current control (CC);
- intermediate control (IC);
- final control (FC).

The 4 credits allocated to the module are collected by the student in 4 semesters under current supervision. The loans allocated to the module are allocated by type of control as follows:

current control (CC);

In current control, it is envisaged to determine and evaluate the degree of acquisition of knowledge, practical skills and competencies of the student on modular topics. On the module for the organization of pharmaceutical production, JN can be carried out in oral, teacher-control tests, work with distribution materials, situational issues, verification of tasks assigned to the house and other forms.

The assessment takes into account the student's level of knowledge, mastery of practical training materials, the level of activity of his participation in the discussion of theoretical material and interactive methods of education, as well as the level of practical knowledge and skill acquisition, competence acquisition (Yani theoretical, analytical and practical approaches). In each session, all students are required to be evaluated. The maximum score is 100, the passing score is 56 points.

The 6 credits allocated for current control are distributed as follows:

semestr 4

Pharmaceutical production general information about enterprises and general principles of Organization, general and private technologies of production. Objectives and objectives of pharmaceutical technology. classification of drug forms. Tools and apparatus used in their preparation. General information on the technology of preparation of medicines in the conditions of the enterprise and the basics of its organization, medicines and auxiliary substances used in the preparation of medicines, technological processes, equipment and apparatus used in the preparation of their performance standards and increasing productivity. What is GMP itself? In the modern world, the rules of GMP - the rules for the production of medicines are mandatory. Struggle for quality: facts of history, determination of GMP rules, GMP history, regulatory documents on GMP, principles of work on GMP, equipment and apparatus used in the preparation of

medicines - 2 credits

Buildings and production site, technological requirements, technological process, cleaning rooms. Ventilation and air conditioning systems, what and how much should be produced, nomenclature and volume of production, all buildings and rooms necessary for production. The specific composition of buildings, buildings and networks depends on the task. The main thing is not to miss important elements and ensure the balance of power throughout the production chain. Particles in the air of cleaning rooms, filtering with an Air Fiber filter, mechanisms for holding fragments. Water treatment, water used for pharmaceutical purposes. Preparation of purified water. Storage and distribution of purified water. Storage and distribution of water for injection. Filtration with Air Fiber filters. General condition. Specific requirements for employees engaged in the production, control and processing of medicines in the rules of GMP. General. Recruitment. Attitude to work. Employee movement. Cleanliness and hygiene. Technological clothing. State of Health. Executive discipline and responsibility. Selection of personnel. Order. Cleanliness and hygiene. Preparation for work - 2 credits

Technological regulations of production. laboratory regulation. Production regulation. Provisional regulation. Principles of regulation. Production basis of the project. Development stage and composition of the project. Technological department-the basis of the project. Certification and examination of the project. The cost of the project and the cost of the object. Simple design errors. Selection of equipment. Construction and installation - 2 credits.

At the end of the semester, the student who scores less than the qualifying score in the current control by module is the academic debtor.

Academic indebted students are given a period of one month to re-master after the end of the semester. During this period, a student who has not mastered the module is excluded from the ranks of students by order of the rector in the prescribed manner on the recommendation of the dean of the faculty.

intermediate control (IC);

0 credits are allocated to intermediate control: in the 4th semester, intermediate control is carried out 1 time. On to 0 credits are allocated. A student who does not receive a full loan from JN is not admitted to on. Onda is envisaged to determine and evaluate the degree of acquisition of knowledge, practical skills and competencies of the student on modular topics. On the organization module of pharmaceutical production can be carried out in such forms as oral, test or written work.

The maximum score is 100, the passing score is 56 points.

In intermediate control, a student who scores less than a qualifying (passing) score and is unable to participate in controls for excuses is given a deadline until the next same control Round, the final control for final intermediate control. Students who have not attended classes due to illness and have not been able to delegate intermediate supervision within the specified periods are allowed to submit within two weeks of starting their studies, according to the order of the dean of the faculty. At the end of the semester, the student who scores less than the qualifying score in the intermediate control by module is the academic debtor.

Academic indebted students are given a period of one month to re-master after the end of the semester. During this period, a student who has not mastered the module is excluded from the ranks of students by order of the rector in the prescribed manner on the recommendation of the dean of the faculty.

If the student collects 6 credits in the 4th semester from the "Organization of pharmaceutical production" module and receives a qualifying score from the moment, he will have mastered the "Organization of pharmaceutical production" module and will receive a referral to the Yan.

The student ranking by module is determined as follows:

rating	ECTS	Definition of ECTS		mark	Description
86-100	A	scope = "row" / 2018 – excellent result, with minimal errors	have systematic, complete and in-depth knowledge of all sections of the module program, be able to substantiate with the necessary evidence; clear, in-place use of terminology (including in scientific, foreign language), logically, stylistically literate expression of questions; can identify problematic questions, substantiate their views in a scientific and practical language; the module is able to know the basic concepts and effectively apply it in solving scientific and practical issues in a short time; able to independently and creatively solve problems in non-standard situations, show the ability; able to independently fully perform	5	excellent

			practical skills (in terms of quality and set number) and fully acquire competencies; its brief, grounded and rational resolution of practical issues; complete and deep slimming of the main and additional literature recommended in the module program; understanding the essence of theories, concepts and directions on the module, giving them a critical assessment and being able to apply the scientific achievements of other modules; it is necessary to participate creatively and independently throughout the entire semester in theoretical and practical classes, be active in group discussions, have a high level of culture in the performance of tasks.		
81-85	B	"very good" - a higher result than the middle, with some errors	have systematic, complete and in-depth knowledge of all sections of the module program, be able to substantiate with the necessary evidence; clear, in-place use of terminology (including in scientific, foreign language), logically, stylistically literate expression of questions; be able to independently bartaf the non-determinants that arise in proving one's opinion or in making another theoretical material; knowledge of the basic concepts of the module, the ability to put scientific and professional tasks in a short time and make the most of it in solving; be able to independently solve problems in standard situations within the framework of the training program; able to independently fully perform practical skills (in terms of quality and set number) and fully acquire competencies; the fact that in practical training he	4	Very good

			demonstrates a good knowledge of regulatory legal documents, is able to apply this knowledge in new situations to the full (but not always rational), is not able to adequately formalize the results of the work performed; mastering the main recommended literature in the module program; able to understand the essence of theories, concepts and directions on the studied module and give them a critical assessment; it is necessary to participate creatively and independently throughout the semester in theoretical and practical classes, be active in group discussions, have a very good level of culture in the performance of tasks.		
71-80	C	"good" - the average result with significant errors	have a systematic, complete and in-depth knowledge of all sections of the module program, be able to substantiate with the necessary evidence, but with some shortcomings; clear, in-place use of terminology (including in scientific, foreign language), logically, stylistically literate expression of questions; be able to independently eliminate the inaccuracies that arise when proving one's opinion or stating another theoretical material; knowledge of the basic concepts of the module, the ability to put scientific and professional tasks in a short time and make the most of it in solving; be able to independently solve problems in standard situations within the framework of the training program; able to independently complete practical skills (in terms of quality and set number) and acquire competencies, but with some disadvantages; the fact that in practical training he		

			demonstrates a good knowledge of regulatory legal documents, is able to apply this knowledge in new situations to the full (but not always rational), is not able to adequately formalize the results of the work performed; mastering the main literature recommended in the module program; able to understand the essence of theories, concepts and directions on the studied module and give them a critical assessment; in theoretical and practical classes, he must participate creatively and independently throughout the semester, be active in group discussions, have a good degree in the performance of tasks.		
60-70	D	"satisfactory" - a sluggish result, with rough flaws	To have sufficient volume of knowledge within the framework of state educational standards (requirements); using terminology, correctly stating answers to questions, but making some mistakes; demonstrate that he has a basic understanding of the module when he has difficulty responding or demonstrating some special skills; Able to fully perform practical skills (in terms of quality and set number) independently, but with errors; taking competencies independently, but with errors; can have partial knowledge of the general concepts of the module and apply it to solving standard (model) situations; the educator can solve standard situations with the help of an employee; able to understand the essence of the main theories, concepts and directions on the module under study, to evaluate	3	satisfactory

			them; in theoretical and practical training, the educator must participate with the help of an employee, have a sufficient level of culture in the performance of tasks.		
56-59	E	"middle" - equal to the minimum result	To have a satisfactory volume of knowledge within the state educational standards (requirements) ; using terminology, correctly stating the answers to questions, but making some gross mistakes in this; to demonstrate that it has a basic understanding of the module when it is difficult to respond or to demonstrate some special inclusions and make mistakes; perform practical skills (in terms of quality and set number) are not independent and complete with errors. competencies are not independent and occupy with errors; can have partial knowledge of the general concepts of the module and apply it to solving standard (model) situations; the educator can solve standard situations with the help of an employee; able to understand the essence of the main theories, concepts and directions on the module under study, to evaluate them; in theoretical and practical training, the educator must participate with the help of an employee, have a sufficient level of culture in the performance of tasks.		
31-55	FX	"unsatisfactory – - additional independent mastering is necessary in order to obtain a	If the state has only some fragmentary knowledge within the standards (requirements) of Education; can not use scientific terms or make serious logical errors in response; participate passively in theoretical and practical training and perform tasks if they have a low level of living culture;	2	unsatisfactory

		minimum level of knowledge	if he does not have practical skills and competencies, he cannot correct his mistakes even with the help of the recommendations of a Hatto pedagogical employee.		
0-30	F	"absolute unsatisfactory" – complete re-appropriation	If the state has only some fragmentary knowledge within the standards (requirements) of Education; when it cannot use terms or makes serious and gross logical errors in response or does not respond at all; participate passively in theoretical and practical training, perform tasks, if they have a low level of culture or do not perform at all; If he does not have practical skills and competencies, he cannot correct his mistakes even with the help of the recommendations of a Hatto pedagogical employee.		

Final control (FC)

A student who has fully accumulated the credit allocated to the JN and has completed the on will be included in the Yan. YaNda the knowledge, skills and qualifications of the student are evaluated within the general content of the module. YaN is conducted in written form after the end of modular training. YaN tickets are drawn up, consisting of three questions. A student who fails to score a Yanda qualifying score (56%) is considered to have not passed Yanda and did not master the module (even if JNda has collected the full credit).

The process of conducting final control with the participation of the commission, established by order of the rector of the educational institution under the direction of the Department of internal control and monitoring, is periodically studied, and in cases where the procedures for conducting it are violated, the results of Final control are canceled and final control is transferred again.

Students who cannot submit Yan due to illness are allowed to submit within two weeks of starting their studies under the orders of the dean of the faculty.

At the end of the semester, the student who scores less than the Yanda qualifying score is the academic debtor.

Academic indebted students are given a period of one month to re-master after the end of the semester. During this period, a student who has not mastered

the module is excluded from the ranks of students by order of the rector in the prescribed manner on the recommendation of the dean of the faculty.

If the student is dissatisfied with the results of the control, within a day from the time of publication of the results of the type of control on the module, he can apply to the dean of the faculty with an application. In this case, according to the submission of the dean of the faculty, by order of the Rector, an appeals commission is established in a composition of no less than 3 (three) members.

The appeals commission will review the students' applications and report their conclusion on the same day.

The conduct and formalization of the assessment on the basis of established requirements is monitored by the dean of the faculty, the head of the department, the training department and the Department of internal control and monitoring.

4. Independent education and independent work, instructions and recommendations for organization

4.1. Subject list of recommended independent work:

Semestr 4

1. The main elements of constructive schemes of industrial buildings
2. Criteria for the placement of auxiliary buildings and rooms
3. Household rooms and standards for their design
4. Ventilation and air conditioning system
5. Production water supply system
6. Lightning protection of buildings and structures
7. Technical preparation of production
8. Planning technical preparation
9. General description of production
10. Types of production.
11. Forms of Organization of production
12. Introduction to the science of organizing pharmaceutical production, prospects for the development of production.
13. Basic concepts and terms of pharmaceutical production.
14. Muddying the system of pharmaceutical development.
15. Good Manufacturing Practice (GMP).
16. Chemical, technological and hardware scheme of production.
17. Pharmaceutical production organizational structure of the enterprise.
18. Materials used in pharmaceutical production.
19. Material balance
20. Description of the types of drugs technological processes.

21. Description of raw materials, materials and intermediate products.
22. Requirements for clean rooms in production
23. Heating production rooms, ventilation, condensing and lighting.
24. Primary raw materials and primary molding materials. Marking and secondary packaging, finished products.
25. Documentation. Requirements for documents.

4.2. Forms of recommended independent work:

When preparing an independent work, the student is recommended to use the following forms, taking into account the characteristics of a particular module:

- completion of individual assignments on the specified topics in independent education;
- writing a written home work (synopsis) on topics allocated to independent work;
- writing abstracts based on information from scientific, educational, foreign literature and internet sites;
- drawing up problematic issues, keys and tests;
- Preparation of presentations and multimedia (videos) on "Power Point".

4.3. General instructions and recommendations for the organization of Independent Education and independent work:

It is mandatory for students to delegate independent educational tasks on the module of Organization of pharmaceutical production.

Independent work on this module is carried out in the auditorium and outside the auditorium.

Taking into account the features of the module of Organization of pharmaceutical production, as well as the degree and ability of academic mastery of each student, the following forms are used in the organization of independent work of students:

4 semesters

- the formation of features of students in the performance of independent work, their deep mastery of the subjects taught, creative approach in the performance of tasks and educational and research work, striving for independent thinking and regular improvement of their knowledge and skills;
- solving situational, problem-oriented situational issues;
- drawing up crosswords, making organizers, etc.
- independent assimilation of certain theoretical topics with the help of educational literature;
- preparation of information (Abstract) on a given topic;

- carry out tasks to the house, independently study new knowledge from additional textbooks and literature, search for the necessary information and determine ways to find them, collect data using internet networks and conduct scientific research, prepare scientific articles and lectures within the framework of a scientific circle or independently using scientific sources;
- solving situational, problem-oriented situational issues;
- drawing up crosswords, making organizers, etc

Instructions and recommendations for the organization of production practices

The practice of production is aimed at strengthening the theoretical knowledge presented in the educational process and the formation of practical skills of students. On the subject of Industrial Pharmacy, production practices are planned, and local enterprises producing ready-made medicines are designated as the base of practice. The practice of production includes strengthening the theoretical knowledge gained at the institute with experiments formed in production, the management system of the enterprise, the organization of production, the requirements for rooms. The tool used in production helps to generate practical skills in equipment.

5. Main and additional educational literature and information sources

5.1. Main literature

Main literature

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3. Береговых В.В., Сапожникова Э.А., Джалилов Х.К., Кузьмичева Е.Л., Пятигорская Н.В. Теоретические основы технологии лекарственных средств. Ташкент "Fan va texnologiya" 2011. С. 244. (ўқув қўлланма)
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6. Чуешов В.И., Гладух Е.В., Сайко И.В. и др. Технология лекарств промышленного производства. Учебник для студ. высш. учеб. завед.: Перевод с укр.: Ч.1. – Винница: Нова Книга, 2014. - 696 с. (дарслик)

Additional literature

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2. Mirziyoev SH.M. Qonun ustuvorligi va inson manfaatlarini ta'minlash yurt taraqqiyoti va xalq farovonligining garovi. "O'zbekiston" NMIU, 2017. – 47b.

3. Mirziyoev SH.M. Buyuk kelajagimizni mard va olijanob xalqimiz bilan birga quramiz. "O'zbekiston" NMIU, 2017. – 485 b.

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Internet sites

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2. <http://medbuy.ru/articles/oborudovanie-dlya-farmaceuticheskogo-proizvodstva>
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**SYLLABUS FROM THE MODULE FOR THE ORGANIZATION OF
FARMASTEVTIC PRODUCTION
(For Semester 3)**

Syllabus from the module for the organization of farmastevtic production			
Full name of the module	Organization of pharmaceutical production		
Code module:	Loan size: 4 credits Hence: CC-2 credit IE-2 credit IC-0 loan (transfer mandatory) FC - 0 loan (transfer mandatory)	Modular transition period: 4 semesters	ECTS qiymati: 5
Direction of Education	60910800-Industrial Pharmacy (by type)	2 stage bachelors	
Module duration	15 weeks		
Size of study hours:	Total hours:	120	
	Also:		
	lecture	30	
	laboratory training	30	
	Independent Education	60	
Status of the training module	Universal modules		
OTM name, address	Tashkent Pharmaceutical Institute 45 Oybek Street, Tashkent		
Department name	Organization of pharmaceutical production		
Information about the teachers of this course	Speaker’s F.N. Laboratory of the trainer’s F.N.	E-mail: E-mail:	
Training time and place			
Module content	The module for organizing pharmaceutical production is considered to be a module indicating the requirements for students ' knowledge, educational skills, factors for perfecting the technology of preparation of types of drugs in modern enterprise conditions, requirements for raw materials and auxiliary substances in pharmaceutical production, special attention should be paid to the normalization of quality in production.		

Prerecivists	The module is a theoretical part of general and Pharmaceutical Chemistry, Biology, Mathematics, biotechnology.
Postrequisites	The module for the organization of pharmaceutical production later serves as a theoretical basis for Biological Chemistry, toxicological chemistry, pharmacognosy modules.
Purpose of the module	To organize the production of pharmaceuticals in students, to train the medicines produced in the conditions of the enterprise, and to develop the skills to implement them in practice.
Module functions	Organization of pharmaceutical production in students theoretical knowledge, practical skills. The formation of such skills as the approach to the problems of the main concepts of technology, its goals and objectives, stages of development, the main directions of scientific investigations in the field of drug technology based on modern scientific achievements.
Requirements for student knowledge, skills and qualifications on the module	The student must have imagination: - Organization of pharmaceutical production preparation of ready-made types of drugs in the conditions of the enterprise, regulatory documents necessary for the enterprise, requirements for it, - Clay the system of pharmaceutical development. - equipment and apparatus, - Good production practice; - Chemical, technological and hardware scheme of production. The student must know: - pharmaceutical production building and rooms. Requirements for them; - requirements for air and water in pharmaceutical production; - be able to work with the equipment used in pharmaceutical production; The student can perform: - Organization of pharmaceutical production preparation of ready-made types of drugs in the conditions of the enterprise, regulatory documents necessary for the enterprise, requirements for it; - correct selection of starting materials used; - use of equipment and apparatus necessary in pharmaceutical production; - adjust the appropriate parameters to the operating mode; The student must have the following skills: - selection of optimal technology in the preparation of drug forms in the conditions of the enterprise in pharmaceutical production ; - application of the knowledge acquired by the module in its

	scientific and production activities.
Teaching methods	Lectures and workshop sessions
Supply	videodars and video tutorials, multimedia training programs, new technologies in teaching methodology, educational-methodological complex, textbooks and teaching aids, independent work assignments, home assignments, tests, situational issues, etc.

Results of training:

The student knows the module when completing 4 semesters:

1. General information about regulatory documents, the basics of preparation and organization of pharmaceutical production, technological processes and regulatory documents;
2. The use of equipment and apparatus necessary in pharmaceutical production and the general and private requirements imposed on them;
3. Pharmaceutical manufacturing building and rooms. Requirements for them;
4. Good Manufacturing Practice (GMP).
5. Chemical, technological and hardware scheme of production.
6. Pharmaceutical production organizational structure of the enterprise.
Materials used in pharmaceutical production.
7. Material balance
8. Description of the types of drugs technological processes.
9. Description of raw materials, materials and intermediate products.
10. Requirements for clean rooms in production
11. Heating, ventilation, condensing and lighting of production rooms.
12. Primary raw materials and primary mowing materials. Marking and secondary packaging, finished products.
13. Documentation. Requirements for documents.
14. Documentation, control of the production process
15. Requirements for storage in clean rooms.
16. Preparation of water for the production of medicines
17. Tool equipment used in the manufacture of medicines, devices and requirements for them.

MINISTRY OF HEALTH OF THE REPUBLIC OF UZBEKISTAN
TASHKENT PHARMACEUTICAL INSTITUTE
Department of organization and quality management of Farmastevtik
production



ORGANIZATION OF PHARMACEUTICAL PRODUCTION
WORKING TRAINING BENCH OF THE MODULE

Field of knowledge: 900000 Health and Social Security

Direction education: 60910800 Industrial Pharmacy (by type)

TOSHKENT – 2023

The working curriculum of the module on the Board of the Tashkent Pharmaceutical Institute 2023" 30.08 " 1 -prepared on the basis of the modular program of the economy of pharmaceutical production, approved by the order of number.

Authors:

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Head of the laboratory of experimental-tenology

The working curriculum of the module was discussed and approved at the Board of the Tashkent Pharmaceutical Institute (2023" 30 " 08 " 1 -number statement)

Toshfarmi Industrial Pharmacy
dean of the faculty:



Z.U. Mamatqulov

Organization of pharmaceutical production
head of the Department of making
and Quality Management:



N.A. Yunusxodjayeva

Head of the educational
and methodological Department



J.A. Xayitboyev

1.Relevance of training modulinig and its role in higher education

President of the Republic of Uzbekistan on April 20, 2017 PQ-2909 "measures for the further development of the higher education system", on May 5, 2017 PQ-2956 "measures for the further reform of the medical education system in the Republic of Uzbekistan", on July 27, 2017 PQ-3151 "measures for the further expansion of the participation of sectors and sectors of the economy in the, PQ-3775 of June 5, 2018 "on measures to improve the quality of education in higher educational institutions and ensure their active participation in the comprehensive reforms carried out in mamalakat", PQ-4310 "on measures for the further development of the system of medical and Pharmaceutical Education and Science module".

The module program covers the prospects for the far future of the science and practice of preparation technology in the production of medicines in the conditions of pharmaceutical production enterprise.

2. Purpose and objectives of the training module

2.1. Purpose of the module:

It consists in the organization of pharmaceutical production in students, the formation and development of their concepts on the technology of preparation in the conditions of the enterprise, teaching them to clearly state their reasoning and conclusions in a reasonable way, and the formation of skills and competencies in the acquired knowledge. The prospects for pharmaceutical production and its development, good production practices, materials used in the manufacture of medicines and their requirements, documentation of the production of medicines, training of documents and the formation of skills for their implementation in practice.

Requirements for employees in the production of medicines in students, Technical Safety, Fire Safety and production sanitation, ensuring the quality of medicines, ensuring stagnation and determining the expiration date, and drawing up a general Pharmacopoeia article for medicines, regulations consists in teaching the requirements of the present time and generating the skill to implement them in practice.

2.2. Module functions:

Theoretical foundations, basic concepts of the science of Organization of pharmaceutical production, its goals and objectives, methodological approach to preparing and assessing the quality of forms of step-by-step teaching students to the level of implementation of practical skills from theoretical education, introducing modern pedagogical technologies into the course process, increasing the level of thinking and maintaining the student's knowledge, stages, it consists in the formation of the main directions of scientific investigations in the field of technology of drugs in the conditions of the enterprise.

Pharmaceutical production requirements for employees in the production of medicines in the conditions of the enterprise, technical safety, fire safety and production sanitation, ensuring the quality of medicines, ensuring stagnation and

determining the shelf life, as well as establishing a general Pharmacopoeia article for the types of drugs to be prepared, drawing up regulations, the procedure for controlling the quality of drug types based on, the organization of the workplace in laboratory and enterprise conditions consists in formulating the use of regulatory documents, reference and scientific literature in solving problems in the specialty, making the necessary calculations based on the physicochemical and technological properties of substances.

2.3. Requirements for knowledge, skills and qualifications of students by module:

4 at the end of the semester

3. 6 credit

Students:

4. - preparation of medicines in the conditions of the enterprise, regulatory documents necessary for this technology, requirements for it,
5. - materials used in pharmaceutical production and requirements for them,
6. - equipment and apparatus,
7. - documentation of the production of medicines in pharmaceutical production,
8. - study of the requirements for documents in pharmaceutical production in the conditions of the enterprise
9. - drawing up a general Pharmacopoeia article, regulations for types of drugs,
- 10.- to have an idea about the choice of the procedure for controlling the quality of drug types in pharmaceutical production on the basis of MH;
- 11.- requirements for employees in pharmaceutical production;
- 12.- Technical Safety, Fire Safety and production sanitation;
- 13.- to the general and specific preparation technologies for them on the preparation of the type of Medicine;
- 14.- the pharmacist can know how to work with the equipment used in production and be able to use them;
- 15.- correct Organization of technology and processes in the preparation of medicines in pharmaceutical production;
- 16.- correct selection of starting materials used;
- 17.- use of equipment and apparatus necessary for the preparation of medicines;
- 18.- adjust the appropriate parameters to the operating mode;
- 19.- must have skills to improve productivity.

Modular structure

3.1. Module loading and types of educational work

Semester	Total load capacity	Lecture (clock)	Practical (seminar) training (clock)	Laboratory training (clock)	Independent Education	Control type and shape	Credit (size)

					(clock)		
4	120	30	30	-	60	Written, test	4
Total:	120	30	30	-	60	Written, test	4

3.2. Lecture trainings

	Lecture topics	Cl ock size	Code of competencies that must be occupied
semestr 4 (15)			
	The main goals of the development of the pharmaceutical industry. The main concepts and terms of the science” organization of pharmaceutical production". International requirements in pharmaceutical production. GMP requirements.	2	UK-1; UK-2; UK-3; UK-4; UKK 1
	Design of premises for pharmaceutical production. Requirements for buildings and buildings. Sex system in pharmaceutical production. Chemical, technological and hardware scheme of production.	2	UK-1; UK-2; UK-3; UK-4; UKK 4;
	Documents. Internal and external documents. State standards and enterprise standards. Regulations and their types. Drawing up regulations	2	UK-1; UK-2; UK-3; UK-4; UKK 4;
	Drawing up a pharmacopoeia article for substance and drug forms.	2	UK-1; UK-2; UK-3; UK-4; UKK 5;
	Technique and fire safety. Pharmaceutical production sanitation	2	UK-1; UK-2; UK-3; UK-4; UKK 1
	Qualification of the ventilation system. Heating, air conditioning and lighting system in pharmaceutical production.	2	UK-1; UK-2; UK-3; UK-4; UKK 2; UKK 4;
	Clean rooms in pharmaceutical production, their classification and requirements for them.	2	UK-1; UK-2; UK-3; UK-4;

			UKK 3; UKK 5;
	Requirements for employees in pharmaceutical production.	2	UK-1; UK-2; UK-3; UK-4; UKK 4;
	Production, storage, transportation and acceptance of material and raw materials in pharmaceutical production. Requirements for the warehouse.	2	UK-1; UK-2; UK-3; UK-4; UKK 4;
	Preparation, storage and distribution of water in pharmaceutical production.	2	UK-1; UK-2; UK-3; UK-4; UKK 1; UKK 4;
	Buildings and equipment for the production of sterile drugs.	2	UK-1; UK-2; UK-3; UK-4; UKK 2; UKK 3; UKK 5;
	Equipment for the production of solid drug forms in pharmaceutical production.	2	UK-1; UK-2; UK-3; UK-4; UKK 4;
	Equipment for the production of soft and liquid drug forms in pharmaceutical production.	2	UK-1; UK-2; UK-3; UK-4; UKK 4;
	Primary raw materials, primary and intermediate packaging materials.	2	UK-1; UK-2; UK-3; UK-4; UKK 4;
	Marking and secondary packaging of finished products. Recycling and neutralizing waste from pharmaceutical production.	2	UK-1; UK-2; UK-3; UK-4; UKK 4; UKK 6
	Jami:	30	

Organization of lecture sessions (form, type, equipment, etc.) in auditoriums equipped with multimedia devices are passed for the flow of academic groups.

3.3. Organization of practical training

Semester 4

	Temas de formación práctica (taller, laboratorio)	Tamaño de las horas de formación teórica	Habilidad es prácticas que deben adquirirse	Competencias que deben ser ocupadas (cod)	Apoyo educativo y metodológico
	The main goals of the development of the pharmaceutical industry. The main concepts and terms of the science" organization of pharmaceutical production". International requirements in pharmaceutical production. GMP requirements.	2	The main goals and objectives of faninig"Organization of pharmaceutical production"	UK-1; UK-2; UK-3; UK-4; UKK 1	Instrucción educativo-manual, instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Design of premises for pharmaceutical production. Requirements for buildings and buildings. Sex system in pharmaceutical production. Chemical, technological and hardware scheme of production.	2	The main goals and objectives of faninig"Organization of pharmaceutical production"	UK-1; UK-2; UK-3; UK-4; UKK 2;	Instrucción educativo-manual, instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Documents. Internal and external documents. State standards and enterprise standards. Regulations and their types. Drawing up regulations	2	The main goals and objectives of faninig"Organization of pharmaceutical	UK-1; UK-2; UK-3; UK-4; UKK 5;	Instrucción educativo-manual, instrucción educativo-metodológica,

			production"		complejo educativo-metodológico, materiales distributivos
	Drawing up a pharmacopoeia article for substance and drug forms.	2	General information about international GMP requirements and departments and enterprises receiving GMP	UK-1; UK-2; UK-3; UK-4; UKK 3; UKK 5;	Instrucción educativo-manual, instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Technique and fire safety. Pharmaceutical production sanitation	2	General international requirements, international standards and understanding of ISO	UK-1; UK-2; UK-3; UK-4; UKK 1; UKK 2; UKK 5;	Instrucción educativo-manual, instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Qualification of the ventilation system. Heating, air conditioning and lighting system in pharmaceutical production.	2	Full information about the project and project documentation. Design of pharmaceutical manufacturing enterprise	UK-1; UK-2; UK-3; UK-4; UKK 1; UKK 2; UKK 5;	Instrucción educativo-manual, instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Clean rooms in pharmaceutical production, their	2	Categories of industrial buildings.Requ	UK-1; UK-2; UK-3;	Instrucción educativo-manual,

	classification and requirements for them.		requirements for industrial buildings. Main production buildings.	UK-4; UKK 1; UKK 4;	instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Requirements for employees in pharmaceutical production.	2	Main production buildings. Auxiliary-production buildings. Service buildings. Complete information about the chemical, technological and hardware scheme of production	UK-1; UK-2; UK-3; UK-4; UKK 1; UKK 4;	Instrucción educativo-manual, instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Production, storage, transportation and acceptance of material and raw materials in pharmaceutical production. Requirements for the warehouse.	2	Complete information about the chemical, technological and hardware scheme of production	UK-1; UK-2; UK-3; UK-4; UKK 2; UKK 4; UKK 6	Instrucción educativo-manual, instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Preparation, storage and distribution of water in pharmaceutical production.	2	Necessary documents in the preparation of medicines. Internal documents of the enterprise	UK-1; UK-2; UK-3; UK-4; UKK 1	Instrucción educativo-manual, instrucción educativo-metodológica, complejo

					educativo- metodológico, materiales distributivos
	Buildings and equipment for the production of sterile drugs.	2	State and enterprise standards. General information about international standards	UK-1; UK-2; UK-3; UK-4; UKK 2;	Instrucción educativo- manual, instrucción educativo- metodológica, complejo educativo- metodológico, materiales distributivos
	Equipment for the production of solid drug forms in pharmaceutical production.	2	General information about regulations and regulations the rules of their formation the requirements for the formation of regulations and their implementation	UK-1; UK-2; UK-3; UK-4; UKK 5;	Instrucción educativo- manual, instrucción educativo- metodológica, complejo educativo- metodológico, materiales distributivos
	Equipment for the production of soft and liquid drug forms in pharmaceutical production.	2	General information about regulations and regulations the rules of their formation the requirements for the formation of regulations and their implementation	UK-1; UK-2; UK-3; UK-4; UKK 3; UKK 5;	Instrucción educativo- manual, instrucción educativo- metodológica, complejo educativo- metodológico, materiales distributivos

	Primary raw materials, primary and intermediate packaging materials.	2	Pharmacopoeia article the concept of the main difference between a state and an enterprise Pharmacopoeia article	UK-1; UK-2; UK-3; UK-4; UKK 1; UKK 2; UKK 5;	Instrucción educativo-manual, instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Marking and secondary packaging of finished products. Recycling and neutralizing waste from pharmaceutical production.	2	Rules for drawing up a pharmacopoeia article for drug forms and substance.	UK-1; UK-2; UK-3; UK-4; UKK 1; UKK 2; UKK 5;	Instrucción educativo-manual, instrucción educativo-metodológica, complejo educativo-metodológico, materiales distributivos
	Jami:	30			

Workshop classes are held separately to each academic group in auditoriums equipped with multimedia devices and laboratory equipment.

3.4. Practical skills

Nº	Practical skills name	number	Necessary provision (equipment)for the performance of practical skills
semestr 4 (number)			
1.	The main goals and objectives of the development of the pharmaceutical network. Science” organization of pharmaceutical	1	Whiteboard, computer, TV, information and technology tools,

	production"		multimedia tools
2.	The main terms used in pharmaceutical production are.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
3.	International GMP requirements for pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
4.	International requirements for pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
5.	Design of pharmaceutical production building.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
6.	Requirements for buildings and rooms.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
7.	Sex system in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
8.	Chemical, technological and hardware scheme of production	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
9.	Documents. Internal	1	Whiteboard,

	documents .		computer, TV, information and technology tools, multimedia tools
10.	State and enterprise standards.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
11.	Types of regulations and regulations.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
12.	Drawing up a regulation and requirements for it.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
13.	Drawing up a pharmacopoeia article for substance.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
14.	Drawing up a pharmacopoeia article for drug forms.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
15.	Technique and fire safety.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
16.	Pharmaceutical production sanitation of the enterprise.	1	Whiteboard, computer, TV,

			information and technology tools, multimedia tools
17.	Requirements for clean rooms in pharmaceutical manufacturing enterprises.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
18.	Classification of clean rooms.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
19.	Buildings and equipment for the production of sterile drugs.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
20.	Cleaning equipment used in the production of sterile drugs.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
21.	Requirements for employees in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
22.	Training and qualification of employees in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
23.	Improving the ventilation system.	1	Whiteboard, computer, TV, information and

			technology tools, multimedia tools
24.	Air conditioning, heating and lighting system of the pharmaceutical enterprise.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
25.	Acceptance, storage and transportation of raw materials and materials in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
26.	Requirements for the warehouse.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
27.	Equipment in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
28.	Equipment for the production of solid drug forms in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
29.	Equipment for the production of liquid drug forms in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
30.	Equipment for the production of soft drug forms in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools,

			multimedia tools
31.	Preparation for water purification in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
32.	Water treatment and storage in pharmaceutical production.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
33.	Primary packaging materials and requirements for them.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
34.	Primary and intermediate packaging materials and requirements for them.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
35.	Marking and secondary packaging of finished products.	1	Whiteboard, computer, TV, information and technology tools, multimedia tools
36.	Recycling and neutralizing pharmaceutical production waste	1	Whiteboard, computer, TV, information and technology tools, multimedia tools

4. Independent education and independent work

4.1. Independent educational topics

№	Independent educational	Cloc	Competencies

	topics	k size	
semestr 4			
1	Enterprises operating in pharmaceutical production and their types	3	Research, Learning, Development
2	Production control and technological process control	3	Research, Learning, Development
3	Lightning protection of the production water supply system, buildings and structures	3	Research, Learning, Development
4	Technical preparation of production, Planning technical preparation	3	Research, Learning, Development
5	General description of production, Types of production.	3	Research, Learning, Development
6	Basic concepts and terms of pharmaceutical production.	3	Research, Learning, Development
7	Organizational structure of quality departments of pharmaceutical production enterprises	3	Research, Learning, Development
8	Mudflat system of pharmaceutical development, good production practice (GMP).	3	Research, Learning, Development
9	Materials used in pharmaceutical production. Material balance	3	Research, Learning, Development
10	The main elements of structural schemes of industrial buildings, criteria for the placement of auxiliary buildings and rooms	3	Research, Learning, Development
11	Pharmaceutical production organizational structure of the process.(On the example of types of solid and liquid drugs)	3	Research, Learning, Development
12	Providing clean air to buildings and rooms in the production of farmsteads	3	Research, Learning, Development

13	Definition of GXP concepts, national, regional GMP rules	2	Research, Learning, Development
14	Documentation of pharmaceutical production enterprises	2	Research, Learning, Development
15	Modern evaporators and their technical characteristics.	2	Research, Learning, Development
16	Chemical and technological systems of production. General concepts	2	Research, Learning, Development
17	Modern filters.Placement of equipment in pharmaceutical Productions	2	Research, Learning, Development
18	Documentation, control of the production process.	2	Research, Learning, Development
18	Equipment used in the chemical-pharmaceutical and biotechnology industries	2	Research, Learning, Development
19	Pharmaceutical production technological classification of equipment	2	Research, Learning, Development
20	Pharmaceutical production requirements for equipment and their productivity indicators	2	Research, Learning, Development
21	Pharmaceutical production equipment maintenance and their cleaning.	2	Research, Learning, Development
22	Pharmaceutical production equipment used to store substances in warehouses	2	Research, Learning, Development
23	Pharmaceutical production equipment used to store raw materials in the workshop	2	Research, Learning, Development
24	Apparatus scheme of production. General concepts	2	Research, Learning, Development
Jami:		60	

Independent educational topics are mastered by students beyond the audience and taken into account in the current assessment of the topic.

4.2. Registration of independent forms of education and types of work on the module :

When preparing an independent work, the student is recommended to use the following forms, taking into account the characteristics of a particular module:

- mastering the part of lectures on textbooks and teaching aids;
- work on sections or topics of modules on special literature;
- study of new techniques, biological examination instruments, processes and technologies;
- in-depth study of modules sections and topics related to the performance of the student's Educational Research;
- training sessions using an active and problematic teaching style;
- distance (distance) education.
- preparation of information (Abstract) on a given topic;
- work and lecture on special or scientific literature (monographs, articles) on sections or topics of the module;
- solving situational issues focused on situational problems;
- keys (case-study based on real-situation issues) solve.
- development and filling of graphic organizers;
- drawing up and solving crosswords;
- wide application in the process of presentation and preparation of videos, as well as in the process of working with mustakil.

General instructions and recommendations for the organization of Independent Education and independent work:

Independent work on the module (Organization of pharmaceutical production) is carried out in addition to the audience and audience.

In the organization of independent work of the student, the forms of the sheep are used:

- to reflect on the numerical and qualitative performance and practical skill acquisition notebooks in the pedagogical control of the practical skills approved

in the trainer, mule and simulation halls/centers in addition to the training of the audience;

- independent assimilation of certain theoretical topics with the help of educational literature;

- preparation of information (Abstract) on a given topic;

- work and lecture on special or scientific literature (monographs, articles) on sections or topics of the module (science;

- solving situational issues focused on situational and pharmaceutical problems;

- SASE (SASE-study based on real pharmaceutical situations and pharmaceutical situational issues) solution;

- making models, making crosswords, making organizers, etc.k.

- The independent work of the student consists in collecting expanded information on the topic under study, making extensive use of the capabilities of Information Technology for this, independently developing the information received and being able to apply it in the quality control of a specific drug, the types and forms of which can be of different appearance. Topics and assignments for independent work are widely covered in methodological manuals developed and regularly updated in the Department for organizing independent work of the student.

- The results of independent education are evaluated on the basis of a rating system. Such as carrying out tasks to the house, independent study of new knowledge from additional textbooks and literature, finding ways to search for the necessary information and find them, collecting data and conducting scientific research using internet networks, preparing scientific articles and lectures within a scientific circle or independently using scientific resources, deepen students ' knowledge gained in the lesson, develop their independent thinking and

4.3. Recommended educational and methodological support for the organization of independent training on the module: applications, literature, photography, mulyage, simulators, tooling, tables, instructional and supervisory tests, computer programs, work in simulation centers, etc.k.

Course work on the module (project). Coursework is not planned.

5.Criteria for monitoring and evaluating student knowledge on the module

5.1. Criteria for control and evaluation of theoretical knowledge in a

modular learner (CC, IC, FC in terms of forms and types of control)

Information about the types of control and evaluation criteria on the module for the organization of pharmaceutical production is published to students in the first training on the module.

The following types of supervision are carried out to ensure the compliance of the degree of modular assimilation of students with state educational standards:

- current control (CC) – 2 credits;
- Independent Education (IC) – 2 credits;
- final control (FC)– 0 credit (transfer mandatory)

The loans allocated to the module are allocated by type of control as follows:

Table 1.

<i>Nº</i>	<i>Type of control</i>	<i>Number of credits</i>
1	<i>current control</i>	2
2	<i>Independent Education</i>	2
3	<i>final control</i>	0
<i>Total</i>		4

* The assessment of theoretical knowledge in modules where practical skills are not foreseen is 100 points.

5.2. Criteria for monitoring and assessing the acquisition of practical skills in students by module

current control (CC)

CC is intended to determine and evaluate the degree of acquisition of knowledge, practical coherence and competencies on the modular subjects of the student. In the form of current control verbal, instructional control tests, Masa solving, instructional control tests, situational issues are carried out on the basis of the pharmaceutical production organization module.

The assessment takes into account the level of knowledge of the student, the appropriation of laboratory training materials, the level of activity of his participation in the discussion of theoretical material and in the interactive methods of Education. In each session, all students are required to be evaluated. The maximum score is 100 points, the passing score is 56 points.

A student who scores less than a qualifying (passing) score on the JN and is unable to participate in the control for excuses is given a deadline until the next same control Round, the final nazotar for the songgi CC

In CC, the student is obliged to fully accumulate the allocated loan, only then it will be included in the final control (IC).

Students who have not attended classes due to illness and have not been able to submit Jn within a set period are allowed to submit it within two weeks of the start of their studies, according to the order of the dean of the faculty.

At the end of the semester, the student who scores less than the qualifying score on the CC by module is the academic debtor.

To students who are academically indebted, after the end of the semester, the Faculty re-submits on the basis of the statute in accordance with the recommendation of the dean.

5.3. Criteria for controlling and evaluating competency acquisition in modular students

The student ranking by module is determined as follows:

rating	ECTS	Definition of ECTS		mark	Description
86-100	A	scope = "row" / 2018 – excellent result, with minimal errors	have systematic, complete and in-depth knowledge of all sections of the module program, be able to substantiate with the necessary evidence; clear, in-place use of terminology (including in scientific, foreign language), logically, stylistically literate expression of questions; can identify problematic questions, substantiate their views in a scientific and practical language; the module is able to know the basic concepts and effectively apply it in solving scientific and practical issues in a short time; able to independently and creatively solve problems in non-standard situations, show the	5	excellent

			ability; able to independently fully perform practical skills (in terms of quality and set number) and fully acquire competencies; its brief, grounded and rational resolution of practical issues; complete and deep slimming of the main and additional literature recommended in the module program; understanding the essence of theories, concepts and directions on the module, giving them a critical assessment and being able to apply the scientific achievements of other modules; it is necessary to participate creatively and independently throughout the entire semester in theoretical and practical classes, be active in group discussions, have a high level of culture in the performance of tasks.		
81-85	B	"very good" - a higher result than the middle, with some errors	have systematic, complete and in-depth knowledge of all sections of the module program, be able to substantiate with the necessary evidence; clear, in-place use of terminology (including in scientific, foreign language), logically, stylistically literate expression of questions; be able to independently bartaf the non-determinants that arise in proving one's opinion or in making another theoretical	4	Very good

			material; knowledge of the basic concepts of the module, the ability to put scientific and professional tasks in a short time and make the most of it in solving; be able to independently solve problems in standard situations within the framework of the training program; able to independently fully perform practical skills (in terms of quality and set number) and fully acquire competencies; the fact that in practical training he demonstrates a good knowledge of regulatory legal documents, is able to apply this knowledge in new situations to the full (but not always rational), is not able to adequately formalize the results of the work performed; mastering the main recommended literature in the module program; able to understand the essence of theories, concepts and directions on the studied module and give them a critical assessment; it is necessary to participate creatively and independently throughout the semester in theoretical and practical classes, be active in group discussions, have a very good level of culture in the performance of tasks.		
71-80	C	"good" - the	have a systematic, complete and		

		average result with significant errors	in-depth knowledge of all sections of the module program, be able to substantiate with the necessary evidence, but with some shortcomings; clear, in-place use of terminology (including in scientific, foreign language), logically, stylistically literate expression of questions; be able to independently eliminate the inaccuracies that arise when proving one's opinion or stating another theoretical material; knowledge of the basic concepts of the module, the ability to put scientific and professional tasks in a short time and make the most of it in solving; be able to independently solve problems in standard situations within the framework of the training program; able to independently complete practical skills (in terms of quality and set number) and acquire competencies, but with some disadvantages; the fact that in practical training he demonstrates a good knowledge of regulatory legal documents, is able to apply this knowledge in new situations to the full (but not always rational), is not able to adequately formalize the results of the work performed;		

			mastering the main literature recommended in the module program; able to understand the essence of theories, concepts and directions on the studied module and give them a critical assessment; in theoretical and practical classes, he must participate creatively and independently throughout the semester, be active in group discussions, have a good degree in the performance of tasks.		
60-70	D	"satisfactory" - a sluggish result, with rough flaws	To have sufficient volume of knowledge within the framework of state educational standards (requirements); using terminology, correctly stating answers to questions, but making some mistakes; demonstrate that he has a basic understanding of the module when he has difficulty responding or demonstrating some special skills; Able to fully perform practical skills (in terms of quality and set number) independently, but with errors; taking competencies independently, but with errors; can have partial knowledge of the general concepts of the module and apply it to solving standard (model) situations; the educator can solve standard	3	satisfactory

			situations with the help of an employee; able to understand the essence of the main theories, concepts and directions on the module under study, to evaluate them; in theoretical and practical training, the educator must participate with the help of an employee, have a sufficient level of culture in the performance of tasks.		
56-59	E	"middle" - equal to the minimum result	To have a satisfactory volume of knowledge within the state educational standards (requirements) ; using terminology, correctly stating the answers to questions, but making some gross mistakes in this; to demonstrate that it has a basic understanding of the module when it is difficult to respond or to demonstrate some special inclusions and make mistakes; perform practical skills (in terms of quality and set number) are not independent and complete with errors. competencies are not independent and occupy with errors; can have partial knowledge of the general concepts of the module and apply it to solving standard (model) situations; the educator can solve standard situations with the help of an		

			employee; able to understand the essence of the main theories, concepts and directions on the module under study, to evaluate them; in theoretical and practical training, the educator must participate with the help of an employee, have a sufficient level of culture in the performance of tasks.		
31-55	FX	"unsatisfactory – - additional independent mastering is necessary in order to obtain a minimum level of knowledge	If the state has only some fragmentary knowledge within the standards (requirements) of Education; can not use scientific terms or make serious logical errors in response; participate passively in theoretical and practical training and perform tasks if they have a low level of living culture; if he does not have practical skills and competencies, he cannot correct his mistakes even with the help of the recommendations of a Hatto pedagogical employee.	2	unsatisfactory
0-30	F	"absolute unsatisfactory" – complete re-appropriation	If the state has only some fragmentary knowledge within the standards (requirements) of Education; when it cannot use terms or makes serious and gross logical errors in response or does not respond at all; participate passively in theoretical and practical training, perform		

			tasks, if they have a low level of culture or do not perform at all; If he does not have practical skills and competencies, he cannot correct his mistakes even with the help of the recommendations of a Hatto pedagogical employee.		

Final control (FC)

A student who has fully accumulated the credit allocated to the JN and has completed the on will be included in the Yan. YaNda the knowledge, skills and qualifications of the student are evaluated within the general content of the module. YaN is conducted in written form after the end of modular training. YaN tickets are drawn up, consisting of three questions. A student who fails to score a Yanda qualifying score (56%) is considered to have not passed Yanda and did not master the module (even if JNda has collected the full credit).

The process of conducting final control with the participation of the commission, established by order of the rector of the educational institution under the direction of the Department of internal control and monitoring, is periodically studied, and in cases where the procedures for conducting it are violated, the results of Final control are canceled and final control is transferred again.

Students who cannot submit Yan due to illness are allowed to submit within two weeks of starting their studies under the orders of the dean of the faculty.

At the end of the semester, the student who scores less than the Yanda qualifying score is the academic debtor.

Academic indebted students are given a period of one month to re-master after the end of the semester. During this period, a student who has not mastered the module is excluded from the ranks of students by order of the rector in the prescribed manner on the recommendation of the dean of the faculty.

If the student is dissatisfied with the results of the control, within a day from the time of publication of the results of the type of control on the module, he can apply to the dean of the faculty with an application. In this case, according to the submission of the dean of the faculty, by order of the Rector, an appeals commission is established in a composition of no less than 3 (three) members.

The appeals commission will review the students ' applications and report their conclusion on the same day.

The conduct and formalization of the assessment on the basis of established

requirements is monitored by the dean of the faculty, the head of the department, the training department and the Department of internal control and monitoring.

6. Main and additional educational literature and information sources

6.1. Main literature

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- 3.Береговых В.В.,Сапожникова Э.А.,Джалилов Х.К.,кузьмичева Е.Л.,Пятигорская Н.В.Теоретические основы технологии лекарственных средств. Ташкент “Fan va texnologiya” 2011. С. 244. (ўқув қўлланма)
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- 6.Чуешов В.И., Гладух Е.В., Сайко И.В. и др. Технология лекарств промышленного производства. Учебник для студ. высш. учеб. завед.: Перевод с укр.: Ч.1. – Винница: Нова Книга, 2014. - 696 с. (дарслик)

6.2.Additional literature

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3. Mirziyoev SH.M. Buyuk kelajagimizni mard va olijanob xalqimiz bilan birga quramiz. “O‘zbekiston” NMIU, 2017. – 485 b.
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- 5.Чуешов В.И., Гладух Е.В., Сайко И.В. и др. Технология лекарств промышленного производства. Учебник для студ. высш. учеб. завед.: Перевод с укр. : Ч.2. – Винница : Нова Книга, 2014. - 664 с.

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Internet sites

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**SYLLABUS FROM THE MODULE FOR THE ORGANIZATION OF
FARMASTEVTIC PRODUCTION
(For Semester 3)**

Syllabus from the module for the organization of farmastevtic production			
Full name of the module	Organization of pharmaceutical production		
Code module:	Loan size: 4 credits Hence: CC-2 credit IE-2 credit IC-0 loan (transfer mandatory) FC - 0 loan (transfer mandatory)	Modular transition period: 4 semesters	ECTS qiymati: 5
Direction of Education	60910800-Industrial Pharmacy (by type)	2 stage bachelors	
Module duration	15 weeks		
Size of study hours:	Total hours:	120	
	Also:		
	lecture	30	
	laboratory training	30	
	Independent Education	60	
Status of the training module	Universal modules		
OTM name, address	Tashkent Pharmaceutical Institute 45 Oybek Street, Tashkent		
Department name	Organization of pharmaceutical production		
Information about the teachers of this course	Speaker’s F.N. Laboratory of the trainer’s F.N.	E-mail:	E-mail:
Training time and place			
Module content	The module for organizing pharmaceutical production is considered to be a module indicating the requirements for students ' knowledge, educational skills, factors for perfecting the technology of preparation of types of drugs in modern enterprise conditions, requirements for raw materials and auxiliary substances in pharmaceutical production, special attention should be paid to the normalization of quality in production.		
Prerecvists	The module is a theoretical part of general and Pharmaceutical Chemistry, Biology, Mathematics, biotechnology.		

Postrequisites	The module for the organization of pharmaceutical production later serves as a theoretical basis for Biological Chemistry, toxicological chemistry, pharmacognosy modules.
Purpose of the module	To organize the production of pharmaceuticals in students, to train the medicines produced in the conditions of the enterprise, and to develop the skills to implement them in practice.
Module functions	Organization of pharmaceutical production in students theoretical knowledge, practical skills. The formation of such skills as the approach to the problems of the main concepts of technology, its goals and objectives, stages of development, the main directions of scientific investigations in the field of drug technology based on modern scientific achievements.
Requirements for student knowledge, skills and qualifications on the module	The student must have imagination: - Organization of pharmaceutical production preparation of ready-made types of drugs in the conditions of the enterprise, regulatory documents necessary for the enterprise, requirements for it, - Clay the system of pharmaceutical development. - equipment and apparatus, - Good production practice; - Chemical, technological and hardware scheme of production. The student must know: - pharmaceutical production building and rooms. Requirements for them; - requirements for air and water in pharmaceutical production; - be able to work with the equipment used in pharmaceutical production; The student can perform: - Organization of pharmaceutical production preparation of ready-made types of drugs in the conditions of the enterprise, regulatory documents necessary for the enterprise, requirements for it; - correct selection of starting materials used; - use of equipment and apparatus necessary in pharmaceutical production; - adjust the appropriate parameters to the operating mode; The student must have the following skills: - selection of optimal technology in the preparation of drug forms in the conditions of the enterprise in pharmaceutical production ; - application of the knowledge acquired by the module in its scientific and production activities.

Teaching methods	Lectures and workshop sessions
Supply	videodars and video tutorials, multimedia training programs, new technologies in teaching methodology, educational-methodological complex, textbooks and teaching aids, independent work assignments, home assignments, tests, situational issues, etc.

Results of training:

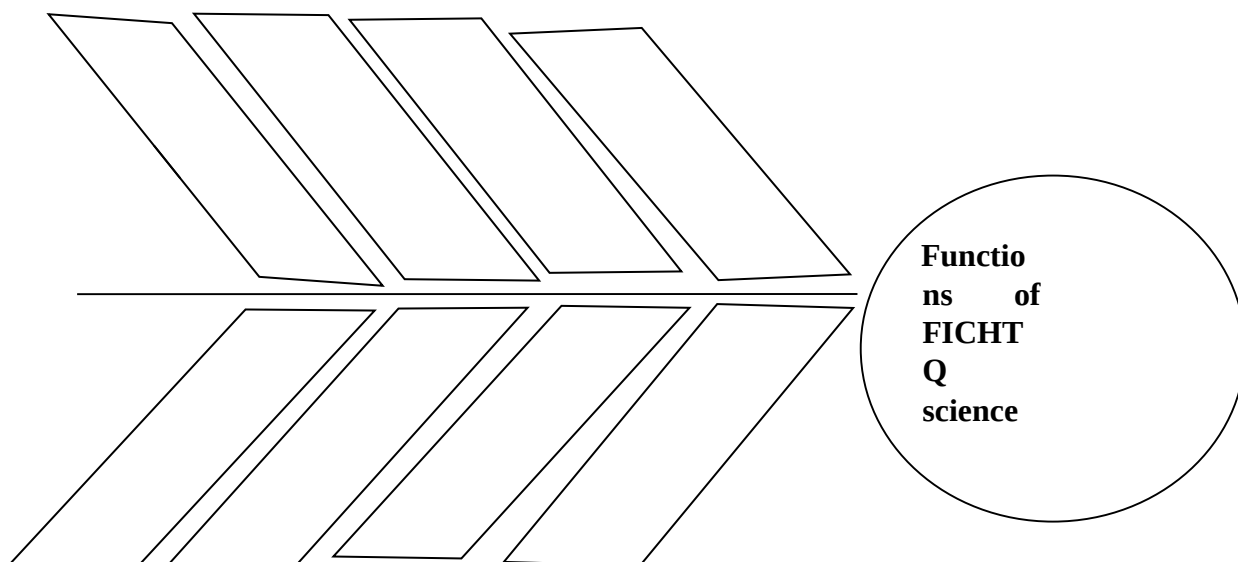
The student knows the module when completing 4 semesters:

1. General information about regulatory documents, the basics of preparation and organization of pharmaceutical production, technological processes and regulatory documents;
2. The use of equipment and apparatus necessary in pharmaceutical production and the general and private requirements imposed on them;
3. Pharmaceutical manufacturing building and rooms. Requirements for them;
4. Good Manufacturing Practice (GMP).
5. Chemical, technological and hardware scheme of production.
6. Pharmaceutical production organizational structure of the enterprise.
- Materials used in pharmaceutical production.
7. Material balance
8. Description of the types of drugs technological processes.
9. Description of raw materials, materials and intermediate products.
10. Requirements for clean rooms in production
11. Heating, ventilation, condensing and lighting of production rooms.
12. Primary raw materials and primary mowing materials. Marking and secondary packaging, finished products.
13. Documentation. Requirements for documents.
14. Documentation, control of the production process
15. Requirements for storage in clean rooms.
16. Preparation of water for the production of medicines
17. Tool equipment used in the manufacture of medicines, devices and requirements for them.



FISH SKELETON GAME

Express the tasks of the fan in the form of a fish skeleton



"BOOMERANG" * TRAINING

Group I Mission

The essence, purpose and objectives of the science of organizing pharmaceutical production.

Group II mission

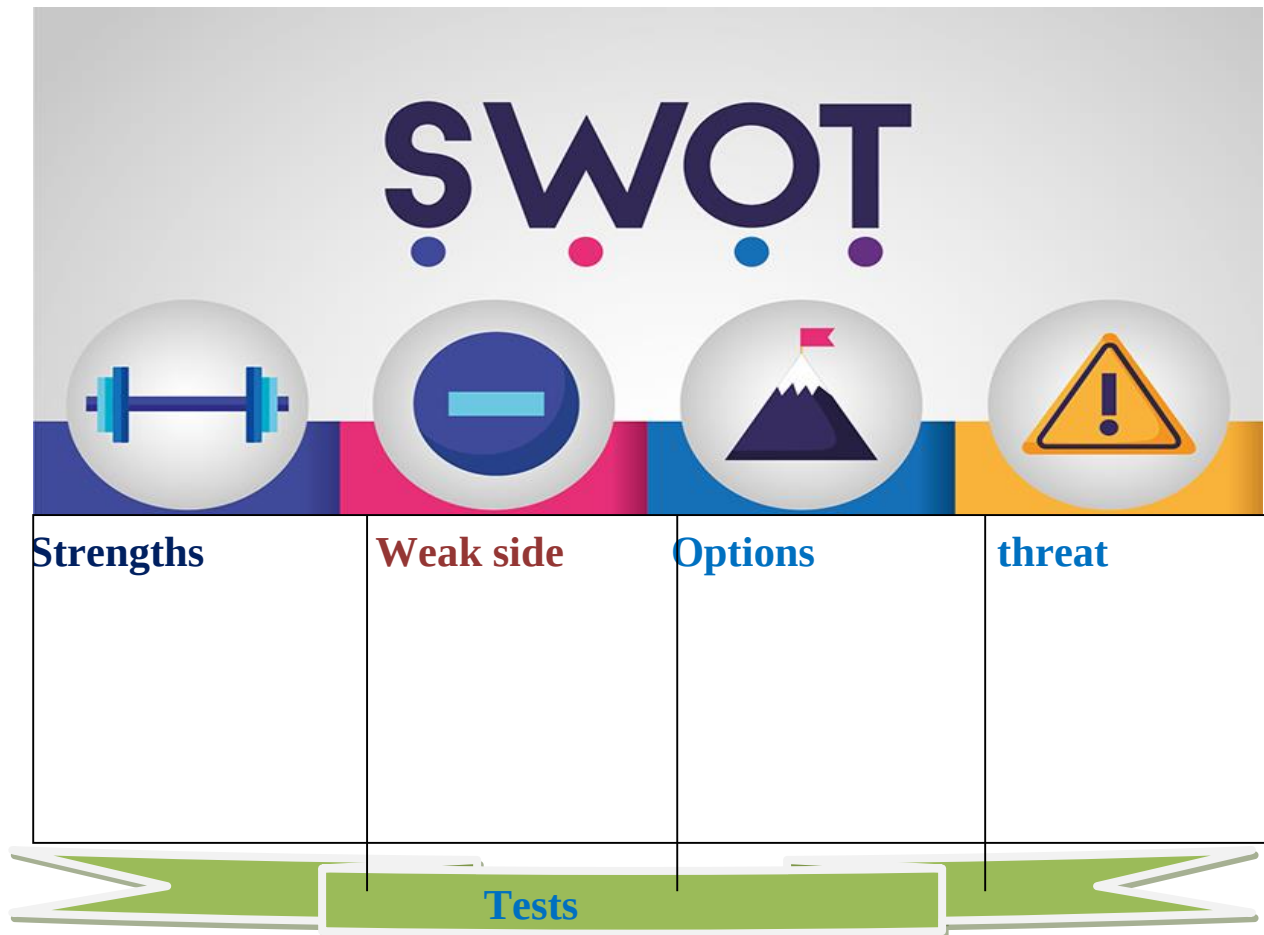
Making a list of terms used in the study of the science of Organization of pharmaceutical production

Group III mission

Description of the types and content of the necessary regulatory documents in the study of the science of Organization of pharmaceutical production

* Students are divided into several subgroups and task written material is distributed, with each group outlining their thoughts and a question answer is left between the groups.

SWOT tahlil



1. Internationally recognized standard regarding the conduct, planning, monitoring, formalization and presentation of conclusions of Clinical Research.

*A) clinical practice

B) laboratory practice

C) manufacturing practice

D) the practice of wholesale sale of medicines

2. The safety and effectiveness of pre-clinical research of drugs is recognized in the Hakki halkaro standard.

A) clinical practice

*B) laboratory practice

C) manufacturing practice

D) the practice of wholesale sale of medicines

3. An internationally recognized standard that monitors the production and quality of medicines in production organizations.
- A) clinical practice
 - B) laboratory practice
 - *V) production practice
 - D) the practice of wholesale sale of medicines
4. Wholesale trade with medicines - the halcaro recognized standard.
- A) clinical practice
 - B) laboratory practice
 - C) manufacturing practice
 - *D) the practice of wholesale sale of medicines
5. GMP what is it?
- A) general management rules
 - B) production processes, and set the procedure for conducting control tests, as well as the type of release, contains the minimum practical instructions for conducting in a modern way
 - C) develop Tdvs that can compete in the high-quality market
 - *D) all answers are correct
6. GMP ning asosiy prinsiplariga nimalar kiradi.
- A) sifatni boshqarish, personal, bino va asbob-uskunalar,
 - B) xujjatlar, ishlab chiqarish, sifatni nazorat qilish,
 - V) shartnoma asosida ishlash, reklama va maxsulot tavsifi va o'z-o'zini nazorat qilish
 - *D) hamma javoblar to'g'ri
7. Confirmation of compliance with the specified requirements of production conditions, technological process, equipment, semi-finished products and quality of finished products on the basis of documents
- *(A) Validation
 - B) GMP
 - V) GLP
 - D) answers B and V are correct
8. What requirements must be met by an employee working in an organization according to the principles of GMP.
- *(A) the safety of GMP principles and the guarantee that you will be able to work with medicines will be shrunk to work in orcali.
 - B) must have many years of work experience under GMP principles.
 - C) the production process must be approached with responsibility.
 - D) hamma javoblar to'g'ri
9. What is included in the documentation of types of training for advanced training?
- A) Organization from the company and seminars in the company;
 - B) training within the company; Standard and training methods;
 - C) holding regular meetings and meetings in departments;
 - Types of skulls of O'kish;
 - *D) all answers are correct
10. What is the level of development bulim head to be blurred?
- A) the drugs must be manufactured and divided in accordance with the sacking cells.
 - B) courses for bondage, quality duration, effect must be ensured and confirmed.
 - C) to be blessed by destitute persons to conduct records, quality control.
 - *D) all answers are correct
11. Requirements for auxiliary substances
- A) it is necessary that the auxiliary substances are proportional to the drug drug
 - B) Auxiliary substances must be harmless from the biological nuktai review
 - C) to ensure that the drug type is stagnant darkor

*D) all answers are correct

12. What classes can be divided into, referring to The Shape of the excipients to the type of drug.

A) solvents, bases for Grease drugs, bases for suppositories

B) bases used in the preparation of powders,

Excipients for pills, surfactants

C) stabilizers, preservatives, substances that improve the taste of the drug (corregents), emulsifiers

*D) all answers are correct

13. How proportionality arises through the departure of a chemical reaction between a drug and an auxiliary substance or between a drug and a drug drug and a drug drug drug.

A) physical imbalance

*B) Chemical Imbalance

C) pharmacological imbalance

D) answers A and B are correct

14. Excipients must be proportional to the drug preparation. In what cases is the physical imbalance in drug preparations manifested.

*A) a change in the type of Medicine is manifested in such conditions as moisturizing, colish, insolubility, non — interference.

B) a chemical reaction may go between the drug and the adjuvant, or between the drug and the drug and the drug.

C) several effects in one type of drug are manifested when drug drugs are given that contradict each other.

D) answers A and B are correct

15. What kind of guruches are divided into carbons, in which the surfactants demonstrate their surface activity property, and not carbons, whether or not they undergo chemical nature, electrolytic dissociation?

A) anionfaol surfactants

B) Cationfaol surfactants

C) Ampholite surfactants

*D) all answers are correct

16. To confirm the compliance of production conditions, technological process, equipment, semi-finished products and the quality of finished products with the specified requirements on the basis of documents?

*(A) Validation

B) GMP

V) GLP

D) answers B and V are correct

17. In what cases is repeated validation carried out?

A) when the jixos are replaced or repaired

B) when changing regulatory technical documents for the finished drug, raw materials, auxiliary substance or sickle, marking materials

C) when technical documents change

*D) all answers are correct

18. In what cases does validation not take place?

*A) equipment that does not affect the quality of semi-or finished products

B) when changing regulatory technical documents for the finished drug, raw materials, auxiliary substance or sickle, marking materials

C) when technical documents change

D) when the jichos are replaced or repaired

19. What does the assumption that validation has taken place include?
- A) Parameters and conditions of technical processes
 - B) the detail of the work of the jichoz and the statement that it corresponds to meior documents
 - C) the results obtained are approximate, suggestions and conclusions
 - *D) all answers are correct
20. Will the validation process be carried out when the production rooms or auxiliary systems (heating, ventilation condensing) are reattached?
- (A) no validation
 - *(B) validation takes place
 - C) does not enter the validation process
 - D) not answered correctly
21. Is the validation process permanent or intermittent?
- *(A) the validation process is conducted continuously
 - (B) the validation process is conducted from time to time
 - C) during the production, the validation process is carried out at the origin of any failure
 - D) periodic validation when the jichoses are replaced or repaired
22. What are the cases of large-scale validation?
- A) reduced product quality
 - B) the quality of the product increases
 - *C) guarantees the quality of the drugs produced
 - D) correct answers
23. Where was the first pharmaceutical production validation carried out?
- *A) 1920 in the United States
 - (B) 1920 in Russia
 - V) in the United States in 1974.
 - (D) 1832 in London
24. Will validation be carried out when replacing or repairing dowels, changing the regulatory technical documents for the finished drug, raw materials, auxiliary substance or sickle, marking materials?
- (A) no validation
 - *(B) validation takes place
 - C) does not enter the validation process
 - D) not answered correctly
25. Where did the validation term first come into practice?
- (A)) in 1920 in the United States
 - (B) 1920 in Russia
 - V) in the United States in 1974.
 - *D) 1832 in London
26. Biologically active substances are extracted from plant raw materials using water, alcohol, ether or head separators, and the separator is partially, sometimes completely, evaporated.
- * A) Extracts
 - B) Tablets
 - C) Grease
 - D) answers A and B are correct
27. How many percent of belladonna dry extract on SF does moisture jump?
- * A) 5%
 - B) 4%
 - V) 3%

D) 3%

28. How many % of the dry concentrate extract of thermopsis contains an alkaloid.

*A) 1%

B) 2%

V) 3%

D) 4%

29. In the conditions of the enterprise, bulging floats with a glandular structure are used in the maxad of swimming bones in a large mikdor.

(A) nutch, druk floats,

B) float-press, centrifugal force floats,

V) clarifiers, kop floats

*D) raw answers tugri

30. How many theories are sought before foreign matter particles and microorganisms can be caught using a repellent.

A) screen theory.

B) hook that occurs in the inner folds of the float wall

*V) 2xil screen theory and a host that occurs in the internal folds of the float wall

D) Calloid theory

31. In terms of productivity and use, such floats will be 4 different.

A) 2xil MFS N 1 (0.15 μm); MFS n 2(0.2 μm

B) 3xil MFS N 1 (0.45 μm); MFS n 2 (0.6 μm); MFS N 3 (0.8 μm ;

*V) 4XIL MFS N 1 (0.15 μm); MFS n 2 (0.2 μm); MFS N 3 (0.45 μm); MFS N 4(0.6 μm

D) 5xil MFS N 1 (0.15 μm); MFS n 2 (0.2 μm); MFS N 3 (0.45 μm); MFS N 4(0.6 μm); MFS N 5 (0.8 μm

32. Are baromembrane floats used for Candide purposes?

A) production of enzymes, hormones, nucleins, acids, viruses, polypeptides, oxyls

B) antibiotic in obtaining enzymes, mining serum, hormones, classification of polysaccharides, separation of bacteria from water

C) in the purification of DNA, viruses, oxyls, vitamins (V12), glucose. In obtaining highly purified apirogenic water

*D) all answers are correct

33.Thin-layer (film) vaporizers are used?

A) applied to thicken high temperature resistant solutions.

B) applied to liquefy solutions that are not resistant to high temperatures.

*C) applied to thicken solutions without resistance to high temperature.

D) applied to liquefy solutions with high temperature resistance.

34. Rotor-what are thin-layer evaporators used for?

*A) used for steaming high temperature resistant, non-corrosive and pasty materials, as well as suspensions

B) used for steaming high temperature resistant, rough and pasty materials

C) used for vaporizing pasteform materials

D) high temperature resistant, used for vaporizing Brown and pasty materials

35.Are the processes of evaporation and evaporation different from each other?

A) the evaporation process is smeared above the boiling point

*B) the evaporation process occurs on the surface of the solution at a temperature lower than the boiling point, at any temperature, while evaporation occurs at a temperature higher than the boiling point, at the entire volume of the solution.

C) evaporation process slurry below boiling point

D) the evaporation process occurs on the surface of the solution at any temperature, while evaporation occurs on the entire volume of the solution.

36. Disadvantages of the method of vaporizing the solution under Vaakum?

- *A) in the process, the cooling of the vacuum increases its cost; in addition to the evaporator, it is necessary to use several additional couplings and devices
- B) the boiling point of the solution is reduced, low pressure vapors can be applied as issykdik eltkich
- C) low efficiency, high energy consumption
- D) the method is expensive

37. What cases can turn away if the number of vaporization traps is large.

- A) in this there is a loss of temperatures.
- B) the efficiency of solution evaporation jaraayon is increased
- C) the process of evaporating solutions is facilitated
- *D) in which the sum of the loss of temperatures can equal or exceed the total difference in temperatures. Without it, it becomes difficult to evaporate solutions and it becomes impossible to carry out the process.

38. How are the processes of processing candles in the conditions of the enterprise carried out?

- A) preparation of the base.
- B) introduction of the medicinal substance into the base.
- C) formation, caducization and laying of candles.
- *D) all answers are correct

39. Find a row in which it is incorrectly indicated that the candlestick bases meet the requirements in the song?

- A) a strong bulib in the room desiccation, melting or cooling in the body desiccation.
- B) that the drug contained in the suppository mixes well with the substance, does not react with them.
- *C) indifferent inferiority in relation to the body.
- D) to be resistant and stable to the effects of air and lightness.

40. What does water-soluble, base-insoluble substances include?

- (A) alkaloid salts, novocaine,
- B) eturridine lactate
- *V) answers A and B are correct
- D) bismuth preparations, zinc oxide

Evaluation criterion

The student ranking by module is determined as follows:

rating	ECTS	Definition of ECTS		mark	Description
86-100	A	scope = "row" / 2018 – excellent result, with minimal errors	have systematic, complete and in-depth knowledge of all sections of the module program, be able to substantiate with the necessary evidence; clear, in-place use of terminology (including in scientific, foreign language), logically, stylistically literate expression of questions; can identify problematic questions, substantiate their views in a scientific and practical language; the module is able to know the basic concepts and effectively apply it in solving scientific and practical issues in a short time; able to independently and creatively solve problems in non-standard situations, show the ability; able to independently fully perform practical skills (in terms of quality and set number) and fully acquire competencies; its brief, grounded and rational resolution of practical issues; complete and deep slimming of the main and additional literature recommended in the module program; understanding the essence of theories, concepts and directions on the module, giving them a critical assessment and being able to apply the scientific achievements of other modules; it is necessary to participate creatively and independently throughout the entire semester in theoretical and practical classes, be active in group discussions, have a high level of culture in the	5	excellent

			performance of tasks.		
81-85	B	"very good" - a higher result than the middle, with some errors	have systematic, complete and in-depth knowledge of all sections of the module program, be able to substantiate with the necessary evidence; clear, in-place use of terminology (including in scientific, foreign language), logically, stylistically literate expression of questions; be able to independently bartaf the non-determinants that arise in proving one's opinion or in making another theoretical material; knowledge of the basic concepts of the module, the ability to put scientific and professional tasks in a short time and make the most of it in solving; be able to independently solve problems in standard situations within the framework of the training program; able to independently fully perform practical skills (in terms of quality and set number) and fully acquire competencies; the fact that in practical training he demonstrates a good knowledge of regulatory legal documents, is able to apply this knowledge in new situations to the full (but not always rational), is not able to adequately formalize the results of the work performed; mastering the main recommended literature in the module program; able to understand the essence of theories, concepts and directions on the studied module and give them a critical assessment; it is necessary to participate creatively and independently throughout the semester in theoretical and practical classes, be active in group discussions, have a very good level of culture in the performance of tasks.	4	Very good

71-80	C	"good" - the average result with significant errors	have a systematic, complete and in-depth knowledge of all sections of the module program, be able to substantiate with the necessary evidence, but with some shortcomings; clear, in-place use of terminology (including in scientific, foreign language), logically, stylistically literate expression of questions; be able to independently eliminate the inaccuracies that arise when proving one's opinion or stating another theoretical material; knowledge of the basic concepts of the module, the ability to put scientific and professional tasks in a short time and make the most of it in solving; be able to independently solve problems in standard situations within the framework of the training program; able to independently complete practical skills (in terms of quality and set number) and acquire competencies, but with some disadvantages; the fact that in practical training he demonstrates a good knowledge of regulatory legal documents, is able to apply this knowledge in new situations to the full (but not always rational), is not able to adequately formalize the results of the work performed; mastering the main literature recommended in the module program; able to understand the essence of theories, concepts and directions on the studied module and give them a critical assessment; in theoretical and practical classes, he must participate creatively and independently throughout the semester, be active in group discussions, have a good degree in the performance of tasks.		

60-70	D	"satisfactory" - a sluggish result, with rough flaws	To have sufficient volume of knowledge within the framework of state educational standards (requirements); using terminology, correctly stating answers to questions, but making some mistakes; demonstrate that he has a basic understanding of the module when he has difficulty responding or demonstrating some special skills; Able to fully perform practical skills (in terms of quality and set number) independently, but with errors; taking competencies independently, but with errors; can have partial knowledge of the general concepts of the module and apply it to solving standard (model) situations; the educator can solve standard situations with the help of an employee; able to understand the essence of the main theories, concepts and directions on the module under study, to evaluate them; in theoretical and practical training, the educator must participate with the help of an employee, have a sufficient level of culture in the performance of tasks.	3	satisfactory
56-59	E	"middle" - equal to the minimum result	To have a satisfactory volume of knowledge within the state educational standards (requirements) ; using terminology, correctly stating the answers to questions, but making some gross mistakes in this; to demonstrate that it has a basic understanding of the module when it is difficult to respond or to demonstrate some special inclusions and make mistakes; perform practical skills (in terms of quality and set number) are not		

			independent and complete with errors. competencies are not independent and occupy with errors; can have partial knowledge of the general concepts of the module and apply it to solving standard (model) situations; the educator can solve standard situations with the help of an employee; able to understand the essence of the main theories, concepts and directions on the module under study, to evaluate them; in theoretical and practical training, the educator must participate with the help of an employee, have a sufficient level of culture in the performance of tasks.		
31-55	FX	"unsatisfactorily – additional independent mastering is necessary in order to obtain a minimum level of knowledge"	If the state has only some fragmentary knowledge within the standards (requirements) of Education; can not use scientific terms or make serious logical errors in response; participate passively in theoretical and practical training and perform tasks if they have a low level of living culture; if he does not have practical skills and competencies, he cannot correct his mistakes even with the help of the recommendations of a Hatto pedagogical employee.	2	unsatisfactory
0-30	F	"absolute unsatisfactory" – complete re-appropriation"	If the state has only some fragmentary knowledge within the standards (requirements) of Education; when it cannot use terms or makes serious and gross logical errors in response or does not respond at all; participate passively in theoretical and practical training, perform tasks, if they have a low level of culture or do not perform at all; If he does not have practical skills and competencies, he cannot correct his mistakes even with the help of the		

			recommendations of a Hatto pedagogical employee.		

Final control (FC)

A student who has fully accumulated the credit allocated to the JN and has completed the on will be included in the Yan. YaNda the knowledge, skills and qualifications of the student are evaluated within the general content of the module. YaN is conducted in written form after the end of modular training. YaN tickets are drawn up, consisting of three questions. A student who fails to score a Yanda qualifying score (56%) is considered to have not passed Yanda and did not master the module (even if JNda has collected the full credit).

The process of conducting final control with the participation of the commission, established by order of the rector of the educational institution under the direction of the Department of internal control and monitoring, is periodically studied, and in cases where the procedures for conducting it are violated, the results of Final control are canceled and final control is transferred again.

Students who cannot submit Yan due to illness are allowed to submit within two weeks of starting their studies under the orders of the dean of the faculty.

At the end of the semester, the student who scores less than the Yanda qualifying score is the academic debtor.

Academic indebted students are given a period of one month to re-master after the end of the semester. During this period, a student who has not mastered the module is excluded from the ranks of students by order of the rector in the prescribed manner on the recommendation of the dean of the faculty.

If the student is dissatisfied with the results of the control, within a day from the time of publication of the results of the type of control on the module, he can apply to the dean of the faculty with an application. In this case, according to the submission of the dean of the faculty, by order of the Rector, an appeals commission is established in a composition of no less than 3 (three) members.

The appeals commission will review the students ' applications and report their conclusion on the same day.

The conduct and formalization of the assessment on the basis of established requirements is monitored by the dean of the faculty, the head of the department, the training department and the Department of internal control and monitoring.

Asosiy va qo'shimcha adabiyotlar hamda axborot manbaalari

Asosiy adabiyotlar

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Qo'shimcha adabiyotlar

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2. Яхши ишлаб чиқариш амалиёти қоидалари (GMP). Тармоқ стандарти Tst 19-01:2003. 60 бет.
3. Производство лекарств по GMP (Сборник статей). Москва. 2005. «Медицинский бизнес» 344. С.

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4. <http://www.minipress.ru/>
5. http://www.fptl.ru/Y4eba_osnovi-gls.html