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КАФЕДРА ОРГАНИЗАЦИИ ФАРМАЦИИ

УЧЕБНАЯ ФАРМАЦЕВТИЧЕСКАЯ ПРОПЕДЕВТИЧЕСКАЯ ПРАКТИКА

PHARMACEUTICAL PROPAEDEUTIC PRACTICAL TRAINING

Методические рекомендации

Минск БГМУ 2019

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Содержит информацию о работе основных организаций, занимающихся фармацевтической деятельностью (фармацевтическое предприятие, аптека 1-й категории, аптечный склад и контрольно-аналитическая лаборатория). Представлен список терминов с определениями, которые используются в фармацевтической сфере, а также перечень вопросов для итоговой аттестации студентов (дифференцированного зачета).

Предназначено для студентов 1-го курса медицинского факультета иностранных учащихся, которые проходят практику на английском языке.

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Методические рекомендации

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EXLANATORY NOTE

Organization and policy of manufacturing practice set by the Decree of the Council of Ministries of the Republic of Belarus from 03 of June 2010 № 860 «About approval of provision of practice for students, cadets, auditors» (at red. of decrees of the Council of Ministries from 04.08.2011 № 1049, 09.12.2011 № 1663, 11.09.2012 № 844, 08.05.2013 № 356, 2.08.2013 № 736) and Provision «About practice for students of educational institute «Belarussian state Medical University» № 88 from 29.01.2014.

Aim of the pharmaceutical propaedeutic practice is formation student's general knowledge of working processes in pharmaceutical organizations

Tasks of educational propaedeutic practice:

– tour to manufacturing plant, pharmacy of I category, pharmaceutical warehouse and analytical laboratory;

– introduction of set-up plan of pharmaceutical organizations, theirs purposes, equipment and facilities;

– introduction of hygiene requirements, attended to facilities, issued for manufacturing, storing, sales of medicines and staff;

– introduction of terminology used in distribution of medicines;

– main tasks and functions of pharmacy, labour protection and safety, hygiene order and formation basic skills for cleaning premises of a pharmacy, washing the pharmacy glassware and sealings.

This practice is prior to study all pharmaceutical subjects and, in particular, the management and economics of pharmacy and pharmaceutical technology.

During the period of propaedeutic practice students have to follow all indoor management rules of base organization.

Student is acceptable for propaedeutic practice only in case of presence of health certificate and after labour protection briefing.

The use of «Pharmaceutical Propaedeutic Practical Training» by students will provide high-quality methodological support of pharmaceutical educational propaedeutic practice. For students studying in English, this manual is particularly important due to the inability to study the normative documentation in the national language.

TERMS AND DEFINITIONS ACCORDING TO THE LAWS OF THE REPUBLIC OF BELARUS «ABOUT MEDICINAL PRODUCTS» AND «ABOUT HEALTHCARE» FOR GRADED CREDIT

Pharmacy is a complex of specialized premises and equipment, intended for manufacturing and sales of medicines and other goods of pharmacy assortment, which belongs on a basis of the right of ownership or other legal right to a legal party or self-employed entrepreneur registered in the Republic of Belarus, foreign legal party or foreign enterprise, set up in accordance with equal state procedure if this organization has a representative office on the territory of the Republic of Belarus with special permission (license) for pharmaceutical activities.

Drug safety is positive characteristic of medicine, based on the comparing analysis of its effectiveness and measurement of potential harm to human life and health.

Health is a person`s condition of full physical, mental and social welfare, and not only the absence of diseases.

Dosage form is a given to a medicine identifying its state according to its usage for proper effectiveness.

Medicinal plant raw materials are whole medicinal plants or their parts according to pharmacopeia articles used in industrial or pharmacy manufacture of medicines.

Medicine is a substance or a compound of several substances of natural, synthetic or biotechnological origin with pharmacological activity in a defined dosage form used for prevention, diagnostics, treatment or medical rehabilitation and as contraception by means of internal or external usage.

Good pharmacy practice is a set of rules for pharmacy medicines manufacturing, quality control, control over shelf life, packaging and labeling, storage conditions, sale of medicines to ensure quality and availability of medicines, and classification of pharmacies according to the category.

Good Wholesale Practice is a set of rules for the wholesale trade of medicines for the purpose of quality and storage assurance.

Good Pharmacovigilance Practice is a set of rules for the organization and carrying out activities to identify adverse changes in the safety profile and efficacy of medicinal products and taking measures to minimize the negative consequences of the use of medicinal products in circulation on the territory of the Republic of Belarus.

Good Manufacturing Practice — set of rules for industrial manufacturing and quality control of medicines.

Shelf Life of the Drug is a time period, during which medicines will not lose safety, effectiveness and quality in case of proper storage conditions.

Active pharmaceutical ingredient (API) is a substance or a compound of substances of natural, synthetic or biotechnology origin with pharmaceutical activity used in industrial or pharmacy medicine manufacturing.

Pharmaceutical activities are activities in the sphere of distribution of medicines, APIs and medicinal plants raw materials, realized by legal parties or self-employed entrepreneurs according to the official order established in accordance with legislation of the Republic of Belarus.

A pharmaceutical worker is a person who has a higher or secondary special pharmaceutical education, confirmed by a document of education, and in accordance with the procedure established by the legislation of the Republic of Belarus engaged in activities related to the circulation of medicines, pharmaceutical substances and herbal medicinal raw materials.

Effectiveness of medicines is a characteristic of the level of positive effect of medicine on prevention, state or duration of a disease or condition, contraceptive effect, recovery of normal vital functions and compensation of functional abilities, impaired as a result of a disease.

QUESTIONS FOR A GRADED CREDIT

1. Categories of pharmacies and characteristics of premises.
2. Sanitary conditions of pharmacies: types of cleaning.
3. Information for customers in the sale area and on the front of the pharmacy.
4. Common principles and miles of medicine storage in pharmacies and pharmaceutical warehouses.
5. Organization of work at a pharmaceutical warehouse (premises and equipment).
6. Aspects of storage of narcotics, psychotropics and medicines from list «A».
7. Organization of glassware cleaning, auxilliary and packing materials in the pharmacy.
8. Procedure of incoming control at a pharmacy.
9. Software and computing facilities in pharmacy and pharmacy warehouses activities.
10. Sanitary-hygienic requirements of personal hygiene of pharmacy staff.
11. Work organization of pharmaceutical plant (classification of premises according to the level of their cleanness).
12. Task and functions of an analytical laboratory.
13. Cold chain. Control of temperature conditions and relative humidity at pharmacies and pharmaceutical warehouses.
14. Aspects of supplying the public health organizations with medicines and medical devices.
15. Facilities of I category pharmacy. Working equipment of provizor-technologist (pharmacist-assistant).

EXCERPT FROM NORMATIVE LEGAL ACTS, REGULATED PHARMACEUTICAL ACTIVITIES IN THE REPUBLIC OF BELARUS

On approval of the Good pharmacy practice

Decree of the Ministry of Health of the Republic of Belarus
27th December 2006 № 120

Depending on the work performed and services that make up the licensed types of activities, occupied rooms of premises and sold medicines, narcotic drugs and psychotropic substances, pharmacies are classified by category into pharmacies of the first, second, third, fourth and fifth categories.

Pharmacy of the first category it is a production pharmacy in which:

– pharmacy production of medicines is realized according to prescriptions of doctors, requirements (applications) of health organizations of the Republic;

– packing operations;

– quality control of manufactured medicines;

– retail sale of medicines to the population, health organizations and other organizations for medical use.

The hospital pharmacy of the first category carries out pharmacy production of medicines and dispensing medicines to health organizations and (or) their structural units.

To organize the work of a pharmacy of the first category (a hospital pharmacy of the first category), a complex of premises is required, consisting of:

– premises (parts of the premises (hereinafter — the zone)) of acceptance;

– storage rooms (at least two);

– premises for public service — a trading hall (for pharmacies that carry out the retail sale of medicines);

– administrative premises (a sanitary unit, an administration room, a staff room and a wardrobe, while the staff room and cloakroom can be combined);

– industrial premises: water treatment; processing of chemist's ware, packing and auxiliary materials; pharmacy manufacturing of medicines; sterilization. At the same time, water treatment facilities and sterilization rooms can be combined;

– premises (zones) for quality control of medicinal products.

If the pharmacy of the first category (hospital pharmacy of the first category) manufacture sterile medicines and medicines in aseptic conditions, sterilization facilities (hereinafter referred to as the aseptic unit with a lock or gateway) are additionally included in the production facilities.

If pharmacy of the first category (hospital pharmacy of the first category) manufacture which are sterile medicines prescribed by a doctor and required by

health organizations in the amount of less than 50 prescription numbers per day in aseptic conditions, it is allowed to combine an aseptic unit with a gateway.

Actually used area of pharmacies of the first category should not be less than 100 square meters. The area of the hospital pharmacy of the first category should correspond to the volume of work performed.

Pharmacy of the second category it is a pharmacy in which retail sales of medicines to the public, health organizations and other organizations for medical use are carried out.

The hospital pharmacy of the second category carries out the dispensing of medicines to health organizations and (or) their structural units.

To organize the work of a pharmacy of the second category (hospital pharmacy of the second category), a complex of premises is required, consisting of:

– premises for supplying the population with medicine and other accompanying goods — a trading hall (for pharmacies that carry out the retail sale of medicines);

– storage facilities (at least two for pharmacies that carry out retail sales of medicines to health organizations);

– administrative premises (a sanitary unit, an administration room, a staff room and a wardrobe, while the staff room and cloakroom can be combined);

– zones of acceptance of goods.

Actually used area of pharmacies of the second category should be at least 60 square meters. The area of the hospital pharmacy of the second category should correspond to the volume of work performed.

Pharmacy of the third category it is a pharmacy in which the retail sale of medicines to the population for medical use is carried out. It is established in rural settlements, agro-towns and only if a legal entity or an individual entrepreneur has a pharmacy of the first or second category.

To organize the work of a pharmacy a complex of premises is required consisting of:

– premises for public service — a trading hall;

– storage rooms;

– zones of acceptance of goods.

The pharmacy of the third category should have a wash-bowl for washing hands.

Actually used area of the pharmacy of the third category should be at least 20 square meters;

Pharmacy of the fourth category it is a pharmacy in which the retail sale of medicines to the population and other organizations for medical use is carried out. It is established in healthcare organizations, if a legal entity or an individual entrepreneur has a pharmacy of the first or second category.

A fourth category pharmacy is located in a room (several rooms), in which the acceptance, storage and service areas of the population are allocated.

Actually used area of the pharmacy of the fourth category should be at least 15 square meters;

Pharmacy of the fifth category it is a pharmacy in which retail sales of medicines to the population, healthcare organizations and other organizations for medical use are being carried out, created in the areas of the greatest concentration of population (shops, markets, stations, hotels, etc.), with a legal entity or individual entrepreneur pharmacies of the first or second category.

The pharmacy of the fifth category should be located in a room isolated from the premises of another purpose, in which the zones of acceptance, storage and service of the population are allocated.

Actually used area of the pharmacy of the fifth category should be at least 15 square meters.

It should be noted that pharmacies of the first and second categories that carry out the retail sale of medicines must have a separate entrance for the buyers and an additional one for obtaining the goods; pharmacies of the third–fifth category should have an entrance for buyers.

The entrance for customers from the street should be equipped with a ramp with handrails for persons with impaired function of the musculoskeletal system, and (or) an electronic speech informer with a call to bell a pharmacy worker and/or other equipment that provides unhindered access for the disabled and other categories of physically weakened persons.

Pharmacies of the third–fifth category can have central heating, water supply, sewerage, supply and exhaust ventilation system, a telephone, fire alarm system common to the owner`s (landlord`s) premises.

The pharmacy should be located in non-residential premises of capital buildings (buildings, structures) and be isolated from other premises, the exception for is the first and second category hospital pharmacies.

The premises (zones) of the pharmacy must ensure the performance of the relevant work and services that constitute the licensed activities. The pharmacy premises (zones) must be sequentially interconnected depending on the work performed.

Information for visitors in the trading hall and on the front of the pharmacy

On the front of the pharmacy there should be a signboard in Russian or Belarusian language with indication of its name, affiliation, mode of operation. 24-hour pharmacy, that carries out retail sales of medicines within 24 hours, must additionally have an illuminated sign, a phone bell to call a pharmacy worker and a window for dispensing medicines.

Information about the closure of the pharmacy in connection with the sanitary day, repairs, refurbishment or due to its liquidation is to be provided to the public in advance by posting an announcement. The schedule of sanitary days is

coordinated with the territorial center of hygiene and epidemiology and is placed on the information stand in the salesroom of the pharmacy.

In the salesroom of pharmacies, depending on the work performed and services that make up pharmaceutical activities, information is provided to buyers, including:

– copies of special permits (licenses) for carried out activities (with the exception of a special permit (license) for activities related to dispensing narcotic drugs, psychotropic substances and their precursors);

– legal address and telephone number of a legal entity or self-employed businessman;

– an extract from this Good Pharmacy Practice on the Rules for the Sale of Medicines;

– on the availability and location of the customer comment book;

– about telephone numbers and addresses of the nearest drugstores, reference pharmaceutical service, public health authorities;

– on the categories of citizens entitled to free dispensing and reimbursement of medicines and bandaging material (for pharmacies that carry it out);

– on categories of citizens entitled to nonroutine maintenance;

– on the schedule for sanitary days;

– about a healthy way of life and (or) struggle against distribution and use of narcotic drugs and (or) prevention of HIV infection and other diseases;

– on the shelf life of medicines manufactured in the pharmacy (for pharmacies of the first category).

General principles and rules for storage of medicinal products in pharmacies and pharmacy warehouses

Storage of medicines in the pharmacy is carried out by pharmacotherapeutic groups, taking into account their physicochemical and toxicological properties in accordance with the conditions indicated on the label, in the instructions for medical use and (or) the leaflet, separately from other goods of the pharmacy assortiment. Drugs in the pharmacy are placed in cabinets, on shelves and in exceptional cases — on dunnage racks. It is not allowed to place medicines on the floor without dunnage rack. Dunnage rack are located on the floor in one row in height.

Medicines listed «A» in the pharmacy are stored in a safe or metal cabinet, attached to the wall or floor. Thermolabile drugs of the «A» list are stored in a refrigerator or refrigerating cabinet on a separate shelf.

Storage of medicinal products of the list «A» is allowed in specially equipped premises in accordance with the legislation of the Republic of Belarus, intended for storage of narcotic drugs and psychotropic substances.

The temperature and relative humidity in the premises (zones) of storage and public service (salesroom) and the temperature in the refrigerating equipment — are recorded at least once a day in the temperature (relative humidity) log-book (log).

Registration of temperature in refrigerating equipment during storage of thermolabile immunobiological medicinal products is carried out 2 times a day.

Pharmacies can display medicines according to pharmacotherapeutic groups, medical devices and goods of the pharmacy assortment that are available in pharmacy displays.

Medications included in the list of medicines of the Belarusian (Russian) production required for the availability of all forms of property in pharmacies that carry out the retail sale of medicines, approved by the Ministry of Health of the Republic of Belarus in accordance with the established procedure, should be displayed in the display-window.

It is forbidden to put narcotic drugs, psychotropic substances and drugs of the list «A», drugs with anabolic activity in the display-window.

For medicines requiring special storage conditions, only a secondary individual package is placed in the display case.

Showcases with medicines, the realization of which is carried out according to the prescription of the doctor, are inscribed with the inscription: «It is released according to the prescription of the doctor».

The order of carrying out the acceptance inspection in the pharmacy

The acceptance inspection is carried out by the acceptance commission, except for pharmacies of the third–fifth category, in which the acceptance control can be carried out by one pharmacist. The acceptance commission is formed from the number of pharmacy workers, including pharmaceutical workers.

Acceptance control includes:

– correctness of accompanying and other documents, including commodity-transport (commodity) waybills (hereinafter, unless otherwise specified, — accompanying documents);

– conformity of the requisites of the medicinal product indicated in the accompanying documents (name, dosage, quantity, lot number) to the actually received medication;

– the integrity of the packaging of medicinal products and their labeling;

– availability of instructions for medical use and (or) an insert in Russian (Belarusian) language in individual or group packaging and the compliance of the number of instructions for medical use and (or) leaflets with the number of primary individual packages of medicines in a group package.

Acceptance control of medicinal plant raw materials received from the population includes:

– checking the compliance of external signs of medicinal plant material with the requirements of the State Pharmacopoeia of the Republic of Belarus;

– selection of samples of medicinal plant raw materials from the received batch and their direction to the testing laboratory for conducting tests according to

the physicochemical parameters of the relevant private pharmacopoeial articles of the State Pharmacopoeia of the Republic of Belarus.

After the acceptance inspection the results of it are made in the register in the form approved by the head of the legal entity or an individual entrepreneur, and are certified by the signature of the chairman of the acceptance commission or the signature of the pharmacy worker who has carried out the acceptance control in pharmacies of the third to fifth category.

In case of any discrepancy to any of the requirements, the incoming lot (batch) of the medicinal product and herbal medicinal raw material is stored separately from other medicines with the designation «Rejected at acceptance inspection» until the causes of the discrepancy are clarified and eliminated.

When accepting medicinal products that require special conditions (thermolabile), they are immediately sent to storage facilities that provide the required conditions (refrigerator, coolroom).

Accepting narcotic drugs, psychotropic substances, as well as radiopharmaceuticals, they are immediately transferred to specially equipped storage facilities. Medicines listed «A» are transferred to safes or metal cabinets attached to the wall or floor.

Pharmaceutical substances used for pharmaceutical manufacture of medicines, before entering the drugstore manufacturing room (assistant's room), are subject to quality control to confirm their authenticity.

On approval of the Sanitary norms and rules «Sanitary-epidemiological requirements for pharmacies» (extraction)

Decree of the Ministry of Health of the Republic of Belarus
1th October 2012 № 154

Sanitary Norms and Rules «Sanitary and epidemiological requirements for pharmacies» (hereinafter — Sanitary Norms and Rules) establish requirements for the territory, water system, sanitation, microclimate, ventilation and lighting of premises, maintenance and exploitation of premises, equipment, furniture and premises, personal hygiene of pharmacy workers, requirements for obtaining, transporting and storing purified water and water for injections, for treatment and disinfection (sterilization) of chemist's utensils, small-scale mechanization and base materials, for making sterile dosage forms and dosage forms manufactured under aseptic conditions, in pharmacies.

These Sanitary Norms and Rules are mandatory for compliance by state organizations, other organizations, individuals, including individual entrepreneurs.

The perpetrators are responsible for violation of these Sanitary Norms and Rules in accordance with the legislative acts of the Republic of Belarus.

The pharmacy should be located in non-residential premises of capital buildings (buildings, structures) and be isolated from other premises, except pharmacies created by hospital organizations. The pharmacy located in the non-residential premises of the residential building should be located on the floor not higher than the first. It is prohibited to place pharmacies in basements, except for pharmacy storage areas. It is allowed to place pharmacies in shopping areas of underground passages.

If there is a land plot in the pharmacy its territory should be landscaped, planted, lighted and kept clean. In winter, access roads, pedestrian paths, porch and stairs should be snow and ice cleaned.

Before entering the building of a pharmacy with a separate entrance, the following must be installed:

– gratings or scrapers for shoe cleaning, should be cleaned as needed, but at least once a day;

– garbage bins should be cleaned as they are filled up, not allowing them to overflow. Pharmacies of the first and second categories should have a separate entrance for buyers and an additional one for obtaining goods, and pharmacies of the third to fifth category should have the entrance for buyers into the public service area (zone).

For persons with impaired functions of the musculoskeletal system, the pharmacy must create the necessary conditions for free access to the pharmacy in accordance with the legislation on the social protection of disabled people in the Republic of Belarus (ramp with rails).

The pharmacy must have a system of electricity, heating, water supply, water disposal, supply and exhaust ventilation.

Small windows, folding transoms and window leafs must be in good condition, in the warm season should be protected from penetration of insects.

The temperature of the air in the storage areas of medicinal products that do not require special storage conditions, in the areas of acceptance of goods, administration and the salesroom should be not lower than 18 ℃ and not higher than 25 ℃. Relative humidity in the premises of pharmacies should be 30–80 %.

In premises of drugstores, except for industrial premises, sterilization room and premises for quality control of medicinal products, suspended ceilings of various designs may be used.

The design and materials of suspended ceilings should provide the possibility of wet cleaning and disinfection.

It is forbidden to lay sewage pipelines under the ceiling of trading halls and industrial premises, as well as in the premises for storing medicines, medical products, medical equipment and pharmacy goods.

The interior trim of industrial premises and storage areas (interior surfaces of walls, ceilings, floors) of pharmacies, as well as interior trim of premises (zones) for acceptance and attendance of the population (internal surfaces of walls, floors) should be permitted for wet cleaning, treatment and disinfection using means of disinfection with washing means or disinfectants.

To ensure the storage and preservation of medicines, medical devices, medical equipment and pharmacy products, pharmacies are equipped with appropriate equipment, furniture and accomodations.

Utilization of the disrepair equipment, furniture and aids is not allowed.

A washbasin, equipped with dosing devices for liquid soap and antiseptic, an electric towel and/or disposable paper towels with fastening devices should be installed to wash the hands of pharmacy workers.

A bin with a lid adjustable by a pedal mechanism must be installed near the sink for disposable paper towels. The pedal mechanism in the bin must be in a good condition.

Protection of pharmacies from rodents and insects should be ensured by carrying out with a complex of engineering and construction measures, and, as far as necessary deratization and disinsection measures should be taken. Cleaning of the pharmacy premises should be done in a wet way with disinfectants, detergents and detergents with disinfectant effect. Dry cleaning of pharmacies is not allowed. Floors should be washed with detergents as far as necessary, but at least once per shift, walls and doors should be washed at least once per week. The ceilings must be cleaned from the dust once a month with a damp rag. In the period of epidemic increase of acute respiratory infections cleaning of the pharmacy premises should be carried out once a week with disifectants.

Employees of pharmacies must undergo mandatory medical examinations in the manner prescribed by the legislation of the Republic of Belarus.

Change of sanitary and hygienic clothing of pharmacy workers should be made as far as become dirty, but at least once a week.

Employees of pharmacies must abbey the following rules:

– when a person comes to a working place, he/she should take off the outer clothing and shoes;

– before starting work sanitary and hygienic clothes should be put on, and shoes need to be changed, hands are to be washed;

– before starting the work related to the manufacture of medicines hygienic treatment of the skin of the hands with an antiseptic is to be performed;

– before going to the sanitation unit, whites need to be taken off and after visiting it hands are to be washed carefully and treated with an antiseptic.

Employees of pharmacies engaged in the manufacture, packaging and quality control of medicinal products are forbidden to keep the items of personal use at workplaces and in the pockets of sanitary and hygienic clothing, except for a clean

handkerchief, as far as wearing jewelry on they hands. The nails on the hands should be short-cuted and not varnished, the hair should be carefully bunched under a tightly fitting sanitary-hygienic headdress.

Employees of pharmacies engaged in the manufacture of dosage forms in aseptic conditions, when entering the lock of the aseptic unit, should put on special shoes, wash their hands and treat them with an antiseptic, put on sterile hygienic clothing and headdress, shoe covers, a sterile mask that must be changed every 4 hours work.

Sanitary and hygienic clothing should be assembled at the wrists and high at the neck. It is not allowed for workers to have voluminous, fleecy clothes under sterile sanitary and hygienic clothes.

Employees of pharmacies are forbidden:

– to take food to the production premises of pharmacies and the premises for quality control of medicines;

– to go outside the pharmacy in sanitary and hygienic clothes and shoes;

– to smoke (consume) tobacco products in the premises of pharmacies.

On approval of the Good Wholesale Practice (extraction)

Decree of the Ministry of Health of the Republic of Belarus
1th January 2007 № 6

Pharmacy warehouse is a complex of specialized premises and equipment intended for acceptance, registration, sampling, storage, sale of medicinal products and ensuring their safety.

Pharmacy warehouse has a punch, round seal with the designation of its name.

The pharmacy warehouse group is established by the higher organization depending on the commodity circulation.

The staff and structure of the pharmacy warehouse are established in accordance with the amount of work and the requirements of Good Wholesale Practice.

In accordance with the main task, the pharmacy warehouse provides:

– acceptance of medicines, medical devices, pharmacy products, ethanol alcohol (further goods) in a sufficient supply and quality in accordance with the procedure and on terms, established by the legislation of the Republic of Belarus and specified in the contract and acceptance inspection;

– conditions of storage of goods in accordance with the requirements of regulatory legal acts, technical regulations, local regulatory legal acts and the Regulations on the Storage Department;

– sampling for quality control of medicines;

– the discipline of prices during their formation and calculations with providers and consumers;

– safety of goods;

– acceptance of applications;

– collection and packaging of goods in accordance with the application;

– removal of medicinal products on the basis of the Decision of the Ministry of Health of the Republic of Belarus, as well as expired shelf life;

– control over the timely sale of goods, taking into account their shelf life;

– maintenance of claim work;

– implementation of sanitary norms and regulations acceding to pharmaceutical order;

– carrying out measures to strengthen and modernize the material and technical base, meet the requirements of fire safety measures in accordance with the Fire Safety Rules of the Republic of Belarus to ensure healthy and safe working conditions in accordance with the OSH management system;

– proper processing of receiving and expenditure documents;

– maintenance of documentation in accordance with the nomenclature of cases;

– compiling and presenting book-keeping and statistical reports in accordance with the current regulatory legal acts, local regulatory legal acts within the prescribed time periods;

– screening submission, placement and continuous improvement of professional knowledge of warehouse employees;

– carrying out measures and works on the management of industrial waste within a framework of the current environmental legislation.

A signboard in Russian or Belarusian language should be placed on the front of the pharmacy warehouse with indications of its name, affiliation, hours of operation, number and date of issue of a special permition (license) on the basis of which the activity is carried out.

Premises of a pharmacy warehouse should be consequently connected, depending on the work and services performed, exclude the intersection of technological flows and to be arranged in the following way:

– premises for acceptance of medicinal products;

– storage room for medicines;

– premises or part of the premises (hereinafter — zone) for dispensing of medicinal products;

– administrative and amenity facilities (office, sanitary and amenity a wardrobe, a room for food exeptance, hygiene facilities).

A pharmacy warehouse should be located in non-residential premises of capital buildings (buildings, structures), herewith storage rooms should be isolated from other premises. Premises of a pharmacy warehouse should be located, as a

rule, in the one building or construction of the same address. It is possible to locate a pharmacy warehouse in several nearby buildings, facilities that have a common isolated territory.

The area of the premises of the pharmacy warehouse, with the exception of administrative and amenity facilities should be at least 100 square meters. In case of the necessary of packaging of pharmaceutical substances in the pharmacy warehouse should be additionally provided with the following premises:

– prepackaging room with an area of at least 20 square meters;

– room for distillation and sterilization with an area of at least 10 square meters;

– washing room with an area of at least 12 square meters.

In the acceptance area a zone should be allocated for cleaning the transport packaging from contamination.

Quarantine zones (rooms, special areas) or cabinets for temporary storage of medicinal products that are prohibited for sale are allocated at the acceptance and storage facilities of medicinal products.

Depending on the work and the services performed that make up the pharmaceutical business, the pharmacy warehouse should have:

– shelvings, cabinets, dunnage racks for storing medicines;

– refrigerating chambers (the volume of the refrigerating chamber should be not less than 1,4 cubic meters);

– technological equipment for packaging of pharmaceutical substances;

– facilities for measuring the mass and volume of medicinal products;

– devices for recording temperature and humidity of the environment (thermometers, psychometric hygrometers);

– mechanized loading and unloading facilities;

– other equipment and inventory that provide sanitation, safety, security, fire safety, environmental protection and safety of goods and non-monetory physical things.

Control and analytical laboratory

Analytical laboratory is not a legal party, it is on the balance of the higher organization and is its structural unit. The analytical laboratory has a stamp, a seal with the designation of its name. The staff of the laboratory is approved by the higher organization.

The main tasks of the analytical laboratory are:

– to carry out the quality control of medicinal products before acceptance them for sale or being in circulation on the territory of the Republic of Belarus in accordance with the requirements of regulatory legal acts of the Republic of Belarus;

– to carry out the quality control of purified water and medicines manufactured in pharmacies;

– to carry out the organizational and methodical management of pharmacies of the first category on the quality control of medicines manufactured in pharmacies.

In accordance with the main tasks the analytical laboratory is responsible for the following functions:

– to conduct tests of samples of domestic medicines for compliance with the requirements of pharmacopoeial articles of the manufacturer and medicinal products of foreign origin for compliance with the requirements of regulatory documents of their manufacturers (documentation);

– to issue test reports on the results of quality control of medicinal products;

– to control the realization of the requirements of legislation in pharmacies of the 1 category during the acceptance inspection, quality control of medicines manufactured in pharmacies, pharmaceutical substances, purified water, excipients used in the manufacture of medicines in pharmacies;

– to monitor the rules and regulations, the requirements of the Good Pharmacy Practice in the manufacture of medicines in pharmacies;

– to make proposals and take measures, established by the legislation, in case of detection of substandard medicines;

– to provide pharmacies of 1th category with reagents and titrated solutions, to monitor their rational use and storage;

– to collect and return to the State Fund of precious metal wastes obtained during the work of the laboratory;

– to participate in targeted and complex inspections of pharmacy organizations and to develop measures for improving the pharmaceutical order, sanitary regime, quality control of medicines manufactured in the pharmacy;

– to carry out methodological guidance on the quality of medicines, intra-pharmacovigilance organizations, drug technology;

– to prepare proposals for the revision of regulatory documents (regulations, instructions, etc.) connected the work of the analytical laboratory for quality control of medicines;

– to conduct research work on determining the shelf life of medicines manufactured in a pharmacy to, develop methods to analyze multicomponent dosage forms.

In its work analytical laboratory is guided by the current legislation of the Republic of Belarus, orders and instructions of the higher organization.

The analytical laboratory should be located in a room that ensures the implementation of its functions and safe working conditions.

The analytical laboratory should have a signboard indicating the subordination, the working hours, which are set up by the higher organization.

In order to perform the assigned tasks, the analytical laboratory should be provided with:

– necessary devices, equipment, reagents, laboratory glassware in accordance with the field of accreditation;

– normative and technical documentation and other normative documents regulating pharmaceutical activities of pharmacy organizations, reference and information literature, internal labor regulations;

– fire system in accordance with the instructions of the fire safety department.

The analytical laboratory is headed by the head-pharmacist.

On approval of the Technical code of common practice «Good Manufacturing Practice» (extraction)

Decree of the Ministry of Health of the Republic of Belarus
19th June 2017 № 64

Guideline «Good Manufacturing Practice» establishes the principles and rules of good manufacturing practice of medicines (hereinafter — GMP rules), including pharmaceutical substances used in the composition of medicines. This Guideline applies to the manufacturing of all types of medicinal products and defines the general requirements for their manufacturing and quality control carried out by legal organizations on the basis of a special permition (license) for pharmaceutical activities in the part of works and services for the industrial manufacturing of medicines and their wholesale distribution.

Terms and Definitions

Airlock is a limited space with two or more doors, located between two or more rooms, for example, different classes of cleanliness, serving to control the flow of air between these rooms, when they need to enter. Air locks are intended and used for personnel passing and movement of materials.

The excipient substance is a substance, with the exception of active pharmaceutical substances, which is a part of a medicinal product in order to give it the necessary properties.

Finished product is a medicinal product that has passed all the stages of the technological process including packaging in the final packaging.

Medicinal plant raw materials are fresh or dried plants, algae, fungi or lichens or parts of them, whole or crushed, used for the production of medicinal products.

Technological process includes all operations connected with the production of a medicinal product starting with the acceptance of raw materials, continuing with processing and packaging and ending with receiption of finished products.

Clean Zone is the area in which the production environment is controlled for the presence of contaminating particles and microorganisms, constructed and operated in such a way as to reduce the penetration, formation and preservation of contaminates within the zone.

Quality Control

Quality control is a part of good manufacturing practices connected with sampling, specifications and testing, as well as with procedures of organizing, documenting and issuing an authorization to ensure that all necessary tests have actually been carried out and that materials will not be authorized for use, and finished products will not be allowed to be sold or delivered until their quality is found to be satisfactory.

To sample, control and test raw materials, intermediate, bulk and finished products appropriate premises and equipment, trained personnel and approved methods should be available.

Product realization is prohibited for sale or delivery before the Qualified Person certifies that it meets the requirements established by state registration.

Personell

The proper production of medicines depends on the personnel. The manufacturer must have a sufficient number of employees with the necessary qualifications and practical experience.

The manufacturer must ensure the training of personnel. Personnel working in areas where contamination poses a danger (in clean zones, in areas where they work with highly active, toxic, infectious substances) must undergo special training. Visitors and/or untrained employees should not be allowed to enter production and quality control areas. If this is unavoidable, they must first be instructed, in particular on the hygienic requirements for personnel and the use of protective clothing. They should be accompanied and monitored.

Persons recruited to work must undergo a medical examination. After an initial medical examination regular follow-up medical examinations should be conducted. The manufacturer must take measures to ensure that persons with infectious diseases or open injuries in the open areas of the body are prevented from drug manufacturing. Persons entering the production zones should wear protective clothing appropriate to the operations performed in these areas.

In production and storage areas smoking, taking food, drinking, chewing, and storage of food, beverages, tobacco products and personal medicines are prohibited.

Premises

Premises and equipment should be located, designed, built, equipped and operated in such a way that they correspond to ongoing operations. Their location and design should minimize the risk of mistakes and enable efficient cleaning and

maintenance in order to avoid cross contamination, the accumulation of dust or dirt and any adverse factors for product quality.

The premises must be designed and equipped in such a way as to provide maximum protection against the penetration of insects and/or animals into them. Lighting, temperature, humidity and ventilation should be appropriate and not adversely affect either medicines during their manufacture and storage nor the proper functioning of the equipment. Production zones should be effectively ventilated and should be means for controlling air parameters there.

Warehouse areas should be large enough to ensure the orderly storage of various categories of materials and products: raw materials and packaging materials, intermediate, bulk and finished products, as well as quarantined products.

On the order of State Control for the quality of medicines, on approval of the Regulations on the procedure for storage, transportation, retirement, restitution to manufacturer or supplier, destruction of medicines, supplement, change and recognition of some forfeit decisions of the Council of Ministers of the Republic of Belarus (extraction)

Decree of the Council of Ministers of the Republic of Belarus
22th December 2009 № 1677

Storage facilities should ensure the proper quality and safety of medicines and also have the necessary equipment for these purposes. Requirements for storage premises and equipment are established by the Ministry of Health.

The technical strength and equipment of fire alarm systems and alarm systems for storage areas must comply with the requirements of the law.

To avoid adverse effects of environmental factors medicines should be stored separately from other products (in a separate room, cabinet, shelf) in accordance with the conditions specified by the manufacturer on the package of the medicinal product, the instructions for medical use and/or the leaflet. Medicines in the storage rooms are placed taking into account their physico-chemical and toxicological properties, with rational use of areas and using the possibility of handling mechanized car loading facilities and the creation of safe working conditions for workers.

Pharmaceutical substances that have specific properties (odorous, coloring) are stored:

– odorous pharmaceutical substances (tar, ichthyol, camphor, xerobes, menthol, phenol, formaldehyde solutions, essential oils and others) separately (in a separate room or cabinet) in a tightly sealed airtight package;

– coloring pharmaceutical substances (brilliant green, potassium permanganate, riboflavin, furacilin and others) separately (in a separate room or cupboard or shelf) in a tight packaging.

Bulk medicinal plant raw materials are stored separately (in a separate room or cabinet in the appropriate packaging) with protection against the insects or animals.

Low-quality and counterfeit medicines, drugs with expired shelf life and other medicines withdrawn from circulation in accordance with the law should be kept separately in a closed room or a cabinet with a warning label «Prohibited to use».

The head of the legal entity, individual entrepreneur appoints the responsible person, ensuring compliance with the rules of storage of medicinal products (hereinafter — the person in charge).

In each storage room, at least once a day, the responsible person monitors and registers temperature and relative humidity of air and temperature in refrigerating equipment with the help of measuring instruments entered in the State Register of Measuring Instruments of the Republic of Belarus.

Temperature and relative humidity of the air are recorded in a log book(log) of temperature and relative humidity which is situated at the location of the measuring instruments.

Registration of temperature in refrigerating equipment during the storage of thermolabile immunobiological medicinal products is carried out 2 times a day.

A book (log) of temperature and relative humidity records is stored for at least one year, not counting the current one.

Transporting of medicines

When storing and transporting immunobiological medicines the cold chain is observed in accordance with the requirements of regulatory legal acts, including technical regulatory legal acts regulating the circulation of immunobiological medicinal products.

Transportation of medicinal products is carried out in conditions that ensure their safety and integrity, as well as protection from the effects of environmental factors in accordance with the requirements specified by the manufacturer of medicines on the package.

The means of transportation of medicinal products (hereinafter referred to as the vehicle) is equipped with special cargo containers, pallets, dunnage racks. In the case of transportation of medicines requiring special temperature storage conditions the vehicle is additionally equipped with thermo containers or refrigerating installations with thermometers.

The vehicle and its equipment must be kept clean and treated with detergent and disinfectant as needed, but at least once a week. The note on carrying out the processing is made in the journal of registration of processing of a vehicle separately for each vehicle.

Responsibility for keeping the vehicle clean is the responsibility of the vehicle owner.

The cold chain is an uninterruptedly functioning system of measures ensuring an optimal temperature regime for storing and transporting immunobiological medicinal products at all stages of their journey from the producer of medicines to the consumer.

On approval of Regulation on the procedure of storage of medical products and medical equipment and Regulations on the procedure for the destruction of medical products and medical equipment (extraction)

Decree of the Council of Ministers of the Republic of Belarus
29th August 2002 № 1178

Premises and equipment intended for the storage of medical products must be suitable and sufficient to ensure its quality and proper preservation.

Requirements for premises, equipment and storage conditions for medical devices and medical equipment are established by the Ministry of Health.

Medical products should be stored separately from other products under conditions specified by the manufacturer in the instructions for medical use in order to avoid damage due to light, humidity or temperature mismatch.

Medical products the quality of which does not comply with the requirements of regulatory documents including counterfeit (falsified) or the expiration date (operation) of which has expired, must be stored separately from the main stocks with a clear labeling of the prohibition against sale and use until return to the supplier or destruction.

On approval of the Instruction on the procedure of acquisition, storage, sale and use of narcotic drugs and psychotropic substances for medical purposes (extraction)

Decree of the Ministry of Health of the Republic of Belarus
28th December 2004 № 51

Legal parties carry out the storage of narcotic drugs and psychotropic substances only in the form of medicines and medical products registered and authorized for medical use in the Republic of Belarus.

Narcotic drugs and psychotropic substances are stored in specially equipped premises that meet the requirements for technical fortification established by the

Ministry of Internal Affairs of the Republic of Belarus and the Ministry of Health of the Republic of Belarus (hereinafter — premises).

In the premises of pharmacy warehouses the storage of:

– narcotic drugs are carried in safes or metal cabinets;

– psychotropic substances are allowed to store on racks or pallets;

– thermolabile psychotropic substances are stored in cold rooms or refrigerating cabinets.

To work with narcotic drugs and psychotropic substances in the form of pharmaceutical substances in the premises of drugstores scales, balances as well as the necessary pharmacy and laboratory utensils are required.

In the premises of legal parties that carry out retail sales of narcotic drugs and psychotropic substances retail sale and pharmacy production of narcotic drugs and psychotropic substances, pharmacy manufacturing and relealization of narcotic drugs and psychotropic substances in the health care organization and storage:

– narcotic drugs are carried out in safes or metal cabinets attached to a wall or floor;

– psychotropic substances are carried out in metal cabinets attached to the wall or floor;

– thermolabile psychotropic substances are carried out in refrigerators or refrigerating cabinets.

During working hours in the departments of pharmacies of finished dosage forms at workplaces and in the prescription and production department of production pharmacies, the storage of psychotropic substances as a finished forms is allowed in the volumes of a one-day need for lockable cabinets and thermolabile psychotropic substances in a refrigerator on a separate shelf.

In the assistant rooms of production pharmacies and pharmacies of health care organizations, the storage of narcotic drugs and psychotropic substances in the form of pharmaceutical substances is carried out in safes or metal cabinets attached to the wall or floor.

During working hours safes and metal cabinets must be locked. Keys from rooms, safes and metal cabinets should be kept by the responsible employees.

At the end of the working day the premises as well as safes (metal cabinets) and a refrigerator in the assistant's rooms of production pharmacies and pharmacies of health care organizations are sealed and the keys to them, sealing tool or a seal are stored in a place that ensures their safety.

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