

MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS

Educational Institution

«BELARUSIAN STATE MEDICAL UNIVERSITY»

**Контрольный
экземпляр**

APPROVED

by Rector of the Educational
Institution «Belarusian State
Medical University»



 S.P. Rubnikovich

26.06.2025

Reg. # UD-0912-01-05/2526 edu.

INDUSTRIAL TECHNOLOGY OF DRUGS

**Curriculum of the educational institution
in the academic discipline for the specialty**

1-79 01 08 «Pharmacy»

Curriculum is based on the educational program «Industrial Technology of Drugs», approved 26.06.2024, registration # УД-0912-01-05/2425/уч.; on the educational plan in the specialty 1-79 01 08 «Pharmacy», approved 16.04.2024, registration # 7-07-0912-01/2526/mf.

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RECOMMENDED FOR APPROVAL:

by the Department of Pharmaceutical Technology with advanced training and retraining course of the Educational Institution «Belarusian State Medical University» (protocol # 14 of 16.05.2025);

by the Scientific and Methodological Council of the Educational Institution «Belarusian State Medical University» (protocol # 10 of 26.06.2025)

EXPLANATORY NOTE

«Industrial Technology of Drugs» is an academic discipline of the Pharmaceutical Technology module, which contains systematized scientific knowledge about raw materials and packaging materials, products, technological processes, quality control, release permits, storage and sale of finished medicines.

The purpose of the academic discipline «Industrial Technology of Drugs» is the formation of specialized competencies for participation in the industrial production of medicines, including biological (immunobiological) medicines.

The objectives of the discipline «Industrial Technology of Drugs» are to form students' scientific knowledge about the basic forms of finished medicines and their production technologies; standard technological and hardware schemes for industrial production; product quality control parameters; skills necessary for the implementation of technological processes for the production of finished dosage forms, assessing the quality of initial and packaging materials, intermediate and final products; regulation and improvement of the technological process in order to produce high-quality finished medicines; organization of the production of medicines according to Good Manufacturing Practice (GMP) rules and environmental safety requirements.

The knowledge, skills, and abilities acquired while studying the academic discipline «Industrial Technology of Drugs» are necessary for the successful study of the following academic disciplines: «Pharmaceutical Development with the Fundamentals of Biopharmaceutics», «Management and Economics of a Pharmaceutical Enterprise», «Modern Methods of Analysis and Standardization of Drugs», «Pharmaceutical Ecology».

Studying the educational discipline «Industrial Technology of Drugs» should ensure the formation of students' specialized competency: to participate in the industrial production of medicines, including biological (immunobiological) medicines.

As a result of studying the academic discipline «Industrial Technology of Drugs» the student should

know:

- basic terms and concepts of industrial technology;
- requirements of GMP for the organization of industrial production of medicines;
- the main dosage forms of finished medicines produced in industrial production;
- quality requirements for starting and packaging materials, intermediate and final products;

- processes and equipment of Industrial Technology of Drugs;
- innovative ways to create medicines;

be able to:

- use the State Pharmacopoeia and the Pharmacopoeia of the Union, regulatory documentation to find information necessary for the production of medicines;

- to draw up technological schemes for the production of medicines and describe the technological process of their production;

- substantiate the technological and hardware design of industrial production;
- to develop technological documentation for ready-made medicines;

ensure compliance with the rules of industrial production organization, industrial hygiene, environmental protection, labor protection and safety;

master:

a range of medicines produced by industrial methods;

practical skills of working with regulatory documentation regulating the production and quality assurance of medicines;

calculation skills necessary for the production of ready-made medicinal forms;

the technique of pharmaceutical and technological tests and interpretation of their results;

modern technologies for the production of finished medicines, including innovative ones.

As part of the educational process in this academic discipline, the student must acquire not only theoretical knowledge, practical skills and specialty skills, but also develop his value-personal, spiritual potential, form the qualities of a patriot and citizen, ready to actively participate in the economic, industrial, socio-cultural and social life of the country.

Total number of hours for the study of the discipline is 335 academic hours, of which 180 classroom hours and 155 hours of student independent work. Classroom hours according to the types of studies: lectures – 48 hours (including 15 hours of supervised student independent work (SSIW)), laboratory classes – 132 hours.

The intermediate assessment is carried out according to the syllabus of the specialty in the form of a credit (7 semester) and the form of examination (8 semester).

The final assessment is a state exam.

Form of higher education – full-time.

ALLOCATION OF ACADEMIC TIME ACCORDING TO SEMESTERS OF STUDY

Code, name of the specialty	Semester	Total number of academic hours	Number of classroom hours				Out-of-class self-studies	Form of intermediate assessment
			Number of classroom hours	including				
				class lectures	SSIW	laboratory classes		
1-79 01 08 «Pharmacy»	7	170	95	18	9	68	75	credit
	8	165	85	15	6	64	80	examination
Total hours		335	180	33	15	132	155	

THEMATIC PLAN

Section (topic) name	Number of class hours	
	lectures (incl. SSIW)	laboratory
1. General principles of organizing the production of medicines at pharmaceutical enterprises	4,5	16
1.1. General principles of organizing the production of medicines at pharmaceutical enterprises. Terminology	1,5	4
1.2. The Rules of Good Manufacturing Practice of the Republic of Belarus and the Eurasian Economic Union. Regulatory documentation of production	1,5	8
1.3. Air and water treatment system at pharmaceutical enterprises	1,5	4
2. Processes and equipment of pharmaceutical technology	7,5	12
2.1. The main processes of industrial technology, their role in the production of medicines. General concepts of machines	1,5	4
2.2. Mechanical processes and equipment	1,5	
2.3. Hydromechanical processes and equipment	1,5	
2.4. Heat-exchanging processes and equipment	1,5	8
2.5. Mass-exchanging processes and equipment	1,5	
3. Industrial Technology of Drugs	36	104
3.1. Industrial technology of solid drug forms. Powders and herbal teas production	1,5	4
3.2. Industrial production of granules. Study of physico-chemical and technological properties of powders and granulates	1,5	4
3.3. Tablets. Methods of production. Theoretical foundations of tableting. Excipients used in the tablets production. Characteristics of tablet machines	1,5	4
3.4. Technological schemes of tablet production	1,5	4
3.5. Evaluation of tablet quality	1,5	4
3.6. Tablets coating. Modern types of tablets	1,5	4
3.7. Industrial production of dragee	1,5	
3.8. Industrial production of capsules. Microencapsulation of medicines	1,5	16
3.9. Industrial production of semi-solid medicines	1,5	4
3.10. Industrial production of suppositories, pessaries and medical pencils	1,5	4
3.11. Industrial production of patches and mustard plasters	1,5	
3.12. Industrial production of liquid medicines for internal and external use	1,5	4

Section (topic) name	Number of class hours	
	lectures (incl. SSIW)	laboratory
3.13. Dilution and strengthening of solutions in their industrial production		
3.14. Industrial production of emulsions and suspensions. Drops. Medicinal shampoos	1,5	4
3.15. Characteristics of medicines for parenteral use. Sterilization. Depyrogenation. Primary packaging – production and preparation	1,5	4
3.16. Technology of parenteral medicines	1,5	4
3.17. Industrial production of eye medicines	1,5	8
3.18. Industrial production of medicines from herbal raw materials. The basics of extraction. Characteristics of galenical medicines	3	4
3.19. Industrial production of tinctures	1,5	6
3.20. Industrial production of extracts	1,5	2
3.21. Medicines from fresh herbal raw materials	1,5	4
3.22. Industrial production of neogalenical medicines, medicinal products from animal raw materials and biogenic stimulants		
3.23. Industrial production of syrups, essential oils, aromatic waters	1,5	4
3.24. Industrial production of aerosols and sprays	1,5	12
3.25. Medicines of prolonged and directed action. Nanotechnology in pharmaceuticals	1,5	
Total hours	48	132

CONTENT OF THE EDUCATIONAL DISCIPLINE

1. General principles of organizing the production of medicines at pharmaceutical enterprises

1.1. General principles of organizing the production of medicines at pharmaceutical enterprises. Terminology

The goals and objectives of «Industrial Technology of Drugs» as an academic discipline. The main terms used in the industrial technology.

Industrial production of medicines in the Republic of Belarus and other countries. Differentiation and specialization of pharmaceutical enterprises.

Terminology: validation, excipients, finished products, starting materials, controlled area, unpacked products, cross-contamination, production, intermediate products, batch, package, technological process, packaging, packaging material, clean area, clean (isolated) area.

Principles of organization of production of medicines at pharmaceutical enterprises. The structure of pharmaceutical enterprises. The workshop principle of organization of production of medicines.

General concepts of technological processes: technological scheme of production, stages and operations; hardware scheme of production and specification of equipment; periodic, continuous and combined processes; types of technological processes (mechanical, hydromechanical, heat-exchanging, mass-exchanging).

The concepts of by-product and waste products, material losses. The material balance. Technological yield, loss, consumption coefficient and consumption norms. Energy balance.

1.2. The Rules of Good Manufacturing Practice of the Republic of Belarus and the Eurasian Economic Union. Regulatory documentation of production

Good Manufacturing Practice (GMP) – the system of requirements for the production and quality control of medicines. GMP structure: introduction, terminology, parts and applications.

Basic requirements. Chapters: pharmaceutical quality system; personnel; premises and equipment; documentation; production; quality control; outsourced activities; complaints and product recalls; self-inspection. Documents related to the rules of Good Manufacturing Practice. Site master file.

The State Pharmacopoeia and the Pharmacopoeia of the Eurasian Economic Union (EAEU).

1.3. Air and water treatment system at pharmaceutical enterprises

Air treatment system in accordance with GMP requirements. Maximum permitted total particle concentration for classification. Maximum permitted microbial contamination level during qualification. Cleanroom classification. «At rest» and «in operation» cleanroom state. Air filtration on pharmaceutical enterprises. The device and the principle of operation of HEPA-filters (high efficiency particulate air). Basic requirements for cleanrooms and control of air parameters in the production of sterile medicines (GMP – Appendix 1).

Water treatment system in accordance with GMP requirements.

Water treatment methods and equipment used: filtration, ion exchange, reverse osmosis, electrodeionization, distillation (multistage and thermocompressed aquadistillators).

Water storage system at pharmaceutical enterprises. The equipment used.

Water quality control parameters.

2. Processes and equipment of pharmaceutical technology

2.1. The main processes of industrial technology, their role in the production of medicines. General concepts of machines

Characteristics of the main processes of industrial technology: mechanical, hydromechanical, heat-exchanging, mass-exchanging. The role and interrelation of technological processes in the production of medicines.

General concepts of machines and apparatuses. A machine as a unit of an engine, transmission and actuating mechanisms. Characteristics of engines, receiving and transmission mechanisms and actuators. Characteristics of apparatuses and reactors. Control and measuring devices and apparatuses.

2.2. Mechanical processes and equipment

General characteristics of mechanical processes. Application in industrial technology.

Grinding. The degree of grinding, its dependence on the strength, hardness, elasticity and brittleness of the material. Theoretical foundations of grinding. Surface and volume theory of grinding. The unified Rebinder grinding theory. The basic rule of grinding. The grinding methods: crushing, splitting, impact, abrasion, etc. Grinding machines, principle and mode of operation. Dismembrators, disintegrators, excelsior mills, hammer mills, ball mills, vibrating mills, jet mills. Features of grinding herbal materials. Purpose and use of grinding in industrial technology.

Cryogrinding, its influence on the quality of the grinding material.

Micronization of pharmaceutical substances, areas of application. Micronization methods.

Classification of solid materials. Basics of air and hydraulic classification of grinding material. Mechanical classification (sifting). Sieve and sieve analysis. Materials and types of sieves (wire-mesh, stamped, grate). Standards and numbering of sieves. The device and the principle of operation of mechanized sieves: swinging, rotating, vibration. Safety of sifting.

Mixing in the industrial production of medicines. Gravity, mechanical and vibration mixers, fluidized bed mixers, device and operating principle. Characteristics of fluidized granular layers. The use of fluidization in pharmaceutical production, its characteristics. Basic properties of the fluidized bed.

2.3. Hydromechanical processes and equipment

General characteristics of hydrodynamic processes. Application in industrial technology. Fundamentals of hydraulics. Laminar and turbulent motion of liquids. Hydrodynamic boundary layer.

Methods of mixing liquid and viscous media: mechanical, pneumatic, gravity, mixing in a pipeline, acoustic, ultrasonic, circulating. Stirrer designs and their characteristics.

Separation of heterogeneous systems. Methods of separation. The rate of sedimentation. Factors affecting the sedimentation rate. The device of periodic and semi-continuous sedimentation tanks.

Separation of solid and liquid phases under the influence of pressure difference. Filtration, filtration methods, filtration equation. Types of filters: nutsch- and druk-filters, filter presses. Filters for cleaning gases from mechanical impurities. Characteristics of filter materials.

Separation in the field of centrifugal forces. Centrifugation, separation factor, filtration and sedimentation centrifuges, periodic and continuous, supercentrifuge, cyclone, scrubbers.

2.4. Heat-exchanging processes and equipment

General characteristics of heat-exchanging processes. Mechanisms of heat transfer: thermal conductivity, convection, radiation.

Heat carriers (heating and cooling agents), characteristics and classification. The direction of movement of heat carriers (direct current, counterflow, cross current,

mixed current) and its effect on the intensity of heat exchange. Application in industrial technology.

Water vapor as the main heat carrier. Wet, dry, saturated and superheated steam. Heating by indirect steam and jet steam.

2.5. Mass-exchanging processes and equipment

General characteristics of mass-exchanging processes. Application in industrial technology. Characteristics and classification.

Evaporation, evaporation methods: under vacuum, atmospheric pressure and high pressure. Side effects during evaporation: inlay, temperature depression, hydrostatic effect, drop entrainment, foamability and ways to eliminate them. The device of evaporation apparatuses. Characteristics of single-effect and multiple-effect evaporators, film evaporators.

Drying. Characteristics and classification. Forms of moisture-material bonding. Static and kinetic of drying. Properties of air as a drying agent: temperature, absolute and relative humidity, moisture content and heat content. Drying methods: contact and convective drying. Contact dryers: vacuum drying cabinets, vacuum roller dryers. Convective dryers: spray, disc and jet-spray. Special types of drying: freeze drying, acoustic drying, radiation drying, etc.

3. Industrial Technology of Drugs

3.1. Industrial technology of solid drug forms. Powders and herbal teas production

Powders. Definition, characterization, classification according to the State Pharmacopoeia and the nomenclature of medicinal forms of the EAEU.

Technological and hardware schemes of powder production in a pharmaceutical enterprise. The main stages and operations. Dosing, packaging, labeling and storage of powders, equipment used. Powder quality control. Preparation of regulatory documentation for the production of powders.

Herbal teas. Definition, characteristics, classification.

Technological and hardware schemes for the production of fees in a pharmaceutical enterprise. The main stages and operations. Dosing, packaging, labeling and storage of herbal teas, equipment used. Quality control of herbal teas. Preparation of regulatory documentation for the production of herbal teas.

Characterization of physical, chemical, technological, structural and mechanical properties of powders. Pharmaceutical and technological tests (flowability, bulk density and density after shrinkage, fractional composition), methods of their determination, equipment used.

Improving the technology of powders and herbal teas. Nomenclature of powders and herbal teas.

3.2. Industrial production of granules. Study of physico-chemical and technological properties of powders and granulates

Granules. Definition, characterization, classification.

Technological and hardware schemes for the production of granules in a pharmaceutical enterprise. The main stages and operations. Excipients used for granulation. Granulation methods (dry, wet and structural granulation; comparative characteristics). Equipment used for granulating and drying pellets. Spheronization of

granules. Dosing, packaging, labeling and storage of granules. Quality control of granules. Preparation of regulatory documentation for the production of granules and pellets.

Pharmaceutical technical procedures of granules (flowability, bulk density and density after shrinkage, fractional composition, moisture content), methods of their determination, equipment used.

Improvement of granules and pellet production technology. The nomenclature of granules of industrial production.

3.3. Tablets. Methods of production. Theoretical foundations of tableting. Excipients used in the tablets production. Characteristics of tablet machines

Tablets. Definition, characteristics, requirements, classification. Production methods (by pressing, molding, lyophilization, extrusion).

Tablets obtained by pressing. Theoretical foundations of tableting: mechanical, capillary theory, electrostatic.

Excipients used in the manufacture of tablets, their characteristics and nomenclature. The effect of excipients on the therapeutic efficacy of active substances in tablets.

Tablet machines. Characteristics and operating principle. The main elements of tablet machines – dies and punches. Tablet machines of double pressing.

3.4. Technological schemes of tablet production

Technological schemes for tablets production: direct pressing and the use of granulation. The algorithm of selection and justification of the technology for obtaining tablets. Characteristics of the stages and operations of the technological process of tablet production. Mixing of granules with antifriction substances.

Characteristics of technological and physico-chemical properties of the tablet mass (porosity, compaction coefficient, compressibility, tablet ejection force from the dies, humidity).

Dosing, packaging, labeling and storage of tablets, equipment used.

3.5. Evaluation of tablet quality

Pharmaceutical technical procedures – methods, devices and equipment used. «Disintegration» and «Dissolution» tests for solid dosage forms. Instruments and methods for the «Dissolution» test: basket apparatus, paddle apparatus, reciprocating cylinder, flow-through cell. The technique of the test «Dissolution» for solid dosage forms with conventional, prolonged and retard release, the results interpretation.

Characteristics of the test «Disintegration of tablets», instruments and methods of the test, the results interpretation for different types of tablets.

The uniformity of dosage units, content uniformity, uniformity of mass, talc and aerosil content. Friability of uncoated tablets and resistance to crushing of tablets.

3.6. Tablets coating. Modern types of tablets

Coating of tablets. Objectives, classification according to State Pharmacopoeia and coating technology.

Film coating. Excipients, nomenclature and characteristics. Characteristics and classification of film coatings of tablets, nomenclature of film-forming agents for film coatings. Modern combined compositions of film coatings. Methods of applying film coatings to tablets and the equipment used.

Dragee coating. Modern application technology. Excipients, purpose and characteristics. The equipment used.

Pressed (dry) coating. Characteristics of the equipment used. Characteristics of multilayer tablets and tablets with a modified release of the active substance.

Defects in tablets and tablet coatings: causes and ways of elimination.

Production of molded tablets, production of lyophilized tablets, etc. Modern ways of tablets improvement.

3.7. Industrial production of dragee

Dragee. Definition, characteristics. Technological and hardware schemes for the production of pills in a pharmaceutical enterprise. The main stages and operations. Excipients used for the production of dragee. Dosing, packaging, labeling and storage of dragee. Quality control of dragee. Preparation of regulatory documentation for the production of dragee. The nomenclature of dragee.

3.8. Industrial production of capsules. Microencapsulation of medicines

Capsules. Definition, characteristics, classification according to the State Pharmacopoeia and the nomenclature of medicinal forms of the EAEU. Methods of production of gelatin capsules.

Materials for the production of capsule shells. Gelatin mass. Technological and hardware production schemes. Excipients. Quality control.

Hard gelatin capsules. Characteristics and classification. Formation of empty gelatin capsules (shells) by immersion. Capsule filling: combinations of fillers for hard gelatin capsules and encapsulation methods. Excipients. The equipment used.

Soft gelatin capsules. Characteristics and classification. The technology of capsule production by pressing (rotary method) and dripping (droplet method). The equipment used.

Technological and hardware schemes for the production of hard and soft gelatin capsules. Packaging, labeling, and storage of capsules. Capsule quality control. Preparation of regulatory documentation for capsule production. The range of capsules of industrial production.

Improvement of capsule production technology. Production of rectal, vaginal and chewable capsules.

Microcapsules, microgranules and microdragee, their characteristics. Microcapsulation of pharmaceutical substances. Methods of microcapsulation: physical, physico-chemical, chemical. Characteristics of excipients for microcapsulation. Evaluation of microcapsule quality.

3.9. Industrial production of semi-solid medicines

Semi-solid medicines, characteristics, classifications.

Ointments. Definition, characteristics, classifications according to the State Pharmacopoeia and the nomenclature of medicinal forms of the EAEU. Hydrophobic, hydrophilic and water-based ointments. Characteristics and classification of ointment bases. Excipients. Structural and mechanical properties of ointments (rheology). Technological and hardware production schemes.

Creams. Definition, characteristics, classifications according to the State Pharmacopoeia and the nomenclature of medicinal forms of the EAEU. Lipophilic and

hydrophilic creams. Excipients, characteristics and classification. Technological and hardware production schemes.

Gels. Definition, characteristics, classifications according to the State Pharmacopoeia and the nomenclature of medicinal forms of the EAEU. Lipophilic and hydrophilic gels. Nomenclature of gelling agents. Excipients, characteristics and classification. Technological and hardware production schemes.

Features of the production of pastes and liniments in pharmaceutical enterprises.

Dosing, packaging, labeling, and storage of semi-solid medicines. Quality control. Preparation of regulatory documentation for production. The nomenclature of semi-solid medicines of industrial production.

3.10. Industrial production of suppositories, pessaries and medical pencils

Suppositories and pessaries. Definition, characterization, classification.

Technological and hardware production schemes. The main stages and operations. Excipients, their characteristics and nomenclature. The effect of excipients on the therapeutic effectiveness of active substances. Characteristics of suppository bases. Equipment used in suppositories production. Packaging and storage of suppositories. Quality control of suppositories: description, particle size, «Dissolution» test, «Disintegration» test, deformation time, melting point, microbiological purity. Methods of their determination, the equipment used. Drafting of regulatory documentation.

Modern types of suppositories. The range of suppositories and pessaries of industrial production.

Medical pencils, characteristics. Types of medical pencils. Methods of obtaining medical pencils: pouring, pressing. Private technology of medical pencils: menthol, hemostatic, etc. Packaging and storage of medical pencils. Modern types of medical pencils.

3.11. Industrial production of patches and mustard plasters

Patches. Definition, characteristics, classifications. Methods of patches production.

The main elements of the patch. Modern adhesive bases for patches (rubber, acrylate, silicone). The range of excipients for the production of patches, their characteristics. Technological and hardware production schemes. Equipment for the production of patches, spreading and drying of patches.

Liquid patches: resin and collodion. Aerosol patches. Medical lacquers. Characteristics of film-forming agents. Production technology.

Transdermal patches. Characteristics, classification and structure. Features of the technology. Excipients assortment for the production of transdermal patches.

Production of mustard plasters. Definition, characteristics, and formulations. Production technology.

Packaging, labeling, and storage of patches and mustard plasters. Quality control. The range of patches and mustard plasters of industrial production.

3.12. Industrial production of liquid medicines for internal and external use

Liquid medicines. Characteristics and classification.

Pharmaceutical solutions. Characterization and classification of solutions depending on the nature of the solvent (aqueous, alcoholic, oily, glycerol) and

concentration. Requirements for solutions. Methods of preparation – by chemical interaction or dissolution. Excipients – purpose, characteristics and nomenclature.

Dissolution as a diffusion-kinetic process. Stages of dissolution. Factors influencing the dissolution process: grinding, temperature change, mixing. Intensification of the dissolution process. Temperature and hydrodynamic conditions in the production of solutions. The indicators of solubility of substances in various solvents and the designation of solubility in the State Pharmacopoeia.

Technological and hardware schemes for the production of solutions by the dissolution method in a pharmaceutical enterprise. The main stages and operations. The equipment used. Packaging, labeling and storage.

Rules for the production of aqueous and non-aqueous solutions.

Quality control. Preparation of regulatory documentation for the production of solutions. The range of solutions for industrial production and the prospects for its expansion.

3.13. Dilution and strengthening of solutions in their industrial production

Methods of expressing the concentration of solutions.

The density of solutions. Determination of density using a hydrometer and a pycnometer: the use of formulas for diluting and strengthening solutions of salts, acids, and alkalis.

Methods for determining alcohol concentration and features of dilution or strengthening of alcohol solutions in pharmaceutical enterprises. Dilution of ethyl alcohol. Alcoholometric tables, rules for using alcoholometric tables.

3.14. Industrial production of emulsions and suspensions. Drops. Medicinal shampoos

Suspensions and emulsions. Characteristics and classification of emulsions and suspensions by type, method of application, concentration of active substance.

Types of instability of suspensions and emulsions: aggregative, sedimentation, phase reversal. Excipients – purpose, characteristics and nomenclature. Emulsifiers. Characteristics and significance of the hydrophilic-lipophilic balance. Stabilizers.

Technological and hardware schemes for the production of emulsions and suspensions.

Methods of obtaining at pharmaceutical enterprises: mechanical mixing, grinding in a liquid medium, ultrasonic dispersion. Features and prospects of using ultrasound in the production of suspensions and emulsions. The equipment used.

Quality control. Preparation of regulatory documentation for the production of suspensions and emulsions. The range of suspensions and emulsions of industrial production and the prospects for its expansion.

Drops. Characteristics, classification, features of production and standardization. Excipients used (purpose, characteristics and nomenclature). Types of primary packaging and dosing devices.

Medicinal shampoos. Characteristics, features of production and standardization. Types of primary packaging.

3.15. Characteristics of medicines for parenteral use. Sterilization. Depyrogenation. Primary packaging – production and preparation

Medicines for parenteral use, their characteristics and classification: injectable medicines, infusion medicines, concentrates and powders for the preparation of injections and infusions, gels for injection, imherbals.

Sterilization of parenteral medicines. Sterility. Classification and characterization of methods – mechanical, physical and chemical. Characteristics of sterilization equipment. Pharmacopoeial sterilization methods. Sterility assurance level. Criteria for choosing the sterilization method. Methods of sterilization control: biological, chemical and physical.

Thermal sterilization. Rules for working with pressure devices. Preparation and carrying out of sterilization in steam sterilizers. Air sterilizers. The modes of thermal sterilization depend on the properties of objects and their quantity. Safety precautions for various sterilization methods.

Mechanical sterilization (filtration sterilization). The principle, equipment, organization of the filtration system and process control.

Bacterial endotoxins – pyrogenicity. Characterization and effect of bacterial endotoxins-pyrogens on the human body. Sources of pyrogenic substances in sterile and aseptically prepared dosage forms. Biological tests for injectable medicines: pyrogenicity, abnormal toxicity, bacterial endotoxins. Depyrogenation.

Containers (ampoules, vials, cartridges, pre-filled syringes) for sterile medicines. Characteristics, materials used, requirements, classes of glass. Quality control of glass containers. Testing for hydrolytic and thermal stability. Packaging selection criteria.

Production and preparation of primary packaging for filling. Production of primary glass packaging: preparation of glass products, calibration, washing, annealing. Preparing the container for filling. External and internal (vacuum and syringe) washing of ampoules. Drying and sterilization. Siliconization.

3.16. Technology of parenteral medicines

Pharmaceutical substances, purity requirements, decontamination, depyrogenation and sterilization. Excipients – purity requirements, purpose, characteristics and nomenclature. Ways to stabilize injection solutions. The range of stabilizers: acids, alkalis, antioxidants, anti-catalysts, etc. The use of gas protection in the production of injection solutions. Characteristics and nomenclature of preservatives.

Production of sterile products depending on the method of achieving sterility: with final sterilization and under aseptic conditions.

Production of injections in ampoules and vials. Technological and hardware schemes for the production of sterile solutions, suspensions and emulsions. Complex mechanization and automation of ampoule production. Methods of filling ampoules: vacuum, syringe. Sealing of ampoules. Sealing of ampoules with gas protection. Methods of filling and capping vials.

Production of sterile medicines in prefilled syringes and cartridges. Technological and hardware schemes. Methods of capping. Nomenclature of medicines in prefilled syringes and cartridges.

Infusions. Production features. Types of infusions. Requirements for infusions. Industrial production of saline, plasma-substituting and detoxification solutions. The nomenclature of infusions of industrial production.

The use of Blow-Fill-Seal (BFS) technology in the production of parenteral medicines. Technological scheme of parenteral medicines using BFS technology.

The use of lyophilization technology in the production of parenteral medicines. The stages of the lyophilization process and the equipment used. Excipients, functions, nomenclature. Technological scheme of production of lyophilized powders.

Quality control of parenteral medicines. Preparation of regulatory documentation for parenteral medicines. Modern nomenclature of parenteral medicines.

3.17. Industrial production of eye medicines

Eye dosage forms. Characteristics and classification: eye drops, inserts and films, lotions, semi-solid dosage forms (ointments, creams and gels), solid eye dosage forms (powders, tablets, lyophilizates). Requirements: stability, absence of mechanical impurities, pH, etc.

Industrial production of eye drops. Excipients. Stabilization and preservation of eye drops, characteristics of preservatives. The use of buffered solvents in the production of eye drops. Prolongation of the effect of eye drops. Features of the technology. Primary packaging: materials used, ways to improve primary packaging to maintain the stability and sterility of eye drops. Sterilization of eye drops. Quality control. Nomenclature, labeling, and storage of industrial eye drops.

Semi-solid eye medicines. Requirements for eye ointments and the basics of eye ointments. Sterility and stability of eye ointments. Technological scheme for the production of eye ointments under aseptic conditions. Quality control. Packaging, labeling, and storage of eye ointments. The nomenclature of eye ointments of industrial production.

Eye inserts. Characteristics, classification, and excipients used. Film-forming agents in the production of eye inserts. Technological scheme for the production of eye inserts. Quality control. Packaging, labeling, and storage of eye inserts. Nomenclature.

Powders for the preparation of eye drops and lotions, their characteristics and quality control.

Modern ophthalmic drug delivery systems (eye imherbals, injectable eye dosage forms in pre-filled syringes).

3.18. Industrial production of medicines from herbal raw materials. The basics of extraction. Characteristics of galenical medicines

Description of herbal raw materials and sources of its production. Structural features of a plant cell. Characteristics of biologically active substances of medicinal herbal raw materials. Characteristics of total (native or galenical) and total purified (neogalenical) medicines. Medicinal products from individual substances isolated from herbals and complex ones.

Extraction of herbal, animal, and microbiological raw materials and tissue cultures in a solid–liquid system.

Technological characteristics of the phases: the content of active, extractive substances and moisture in the raw materials; the quality of the raw materials, the rate

and magnitude of the swelling coefficient of the raw materials, density, bulk mass of the raw materials, porosity of the raw materials, the grinding degree of the raw materials, the surface of the particles of the raw materials, the absorption coefficient.

Characteristics of extractive solvents. Requirements for extractive solvents: solubility, selectivity, polarity, viscosity, surface tension, reaction of the medium. Criteria for the selection of extractive solvents. Classification and modern range of extractive solvents: water, ethyl alcohol, chloroform, ether, acetone, etc. The use of liquefied gases in the production of extractive medicines.

Extraction stages: penetration of the extractive solvents into the raw material, dissolution and desorption, internal molecular diffusion, external molecular and convective diffusion. Diffusion equations. Coefficients of internal, molecular and convective diffusion.

Methods of extraction of animal and herbal raw materials: static and dynamic, periodic and continuous. Maceration, remaceration, percolation, repercolation, fast-flowing repercolation, continuous extraction, circulation extraction.

Equipment for extracting animal and herbal raw materials: maceration tanks, batteries of extractors (percolators), continuous extractors, rotary pulsation devices. Extractors, classification, device and operating principle.

Ways to intensify the extraction process: changes in hydrodynamic conditions, grinding of raw materials in the extractive solvents, ultrasound, electromagnetic field, electric pulse discharges, surfactants, etc.

3.19. Industrial production of tinctures

Tinctures, characteristics, classification. Methods of obtaining tincture: extraction and dissolution of soft and dry extracts. Extraction methods: maceration and its modifications, turbo extraction, percolation. Purification from ballast substances.

Technological and hardware production schemes. Quality control. Packaging, labeling, and storage of tinctures. Preparation of regulatory documentation for production. The range of tinctures of industrial production and the prospects for its expansion.

Private technology for the production of tinctures: valerian, hawthorn, St. John's wort, ginseng, calendula, peony, motherwort, eucalyptus, etc. Special cases of tinctures obtaining – peppermint tincture. Production of complex tinctures.

Recovery of alcohol from waste raw materials by water displacement and steam distillation. Rectification. The equipment used and the principle of its operation.

3.20. Industrial production of extracts

Extracts, classification by consistency and extractant used.

Liquid extracts, characteristics. Methods of obtaining liquid extracts: percolation, repercolation with a finished and unfinished cycle. Purification from ballast substances. Technological scheme for the production of liquid extracts. Quality control. Packaging, labeling, and storage of liquid extracts. Preparation of regulatory documentation for production.

The range of liquid extracts (hawthorn, thyme, eleutherococcus, passionflower, etc.) of industrial production and the prospects for its expansion.

Soft and dry extracts, characteristics, classification. Methods of obtaining soft and dry extracts: bismaceration, percolation, repercolation, countercurrent extraction,

circulation extraction. Purification of water and alcohol extracts from ballast substances. Evaporation and drying of extracts.

Technological scheme of production of Soft and dry extracts. Quality control. Packaging, labeling, and storage of Soft and dry extracts. Preparation of regulatory documentation for production.

Private technology for the production of soft and dry – ivy extract.

Nomenclature of soft extracts: licorice root, valerian, etc.

Nomenclature of dry extracts: licorice root, althea root, etc.

Oil extracts and CO₂-extracts. Characteristics and methods of obtaining. Private technology for the production of rosehip oil, milk thistle and sea buckthorn. Features of quality control.

Extracts-concentrates, characteristics, classification. Features of the technology of production of extracts-concentrates. Nomenclature of liquid and dry extracts-concentrates.

3.21. Medicines from fresh herbal raw materials

Extraction features of biological active substances (BAS) from fresh herbal raw materials. Juices (not condensed, condensed, dry), tinctures and extracts, and the specifics of their production. Private technology for obtaining psyllium juice. Nomenclature of juices: herbalain, echinacea, artichoke, celandine, etc. Tinctures from fresh medicinal herbal raw materials.

3.22. Industrial production of neogalenical medicines, medicinal products from animal raw materials and biogenic stimulants

Neogalenical medicines, characteristics, classification. Total neogalenical medicines. Methods of purification of extracts from ballast and related substances: fractional precipitation, solvent change, liquid extraction, chromatography, etc. Quality control.

Preparations of individual substances, characteristics. Classification and technology of production of medicines from individual substances of herbal raw materials (digoxin).

Medicinal products from animal raw materials, characteristics, classifications of medicinal products (by medical use, nature of active substances and methods of preparation). Features of the use of animal raw materials in the manufacture of medicines. Technological scheme for the production of medicines from dried and fat-free animal organs for internal and injectable use.

Biostimulants, characteristics, classification, properties and conditions of production. Biostimulants of herbal origin (aloe extract), animal origin (actovegin, alflutop, diaviton, appylak, propolis, viprosal) and mineral origin (bischofite). Production features.

3.23. Industrial production of syrups, essential oils, aromatic waters

Syrups, characteristics, classification: flavoring and medicinal (based on herbal raw materials and synthetic substances). Excipients used in the production of syrups. Technological schemes for the production of syrups at pharmaceutical enterprises (based on flavor syrups and based on synthetic sweeteners).

Quality control. Packaging, labeling, and storage of syrups. Preparation of regulatory documentation for the production of syrups. The nomenclature of syrups.

Essential oils, characteristics. Production of essential oils. The equipment used. Quality control: relative density, refractive index, optical rotation, fatty oils and mineral oils in essential oils. Additional tests for essential oils. Packaging, labeling, and storage.

Aromatic waters, characteristics, classification. Technological scheme for the production of aromatic waters. Equipment for the production of distilled aromatic waters. Assessment of the quality of aromatic waters. Packaging, labeling, and storage of aromatic waters.

3.24. Industrial production of aerosols and sprays

Aerosols. Characteristics and classification. Characteristics of the inhalation route of drug administration. Excipients used in the production of aerosols: propellants, solvents, solubilizers, surfactants, film-forming agents, etc. Characteristics of aerosol cans, valve-spray systems. Requirements for medicines under pressure: particle size, the dose obtained by pressing the dosing valve, etc.

Technological scheme of aerosol production. Methods of filling aerosol cans. Evaluation of aerosol packaging quality. Aerosols quality control. Aerodynamic particle size distribution (APSD): techniques, equipment used and its principle of operation. Drafting of regulatory documentation. Labeling, storage of aerosols. The nomenclature of aerosols.

Safety precautions in the production, transportation and storage of aerosol packages. Environmental problems of aerosol production.

Modern methods of aerosol delivery of medicines (multidisk, turbocharger, twisthaler, etc.). Powders for inhalation, their tests: particle size, number of doses in a multi-dose inhaler.

Sprays. Characteristics and classification. Excipients. Technological scheme of spray production. Features of primary packaging and spray devices. Spray quality control. Drafting of regulatory documentation. Labeling, storage, and nomenclature.

Medicinal foams. Characteristics and classifications. Excipients. Features of production technology. Quality control. Drafting of regulatory documentation. Labeling, storage, and nomenclature.

3.25. Medicines of prolonged and directed action. Nanotechnology in pharmaceuticals

Medicines of prolonged and directed action. Characteristics and classifications (according to the duration of action and the nature of the distribution of active substances in the human body).

Methods of prolonging the action of medicines: reducing the rate of excretion from the body, slowing biotransformation, inhibition and duration of absorption. Immobilization of medicines on inorganic and organic carriers. Methods of drug immobilization: physical (adsorption, incorporation into a gel, microcapsulation), physico-chemical (formation of inclusion compounds, solid dispersions) and chemical (covalent binding of a drug to a polymer carrier, crosslinking of drug molecules with a polymer using bifunctional reagents, etc.).

Nanoparticles as a means of drug delivery. Targeted design of new medicines (drug design). Delivery systems used in nanotechnology: nanocrystals, liposomes, polymer nanoparticles, micelles, dendrimers, etc.

Liposomes, characteristics, classification. Single-layer and multi-layer liposomes. Liposomes (thermosensitive and pH-sensitive). Excipients for liposome production. Natural phospholipids. Methods of obtaining liposomes. Obtaining liposomes by ultrasound. Incorporation of medicines into liposomes. Directed transport of liposomes.

REQUIREMENTS FOR THE COURSE WORK

The course work is completed in the 8th semester.

The main objective of the course work is to provide students with systematic scientific knowledge on the chosen topic, concerning the technology of obtaining medicines in industrial conditions, drawing up technological and hardware schemes of the production process, and conducting quality control.

When writing the course work, the student must acquire the following practical skills: patent and information retrieval of material; analysis of existing technologies for the production of medicines; preparation of technological documentation for the production of finished medicines; conducting market research on medicinal forms.

The topics of the work are approved annually at the department meeting. The assignment for completing the course work is given to the student in the first two weeks of the semester. By the decision of the department, students may be offered a topic on the scientific topic of the department.

The management, consultation and review of the course work is carried out by the staff of the department. If it is planned to carry out complex work in the scientific areas of the faculty, then teachers from other departments can be consultants of the work.

The defense of the work is carried out at the department on time.

ACADEMIC DISCIPLINE CURRICULAR CHART

Section, topic #	Section (topic) name	Number of hours		Supervised student independent work	Literature	Practical skills	Form of control	
		lectures	laboratory				of practical skills	of current / intermediate assessment
7 semester								
	Lectures	18	-	9				
1.	Principles of organization of production of medicines. Terminology	1,5	-	-	1, 2, 11, 15			
2.	The Rules of Good Manufacturing Practice of the Republic of Belarus and the Eurasian Economic Union. Regulatory documentation of production	-	-	1,5	13, 14, 15			Computer testing
3.	Air and water treatment system at pharmaceutical enterprises	1,5	-	-	13, 14, 15			
4.	The main processes of industrial technology, their role in the production of medicines. General concepts of machines	1,5	-	-	1-3, 5, 15			
5.	Mechanical processes and equipment	-	-	1,5	1-4, 15			Computer testing
6.	Hydromechanical processes and equipment	1,5	-		1-4, 15			
7.	Heat-exchanging processes and equipment	-	-	1,5	1-4, 15			Presentation, report
8.	Mass-exchanging processes and equipment	1,5	-		1-4, 15			
9.	Industrial technology of solid drug forms. Powders and herbal teas production	1,5	-	-	1, 2, 10, 15			
10.	Industrial production of granules. Study of physico-chemical and technological properties of powders and granulates	-	-	1,5	1, 2, 11, 15			Presentation, report
11.	Tablets. Methods of production. Theoretical foundations of tableting. Excipients used in the	1,5	-	-	1, 2, 12, 15			

	tablets production. Characteristics of tablet machines							
12.	Technological schemes of tablet production	-	-	1,5	1-3, 15			Computer testing
13.	Evaluation of tablet quality	1,5	-	-	1-3, 15			
14.	Tablets coating. Modern types of tablets	1,5	-	-	1-3, 15			
15.	Industrial production of dragee	-	-	1,5	1, 15			Presentation, report
16.	Industrial production of capsules. Microencapsulation of medicines	1,5	-	-	1-3, 15			
17.	Industrial production of semi-solid medicines	1,5	-	-	1-4, 15			
18.	Industrial production of suppositories, pessaries and medical pencils	1,5	-	-	1-3, 5, 15			
	Laboratory classes	-	68	-				
1.1.	Principles of organization of production of medicines. Terminology	-	4	-	1, 2, 11, 15			Account of practical exercise
1.2.	The Rules of Good Manufacturing Practice of the Republic of Belarus and the Eurasian Economic Union	-	4	-	13, 14, 15	1. The procedure for personnel to work in industrial premises of purity class «D» (using VR-factory simulation equipment). 2. Organization of the operation «Sampling of raw materials» (using VR-factory simulation equipment). 3. Organization of the «Weighing» operation of the starting materials for the production of a batch of medicinal products (using VR-factory simulation equipment)	Situational tasks solving	Visual laboratory classes, interview, tests
1.2.	Regulatory documentation of production	-	4	-	13, 14, 15	Organization of storage of materials in the warehouse of a pharmaceutical	Situational tasks solving	Express-interview, assessment based on the project

						company (using VR-factory simulation equipment)		method
1.3.	Air and water treatment system at pharmaceutical enterprises	-	4	-	13, 14, 15			Assessment of problem solving
2.1. 2.2. 2.3.	The main processes of industrial technology, their role in the production of medicines. General concepts of machines. Mechanical processes and equipment. Hydromechanical processes and equipment	-	4	-	1-3, 5, 15			Interview, situational tasks solving
2.4. 2.5.	Heat-exchanging processes and equipment. Mass-exchanging processes and equipment	-	4	-	1-4, 15			Defense of the abstract (report)
2.5.	Final lesson on sections «General principles of organizing the production of medicines at pharmaceutical enterprises», «Processes and equipment of pharmaceutical technology»	-	4	-	1-5, 13, 14, 15			Account of practical exercise, colloquium, interview, assessment of written problem solving*
3.1.	Industrial technology of solid drug forms. Powders and herbal teas production	-	4	-	1, 2, 10, 15	Manufacture of herbal species, granules, tablets, capsules	Report on laboratory work	Visual laboratory classes
3.2.	Industrial production of granules. Study of physico-chemical and technological properties of powders and granulates	-	4	-	1, 2, 11, 15	1. Manufacture of herbal species, granules, tablets, capsules. 2. Conducting pharmaceutical and technological tests of herbal species, powders, granules: description, fractional composition, bulk density before and after shrinkage, flowability	Report on laboratory work	Interview, tests
3.3.	Tablets. Methods of production. Theoretical foundations of tableting. Excipients used in the	-	4	-	1, 2, 12, 15			Interview, tests

	tablets production. Characteristics of tablet machines							
3.4.	Technological schemes of tablet production	-	4	-	1-3, 7, 15	1. Manufacture of herbal species, granules, tablets, capsules. 2. Organization of the tablet production process (using VR factory simulation equipment)	Report on laboratory work	Assessment of written problem solving
3.5.	Evaluation of tablet quality	-	4	-	1-3, 7, 15	Conducting pharmaceutical and technological tests of tablets: description, average weight, uniformity of mass for a unit of a dosed medicinal product, disintegration, dissolution, abrasion resistance	Report on laboratory work	Visual laboratory classes
3.6. 3.7.	Tablets coating. Modern types of tablets. Industrial production of dragee	-	4	-	1-3, 7, 15			Interview, tests
3.8.	Industrial production of capsules. Microencapsulation of medicines	-	4	-	1-3, 8, 15	1. Manufacture of herbal species, granules, tablets, capsules. 2. Conducting pharmaceutical and technological tests of capsules: description, uniformity of mass for a unit of a dosed medicinal product, disintegration, dissolution	Report on laboratory work	Express-interview, tests
3.8.	Final lesson on section «Industrial technology of solid drug forms»	-	4	-	1-8, 10-12, 15			Account of practical exercise, colloquium, interview, assessment of written problem solving*

3.8.	Practical skills	-	4	-	1-8, 10-14, 15			Report on laboratory work with oral defense
3.8.	Final lesson on sections «General principles of organizing the production of medicines at pharmaceutical enterprises», «Processes and equipment of pharmaceutical technology», «Industrial technology of solid drug forms»	-	4	-	1-8, 10-14, 15			Credit

8 semester

	Lectures	15	-	6				
1.	Industrial production of patches and mustard plasters	1,5	-	-	1, 3, 15			
2.	Industrial production of liquid medicines for internal and external use	1,5	-	-	1, 5, 15			
3.	Industrial production of emulsions and suspensions. Drops. Medicinal shampoos	-	-	1,5	1, 2, 6, 15			Computer testing
4.	Characteristics of medicines for parenteral use. Sterilization. Depyrogenation. Primary packaging – production and preparation	1,5	-	-	1, 2, 6, 15			
5.	Technology of parenteral medicines	1,5	-	-	2, 5, 15			
6.	Industrial production of eye medicines	1,5	-	-	2, 5, 15			
7.	Industrial production of medicines from herbal raw materials. The basics of extraction	1,5	-	-	2, 3, 15			
8.	Characteristics of galenical medicines	1,5	-	-	2, 3, 15			
9.	Industrial production of tinctures	-	-	1,5	2, 3, 15			Presentation, report
10.	Industrial production of extracts	1,5	-	-	2, 3, 15			
11.	Medicines from fresh herbal raw materials. Industrial production of neogalenical medicines, medicinal products from animal raw materials and biogenic stimulants	-	-	1,5	2, 3, 15			Computer testing
12.	Industrial production of syrups, essential oils, aromatic waters	1,5	-	-	2, 3, 15			
13.	Industrial production of aerosols and sprays	1,5	-	-	1-4, 15			

14.	Medicines of prolonged and directed action. Nanotechnology in pharmaceuticals	-	-	1,5	9, 15			Presentation, report
	Laboratory classes	-	64	-				
3.9.	Industrial production of semi-solid medicines	-	4	-	1-4, 15	1. Manufacture of semi-solid (ointments, creams, gels, suppositories) and liquid (suspensions, emulsions, syrups) dosage forms. 2. Conducting pharmaceutical and technological tests of ointments, creams, gels: description, uniformity, thermal stability, release of medicinal substances, pH	Report on laboratory work	Express-interview, tests
3.10. 3.11.	Industrial production of suppositories, pessaries and medical pencils. Industrial production of patches and mustard plasters	-	4	-	1-3, 5, 15	1. Conducting pharmaceutical and technological tests of suppositories: description, average weight, uniformity of mass for a unit of a dosed medicinal product, disintegration, dissolution	Report on laboratory work	Assessment of problem solving
3.12. 3.13.	Industrial production of liquid medicines for internal and external use. Dilution and strengthening of solutions in their industrial production	-	4	-	1, 5, 15	Manufacture of semi-solid (ointments, creams, gels, suppositories) and liquid (suspensions, emulsions, syrups) dosage forms	Report on laboratory work	Assessment of written problem solving
3.14.	Industrial production of emulsions and suspensions. Drops. Medicinal shampoos	-	4	-	1, 2, 6, 15	1. Manufacture of semi-solid (ointments, creams, gels, suppositories) and liquid (suspensions, emulsions, syrups) dosage forms. 2. Conducting pharmaceutical and technological tests of suspensions, emulsions:	Report on laboratory work	

						description, pH, density, type of emulsion, stability of the emulsion		
3.15.	Characteristics of medicines for parenteral use. Sterilization. Depyrogenation. Primary packaging – production and preparation	-	4	-	1, 2, 6, 15			Control work
3.16.	Technology of parenteral medicines	-	4	-	2, 5, 15			Interview, tests
3.17.	Industrial production of eye medicines	-	4	-	2, 5, 15			Interview, tests
3.17.	Final lesson on sections «Industrial production of semi-solid medicines», «Industrial production of liquid medicines for internal and external use»	-	4	-	1-6, 15			Account of practical exercise, colloquium, interview, assessment of written problem solving*
3.18.	Industrial production of medicines from herbal raw materials. The basics of extraction. Characteristics of galenical medicines	-	4	-	2, 3, 15			Interview, tests
3.19.	Industrial production of tinctures	-	4	-	2, 3, 15	Conducting pharmaceutical and technological tests of tincture: description, density, dry residue	Report on laboratory work	Interview, tests, situational tasks
3.20.	Industrial production of extracts	-	4	-	2, 3, 15			Interview, tests, situational tasks
3.21. 3.22.	Medicines from fresh herbal raw materials. Industrial production of neogalenical medicines, medicinal products from animal raw materials and biogenic stimulants	-	4	-	2, 3, 15			Defense of the abstract (report)
3.23.	Industrial production of syrups, essential oils, aromatic waters	-	4		2, 3, 15	Conducting pharmaceutical and technological tests of syrup: description, pH, density, refractive index, sucrose content	Report on laboratory work	Visual laboratory classes

3.24.	Industrial production of aerosols and sprays.	-	4	-	1-4, 9, 15			interview, tests
3.25.	Medicines of prolonged and directed action. Nanotechnology in pharmaceuticals	-	4	-	1-4, 9, 15			
3.25	Final lesson on sections «Industrial production of medicines from herbal raw materials», «Industrial production of aerosols and sprays»	-	4	-	1-4, 9, 15			Account of practical exercise, colloquium, interview, assessment of written problem solving*
3.25.	Practical skills	-	4	-	1-6, 9, 15			Report on laboratory work with oral defense
	Total hours	33	132	15				Exam

*This is a mandatory form of current certification.

INFORMATION AND INSTRUCTIONAL UNIT

LITERATURE

Basic:

1. Pharmaceutical Dosage Forms and Drug Delivery. Revised and Expanded. – 4th ed. / edited by Ram I. Mahato, Ajit S. Narang, V. Kumar. – CRC Press, 2024. – 566 p.

Additional:

2. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems / Loyd V. Allen; Timothy B. McPherson. – 12th edition. – Wolters Kluwer, 2023. – 704 p.
3. Aulton's Pharmaceutics. The Design and Manufacture of Medicines / Kevin M. G. Taylor, Michael E. Aulton. – 6th edition – Elsevier, 2021. – 968 p.
4. Basics of Pharmaceutical Manufacturing and Quality Operations. A Comprehensive Guide / Erfan S. Asif, Shahid B. Usmanio. – 1st edition. – CRC Press, 2024. – 266 p.
5. Handbook of Pharmaceutical Manufacturing Formulations / Sarfaraz K. Niazi. – 2nd edition. – CRC Press, 2024. – 646 p.
6. Lachman & Lieberman's Theory and Practice of Industrial Pharmacy / Roop K. Khar, S. P. Vyas [et al.]. – 4th edition. – CBS Publishers & Distributors, 2017. – 416 p.
7. Pharmaceutical Dosage Forms: Tablets / Larry L. Augsburger, Stephen W. Hoag. – 3rd ed. – Taylor & Francis, 2024. – 570 p.
8. Pharmaceutical Dosage Forms: Capsules / Larry L. Augsburger, Stephen W. Hoag. – CRC Press, 2017. – 435 p.
9. Novel Drug Delivery System (NDDS) / P. Kumar Singh, R. Bhasin [et al.] / IP Innovative Publication, 2024. – 372 p.

Normative regulatory acts:

10. European Pharmacopoeia. 11th Edition – Publisher: Council of Europe, Strasbourg, 2022.
11. Pharmacopoeia of the Eurasian Economic Union. Volume 1, part 1. Eurasian Economic Commission, Moscow, 2020.
12. Pharmacopoeia of the Eurasian Economic Union. Volume 1, part 2. Eurasian Economic Commission, Moscow, 2022.
13. European Medicine Agency. Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Public Health. EudraLex - Volume 4, 2018.
14. WHO Good Manufacturing Practices: main principles for pharmaceutical products. Geneva, World Health Organization, 2016.

Electronic courseware for the educational discipline «Industrial Technology of Drugs»

15. <https://etest.bsmu.by/course/view.php?id=949>

METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF STUDENT INDEPENDENT WORK IN THE ACADEMIC DISCIPLINE

The time allocated for independent work can be used by students for:

- preparing for lectures and laboratory classes;
- preparing for colloquiums, final lessons and exam in the academic discipline;
- studying the topics (issues) designed for independent work;
- problem solving;
- performing research and creative tasks;
- preparing thematic reports, abstracts, presentations;
- taking notes of educational literature;
- preparing reports;
- compiling a review of scientific literature on a given topic;
- execution of information and demonstration materials (stands, posters, graphs, tables, newspapers, etc.);
- making models, laboratory teaching aids;
- compilation of a thematic selection of literature sources, Internet sources;
- preparation of tests by students for the organization of mutual knowledge assessment.

METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF SUPERVISED STUDENT INDEPENDENT WORK IN THE ACADEMIC DISCIPLINE

Approximate list of tasks for supervised student independent work:

- preparation and presentation of abstracts;
- presentation of reports;
- studying topics and problems that have not been discussed at the lectures;
- computer testing;
- participation in active forms of education.

Forms of control of supervised student independent work:

- computer testing;
- presentation, report.

LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competence assessment:

- defense of the abstract (report);
- express-interview;
- interview;
- colloquium;
- situational tasks;
- assessment of written problem solving;
- tests;
- control work;

account of practical exercise;
 report on laboratory work with oral defense;
 assessment based on the project method;
 visual laboratory classes.

LIST OF AVAILABLE TEACHING METHODS

Traditional method;
 Active (interactive) methods:
 Problem-Based Learning (PBL);
 Team-Based Learning (TBL);
 Research-Based Learning (RBL).

LIST OF PRACTICAL SKILLS

Name of practical skills	Form of practical skills control
1. Manufacture of herbal species, granules, tablets, capsules	Report on laboratory work
2. Conducting pharmaceutical and technological tests of herbal species, powders, granules: description, fractional composition, bulk density before and after shrinkage, flowability	Report on laboratory work
3. Conducting pharmaceutical and technological tests of tablets: description, average weight, uniformity of mass for a unit of a dosed medicinal product, disintegration, dissolution, abrasion resistance	Report on laboratory work
4. Conducting pharmaceutical and technological tests of capsules: description, uniformity of mass for a unit of a dosed medicinal product, disintegration, dissolution	Report on laboratory work
5. The procedure for personnel to work in industrial premises of purity class «D» (using VR-factory simulation equipment)	Situational tasks solving
6. Organization of the operation «Sampling of raw materials» (using VR-factory simulation equipment)	Situational tasks solving
7. Organization of the «Weighing» operation of the starting materials for the production of a batch of medicinal products (using VR-factory simulation equipment)	Situational tasks solving
8. Organization of storage of materials in the warehouse of a pharmaceutical company (using VR-factory simulation equipment)	Situational tasks solving
9. Organization of the tablet production process (using VR factory simulation equipment)	Situational tasks solving

10. Manufacture of semi-solid (ointments, creams, gels, suppositories) and liquid (suspensions, emulsions, syrups) dosage forms	Report on laboratory work
11. Conducting pharmaceutical and technological tests of ointments, creams, gels: description, uniformity, thermal stability, release of medicinal substances, pH	Report on laboratory work
12. Conducting pharmaceutical and technological tests of suppositories: description, average weight, uniformity of mass for a unit of a dosed medicinal product, disintegration, dissolution	Report on laboratory work
13. Conducting pharmaceutical and technological tests of suspensions, emulsions: description, pH, density, type of emulsion, stability of the emulsion	Report on laboratory work
14. Conducting pharmaceutical and technological tests of syrup: description, pH, density, refractive index, sucrose content	Report on laboratory work
15. Conducting pharmaceutical and technological tests of tincture: description, density, dry residue	Report on laboratory work

LIST OF SIMULATION EQUIPMENT USED

1. A virtual factory VR «Production of solid dosage forms».

**PROTOCOL OF THE CURRICULUM APPROVAL
BY OTHER DEPARTMENTS**

Title of the discipline requiring approval	Department	Amendments to the curriculum in the academic discipline	Decision of the department, which designed the curriculum (date, protocol #)
1. Modern Methods of Analysis and Standardization of Drugs	Pharmaceutical Chemistry with advanced training and retraining course	There are no offers	protocol # 14 of 16.05.2025
2. Pharmaceutical Ecology	Pharmaceutical Chemistry with advanced training and retraining course	There are no offers	protocol # 14 of 16.05.2025
3. Pharmaceutical Development with the Fundamentals of Biopharmaceutics	Pharmaceutical Technology with advanced training and retraining course	There are no offers	protocol # 14 of 16.05.2025
4. Management and Economics of a Pharmaceutical Enterprise	Pharmaceutical Technology with advanced training and retraining course	There are no offers	protocol # 14 of 16.05.2025

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Head of the Department of Pharmaceutical Technology with advanced training and retraining course of the Educational Institution «Belarusian State Medical University», PhD, Associate Professor



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O.A.Sushinskaya

Curriculum content, composition and the accompanying documents comply with the established requirements.

Head of the Office of Educational Activities of the educational Institution «Belarusian State Medical University»

24.06.2025



I.L.Kotovich

Methodologist of the Educational and Methodological Department of the Office of Educational Activities of the educational institution «Belarusian State Medical University»

24.06.2025



S.V.Zaturanova