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
25.06.2026
Reg. # UD-0912-01-34/2621/edu.

INDUSTRIAL TECHNOLOGY OF DRUGS

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

7-07-0912-01 «Pharmacy»

2026

Curriculum is based on the educational program «Industrial Technology of Drugs», approved 01.12.2025, registration # УД-0912-01-34/2526/уч.; on the educational plan in the specialty «Pharmacy», approved 15.04.2026, registration # 7-07-0912-01/2627/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 25.06.2026)

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 academic 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.

Relations to other academic disciplines

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 Pharmaceutical Enterprises», «Modern Methods of Analysis and Standardization of Drugs», «Pharmaceutical Ecology».

Studying the academic 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;

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;

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.

Total number of hours for the study of the discipline is 335 academic hours, of which 176 classroom hours and 159 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 – 128 hours.

Form of higher education – full-time.

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).

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		
7-07-0912-01	7	170	91	18	9	64	79	credit
«Pharmacy»	8	165	85	15	6	64	80	examination
Total hours		**335**	**176**	**33**	**15**	**128**	**159**	

THEMATIC PLAN

Section (topic) name	Number of class hours	
	lectures (incl. SSIW)	laboratory
1. General principles of organization of medicinal product manufacturing at pharmaceutical enterprises. Processes and equipment of pharmaceutical technology	**10,5**	**28**
1.1. Principles of organization of medicinal product manufacturing. Terminology	1,5	4
1.2. Basic processes of industrial technology, their role in the production of medicinal products. General concepts of machines and apparatuses		
1.3. Mechanical processes and equipment	3	4
1.4. Hydromechanical processes and equipment		
1.5. Heat-exchanging processes and equipment	3	4
1.6. Mass transfer processes and equipment		
1.7. Good Manufacturing Practice (GMP) Rules of the Republic of Belarus and the Eurasian Economic Union. Regulatory documentation for manufacturing	1,5	8
1.8. Air and water preparation systems at pharmaceutical enterprises	1,5	8
2. Industrial production of drugs	**37,5**	**100**
2.1. Technology for industrial production of solid dosage forms. Production of powders and herbal mixtures. Study of pharmaceutical-technological properties of powders	1,5	4
2.2. Industrial production of granules. Study of pharmaceutical-technological properties of granules	3	4
2.3. Tablets. Methods of production. Theoretical basis of tableting. Excipients used in tablet production	1,5	4
2.4. Technological schemes for tablet production. Characteristics of tablet presses	1,5	4
2.5. Quality evaluation of tablets	1,5	4
2.6. Coating of tablets. Modern types of tablets	1,5	4
2.7. Industrial production of dragees	1,5	
2.8. Industrial production of hard gelatin capsules	1,5	4
2.9. Industrial production of soft gelatin capsules. Microencapsulation of medicinal products		8
2.10. Industrial production of semi-solid dosage forms. Production of ointments, creams, gels, pastes	1,5	4

2.11. Industrial production of suppositories, pessaries and medical pencils	1,5	4
2.12. Industrial production of patches and mustard plasters	1,5	
2.13. Industrial production of liquid dosage forms for internal and external use	1,5	4
2.14. Dilution and concentration of solutions in their industrial production	1,5	
2.15. Industrial production of emulsions and suspensions. Drops. Medicated shampoos	1,5	4
2.16. Characteristics of parenteral dosage forms. Sterilization. Depyrogenation. Primary packaging – production and preparation	1,5	4
2.17. Technology for production of parenteral dosage forms	1,5	4
2.18. Industrial production of ophthalmic dosage forms	1,5	8
2.19. Industrial production of medicinal products from natural raw materials. Basic principles of extraction. Characteristics of galenical preparations	1,5	4
2.20. Industrial production of tinctures	1,5	4
2.21. Industrial production of extracts		4
2.22. Medicinal products from fresh plant raw materials	1,5	4
2.23. Industrial production of neogalenical preparations, medicinal products from animal raw materials and biogenic stimulants	1,5	
2.24. Industrial production of syrups, essential oils, aromatic waters	1,5	4
2.25. Industrial production of aerosols and sprays	1,5	8
2.26. Prolonged-release and targeted-action medicinal products. Nanotechnologies in pharmaceutics	1,5	4
Total hours	**48**	**128**

CONTENT OF THE ACADEMIC DISCIPLINE

1. General principles of organization of medicinal product manufacturing at pharmaceutical enterprises. Processes and equipment of pharmaceutical technology

1.1. Principles of organization of medicinal product manufacturing. Terminology

Goals and objectives of industrial pharmaceutical technology as an academic discipline. Difference between industrial pharmaceutical technology and pharmacy (compounding) technology.

Industrial production of medicinal products in the Republic of Belarus.

Differentiation and specialization of pharmaceutical enterprises.

Terminology: pharmaceutical technology, medicinal product, dosage form, production, starting materials, excipient, intermediate product, bulk product, finished product, batch (lot), validation, controlled area, clean area, clean (isolated) area, cross-contamination, manufacturing, technological process, container, packaging, packaging material.

Principles of organization of medicinal product manufacturing at pharmaceutical enterprises. Structure of pharmaceutical enterprises. Workshop-based principle of organizing medicinal product manufacturing.

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

Concepts of by-product, production waste and refuse, material losses. Material balance. Technological yield, loss, consumption coefficient and working formulas. Energy balance and technical-economic balance.

1.2. Basic processes of industrial technology, their role in the production of medicinal products. General concepts of machines and apparatuses

Characteristics of the main technological processes in industrial technology: mechanical, hydromechanical, heat-exchanging, mass transfer. Role and interrelation of technological processes in the production of medicinal products.

General concepts of machines and apparatuses. Machine as a unity of motor, transmission and actuating mechanism. Characteristics of motors, transmission and actuating mechanisms. Characteristics of apparatuses and reactors. Control and measuring instruments and devices.

1.3. Mechanical processes and equipment

General characteristics of mechanical processes. Application in industrial technology.

Grinding of materials. Degree of grinding, its dependence on material strength, hardness, elasticity and brittleness. Theoretical foundations of material grinding. Surface theory and volume theory of material grinding. Rehbinder's combined theory of grinding. Basic rule of material grinding. Grinding methods: crushing, splitting, impact, abrasion, etc.

Concept of cryogrinding, areas of application.

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

Grinding machines, design and operating principle (disintegrator, impact mill, excelsior mill, hammer mill, ball mill, vibration mill, jet mill). Specific features of grinding plant materials. Purpose and use of grinding in industrial technology.

Classification of solid materials (air classification, hydraulic classification and mechanical classification), general characteristics.

Mechanical classification (sieving). Sieves and sieve analysis. Materials and types of mesh (woven, punched, bar screens). Standards and numbering of sieves. Design and operating principle of mechanized sieves: oscillating, rotating, vibrating. Safety precautions during sieving.

Mixing in industrial production of medicinal products. Mixers of gravitational, mechanical and vibratory action, fluidized bed mixers, design and operating principle. Characteristics of fluidized (boiling) granular layers. Use of fluidization in pharmaceutical production, its characteristics. Basic properties of the fluidized bed.

1.4. Hydromechanical processes and equipment

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

Methods of mixing liquid and viscous media: mechanical, pneumatic, gravitational, in-line mixing, acoustic (ultrasonic), circulation mixing. Designs of agitators (mixers), their characteristics.

Separation of heterogeneous systems. Sedimentation methods. Sedimentation rate. Factors affecting sedimentation rate. Design and operating principle of sedimentation tanks (settlers).

Separation of solid and liquid phases under pressure difference. Filtration, filtration methods, filtration equation. Filter media, characteristics. Design and operating principle of filters: Nutsch filters, Druck filters, filter presses.

Phase separation in a centrifugal force field. Centrifugation, separation factor. Design and operating principle of centrifuges (filtering and sedimentation centrifuges, batch and continuous action centrifuges, ultracentrifuges), cyclones, scrubbers.

1.5. Heat-exchanging processes and equipment

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

Heat transfer media (heating and cooling agents), characteristics and classifications. Direction of heat transfer media flow (parallel flow, countercurrent flow, cross flow, mixed flow) and its influence on the intensity of heat exchange. Application in industrial technology.

Steam as the main heat transfer medium. Wet, dry, saturated and superheated steam. Heating with direct (live) steam and indirect (closed) steam.

Heat exchange equipment and its classification. Design and operating principle of heat exchangers: surface heat exchangers, direct contact (mixing) heat exchangers, regenerative heat exchangers and those with internal heat generation (coil heat exchangers, shell-and-tube heat exchangers, double-pipe heat exchangers, finned tube heat exchangers, steam jackets, etc.).

1.6. Mass transfer processes and equipment

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

Evaporation: characteristics and methods of evaporation (under vacuum, at atmospheric pressure and under increased pressure). Secondary phenomena during evaporation (incrustation, boiling point elevation (temperature depression), hydrostatic effect, entrainment, foaming) and ways to eliminate them. Design and operating principle of evaporation units and evaporators (single-effect and multi-effect evaporators, film evaporators, etc.).

Drying: characteristics and classification. Forms of moisture binding with the material. Statics and kinetics of drying. Properties of air as a drying agent: temperature,

absolute and relative humidity, moisture content and enthalpy (heat content). Drying methods (contact and convective). Contact dryers: vacuum drying ovens, vacuum drum dryers. Convective dryers: spray dryers, disc dryers, jet spray dryers. Special drying methods: freeze drying (lyophilization), acoustic drying, radiation drying, etc. Design and operating principle of equipment.

1.7. Good Manufacturing Practice (GMP) Rules of the Republic of Belarus and the Eurasian Economic Union. Regulatory documentation for manufacturing

System of requirements for the manufacturing and quality control of medicinal products – Good Manufacturing Practice (GMP).

Structure of GMP: introduction, terminology, parts and annexes.

Basic requirements. Chapters: pharmaceutical quality system; personnel; premises and equipment; documentation; production; quality control; outsourcing (contract activities); complaints, quality defects and product recalls; self-inspection.

Documents related to Good Manufacturing Practice rules. Explanatory notes on the preparation of the manufacturing site dossier (Site Master File).

State Pharmacopoeia and the Eurasian Economic Union (EAEU, Union) Pharmacopoeia, Manufacturer's Pharmacopoeial Monograph. Pharmacopoeial standardization of manufacturing and quality of finished dosage forms.

Computer technologies in pharmaceutical manufacturing. Manufacturing process analysis technology (Process Analytical Technology – PAT).

1.8. Air and water preparation systems at pharmaceutical enterprises

Air handling system in accordance with GMP requirements. Particulate contamination levels for various zones in the «at rest» and «in operation» states. Air filtration at pharmaceutical enterprises. Filters for removing mechanical impurities from gases. Design and operating principle of HEPA filters. Basic requirements for «clean» rooms and control of air environment parameters in the production of sterile medicinal products.

Water preparation system in accordance with GMP requirements.

Water preparation methods, design and operating principle of equipment used: filtration, ion exchange, reverse osmosis, electrodeionization, distillation (multi-effect water stills and thermocompression stills).

Water storage system at pharmaceutical enterprises. Equipment used.

Water quality control parameters.

2. Industrial production of drugs

2.1. Technology for industrial production of solid dosage forms. Production of powders and herbal mixtures. Study of pharmaceutical-technological properties of powders

Powders: definition, characteristics, classification according to the Pharmacopoeia of the Republic of Belarus and the nomenclature of dosage forms of the EAEU.

Technological and equipment flow charts for powder production at a pharmaceutical enterprise. Main stages and operations. Dosing, filling, packaging, labeling and storage of powders, equipment used. Quality control of powders.

Preparation of regulatory documentation for powder production.

Herbal mixtures (medicinal herbal mixtures): definition, characteristics, classification.

Technological and equipment flow charts for the production of herbal mixtures at a pharmaceutical enterprise. Main stages and operations. Dosing, filling, packaging, labeling and storage of herbal mixtures, equipment used. Quality control of herbal mixtures. Preparation of regulatory documentation for the production of herbal mixtures.

Characteristics of physical, chemical, technological and structural-mechanical properties of powders. Pharmaceutical-technological tests (flowability, bulk density and tapped density, particle size distribution), test methods, equipment used.

Improvement of powder and herbal mixture technology. Nomenclature of industrially produced powders and herbal mixtures.

2.2. Industrial production of granules. Study of pharmaceutical-technological properties of granules

Granules: definition, characteristics, classification.

Technological and equipment flow charts for granule production at a pharmaceutical enterprise. Main stages and operations. Excipients used for granulation. Granulation methods (dry, wet and structural granulation; comparative characteristics). Equipment used for granulation and drying of granules. Spheronization of granules. Dosing, filling, packaging, labeling and storage of granules. Quality control of granules. Preparation of regulatory documentation for granule production.

Pharmaceutical-technological tests of granules (flowability, bulk density and tapped density, particle size distribution, moisture content), test methods, equipment used.

Improvement of granule production technology. Nomenclature of industrially produced granules.

2.3. Tablets. Methods of production. Theoretical basis of tableting. Excipients used in tablet production

Tablets: definition, characteristics, requirements, classification. Methods of production (compression, molding, lyophilization, extrusion).

Tablets obtained by compression. Theoretical basis of tableting: mechanical theory, capillary theory, electrostatic theory.

Excipients used in tablet production (fillers/diluents, disintegrants, glidants, binders, anti-adherents/lubricants, colorants, taste corrigents, release retardants), their characteristics and nomenclature. Influence of excipients on the therapeutic efficacy of active substances in tablets.

2.4. Technological schemes for tablet production. Characteristics of tablet presses

Technological schemes for tablet production: direct compression and using granulation. Algorithm for selection and justification of tablet production technology. Characteristics of stages and operations of the tablet production process. Dusting of granules with anti-adherent substances.

Characteristics of technological and physicochemical properties of tablet mass

(porosity, compression ratio, compressibility, ejection force, moisture content).

Tablet presses. Characteristics and operating principle. Main elements of tablet presses: dies and punches. Double-sided compression tablet presses.

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

2.5. Quality evaluation of tablets

Pharmaceutical-technological tests – methods and instruments/equipment used: disintegration, dissolution test for solid dosage forms, uniformity of mass of single-dose preparations, uniformity of content of active substance in single-dose preparations, friability of uncoated tablets, tablet crushing strength (hardness), uniformity of dosage units. Interpretation of results.

Preparation of regulatory documentation for tablet production.

2.6. Coating of tablets. Modern types of tablets

Coating of tablets. Objectives, classification according to the Pharmacopoeia of the Republic of Belarus and coating technology.

Film coating: characteristics and classification of film coatings for tablets, nomenclature of film-forming agents for film coatings. Excipients, range and characteristics. Modern combined film coating compositions. Methods of applying film coatings to tablets, design and operating principle of equipment used.

Sugar coating. Modern coating technology. Excipients, purpose and characteristics. Equipment used, design and operating principle.

Compression coating (dry coating). Characteristics, equipment used, its design and operating principle.

Characteristics of multilayer tablets and tablets with modified release of the active substance.

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

Production of molded tablets, lyophilized tablets, etc. Modern ways of improving tablets.

2.7. Industrial production of dragees

Dragees: definition, characteristics. Technological and equipment flow charts for dragee production at a pharmaceutical enterprise. Main stages and operations. Excipients used for dragee production. Dosing, filling, packaging, labeling and storage of dragees. Quality control of dragees. Design and operating principle of equipment used. Preparation of regulatory documentation for dragee production. Nomenclature of industrially produced dragees.

2.8. Industrial production of hard gelatin capsules

Capsules: definition, characteristics, classification according to the Pharmacopoeia of the Republic of Belarus and the nomenclature of dosage forms of the EAEU. Methods for producing gelatin capsules.

Materials for capsule shell production. Gelatin mass. Technological and equipment flow charts. Excipients. Quality control.

Hard gelatin capsules. Characteristics, classification. Formation of empty gelatin capsules (shells) by dip molding. Filling of capsules with contents: combinations of fillers for hard gelatin capsules and encapsulation methods. Excipients. Equipment used, design and operating principle.

2.9. Industrial production of soft gelatin capsules. Microencapsulation of medicinal products

Soft gelatin capsules: characteristics, classification. Technology for producing capsules by rotary die (press) method and drop method. Equipment used, design and operating principle.

Technological and equipment flow charts for the production of hard and soft gelatin capsules. Filling, packaging, labeling and storage of capsules. Quality control of capsules. Preparation of regulatory documentation for capsule production. Nomenclature of industrially produced capsules.

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

Microcapsules, microgranules and microdragees, their characteristics. Microencapsulation of pharmaceutical substances. Microencapsulation methods: physical, physicochemical, chemical. Characteristics of excipients for microencapsulation. Quality evaluation of microcapsules.

2.10. Industrial production of semi-solid dosage forms. Production of ointments, creams, gels, pastes

Semi-solid dosage forms, characteristics, classifications.

Ointments: definition, characteristics, classifications according to the Pharmacopoeia of the Republic of Belarus and the nomenclature of dosage forms of the EAEU. Hydrophobic, hydrophilic and water-emulsion ointments. Characteristics and classification of ointment bases. Excipients. Structural-mechanical properties of ointments (rheology). Technological and equipment flow charts.

Creams: definition, characteristics, classifications according to the Pharmacopoeia of the Republic of Belarus and the nomenclature of dosage forms of the EAEU. Lipophilic and hydrophilic creams. Excipients, characteristics and classification. Technological and equipment flow charts.

Gels: definition, characteristics, classifications according to the Pharmacopoeia of the Republic of Belarus and the nomenclature of dosage forms of the EAEU. Lipophilic and hydrophilic gels. Nomenclature of gelling agents. Excipients, characteristics and classification. Technological and equipment flow charts.

Specific features of paste and liniment production at pharmaceutical enterprises.

Dosing, filling, packaging, labeling and storage of soft dosage forms. Quality control. Preparation of regulatory documentation for production. Nomenclature of industrially produced soft dosage forms.

Equipment used, design and operating principle.

2.11. Industrial production of suppositories, pessaries and medical pencils

Suppositories and pessaries: definition, characteristics, classification.

Technological and equipment flow charts for production at a pharmaceutical enterprise. Main stages and operations. Excipients, their characteristics and nomenclature. Influence of excipients on the therapeutic efficacy of active substances. Characteristics of suppository bases. Equipment used in suppository production, design and operating principle. Packaging and storage of suppositories. Quality indicators of suppositories: description, quantitative determination of active substances, identification, particle size, dissolution test, disintegration test, time of complete

deformation, melting point, microbiological purity. Test methods, equipment used. Preparation of regulatory documentation.

Modern types of suppositories. Nomenclature of industrially produced suppositories and pessaries.

Medical pencils, characteristics. Types of medical pencils. Methods of producing medical pencils: casting, compression. Specific technology of medical pencils: silver nitrate pencils, menthol pencils, hemostatic pencils, etc. Packaging and storage of medical pencils. Modern types of medical pencils.

2.12. Industrial production of patches and mustard plasters

Patches: definition, characteristics, classifications. Methods of patch production.

Main components of a patch. Modern adhesive bases for patches (rubber-based, acrylate-based, silicone-based). Range of excipients for patch production, their characteristics. Technological and equipment flow charts. Equipment for preparing patch masses, spreading and drying patches. Design and operating principle.

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

Transdermal patches. Characteristics, classification and structure. Technology features. Range of excipients for transdermal patch production.

Production of mustard plasters. Definition, characteristics and compositions. Technology for producing mustard plasters.

Packaging, labeling, storage of patches and mustard plasters. Quality control. Nomenclature of industrially produced patches and mustard plasters.

2.13. Industrial production of liquid dosage forms for internal and external use

Liquid dosage forms: characteristics and classification.

Pharmaceutical solutions: characteristics, classification of solutions depending on the nature of the solvent (aqueous, alcoholic, oily, glycerin-based) 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 affecting the dissolution process: grinding, temperature change, stirring. Temperature and hydrodynamic conditions in solution production. Solubility indicators of substances in various solvents and solubility designation in the Pharmacopoeia of the Republic of Belarus.

Technological and equipment flow charts for solution production by the dissolution method at a pharmaceutical enterprise. Main stages and operations. Equipment used, design and operating principle. Packaging, labeling and storage.

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

Quality control. Preparation of regulatory documentation for solution production. Nomenclature of industrially produced solutions and prospects for its expansion.

2.14. Dilution and concentration of solutions in their industrial production

Density of solutions. Determination of density using an areometer and pycnometer: use of formulas for dilution and concentration of salt, acid and alkali solutions.

Methods for determining alcohol concentration and features of dilution or

concentration of alcoholic solutions at pharmaceutical enterprises. Dilution of ethyl alcohol. Alcoholometric tables, rules for using alcoholometric tables.

2.15. Industrial production of emulsions and suspensions. Drops. Medicated shampoos

Suspensions and emulsions: characteristics, classification by type, route of administration, concentration of active substance.

Types of instability of suspensions and emulsions: aggregative, sedimentation, phase inversion. Excipients: purpose, characteristics and nomenclature. Emulsifiers: characteristics, significance of hydrophilic-lipophilic balance (HLB). Stabilizers: characteristics, significance.

Technological and equipment flow charts for the production of emulsions and suspensions.

Methods of production at pharmaceutical enterprises: mechanical stirring, grinding in a liquid medium, ultrasonic dispersion. Features and prospects of using ultrasound in the production of suspensions and emulsions. Equipment used, design and operating principle.

Quality control. Preparation of regulatory documentation for the production of suspensions and emulsions. Nomenclature of industrially produced suspensions and emulsions and 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.

Medicated shampoos: characteristics, features of production and standardization. Excipients used. Types of primary packaging.

2.16. Characteristics of parenteral dosage forms. Sterilization. Depyrogenation. Primary packaging – production and preparation

Parenteral dosage forms, their characteristics and classification: injectable medicinal products, infusion medicinal products, concentrates and powders for reconstitution into injections and infusions, gels for injection, implants and wipes.

Sterilization of parenteral dosage forms. Sterility. Bioburden. Classification and characteristics of methods – mechanical, physical and chemical. Characteristics of sterilization equipment. Pharmacopoeial sterilization methods (Pharmacopoeia of the Republic of Belarus, Vol. 1, articles 5.1.1, 5.1.2). Sterility assurance level (SAL). Criteria for choosing a sterilization method. Sterilization control methods: biological, chemical and physical.

TCP 433-2012 (02041) Production of medicinal products. Validation of sterile medicinal product manufacturing processes.

Recommendation of the Board of the Eurasian Economic Commission dated March 1, 2021 No. 6 «On the Guide to Aseptic Processes in Pharmaceutical Manufacturing».

Thermal sterilization. Safety rules for working with pressure equipment. Preparation and conduct of sterilization in steam sterilizers. Air sterilizers (hot air ovens). Thermal sterilization regimes depending on the properties of objects and their quantity. Safety precautions for various sterilization methods.

Mechanical sterilization (sterilizing filtration). Principle, equipment,

organization of the filtration system and routine process control.

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

Containers (ampoules, vials, cartridges, prefilled syringes) for sterile medicinal products. Characteristics, materials used, requirements, glass classes. Union Pharmacopoeia article 2.4.2; Pharmacopoeia of the Republic of Belarus, Vol. 1, articles 3.1 and 3.2. Quality testing of glass containers. Hydrolytic and thermal resistance testing. Closures, seal integrity and container-closure system integrity. Criteria for choosing packaging.

Production and preparation of primary packaging for filling. Production of glass primary packaging: preparation of glass tubing, calibration, washing. Processing on semi-automatic machines, annealing. Preparation of containers for filling. External and internal (vacuum and syringe) washing of ampoules. Drying and sterilization. Silicone coating.

2.17. Technology for production of parenteral dosage forms

Pharmaceutical substances, purity requirements, decontamination, depyrogenation and sterilization. Excipients – purity requirements, purpose, characteristics and nomenclature. Stabilization of injection solutions of salts of weak bases and strong acids; salts of strong bases and weak acids; easily oxidizable substances. Methods of stabilizing injection solutions. Range of stabilizers: acids, alkalis, antioxidants, anticatalysts, etc. 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 terminal sterilization and under aseptic conditions.

Production of injections in ampoules and vials. Technological and equipment flow charts for the production of sterile solutions, suspensions and emulsions. Comprehensive mechanization and automation of ampoule production. Methods of filling ampoules: vacuum method, syringe method. Sealing of ampoules. Semi-automatic machines for ampoule sealing. Sealing of ampoules with gas protection. Methods of filling, closing and sealing vials. Labeling of medicinal products. Storage of medicinal products.

Infusions: production features. Types of infusions: plasma substitutes, regulators of water-salt balance, for parenteral nutrition, oxygen carriers and polyfunctional ones. Requirements for isotonicity, isohydricity, isoionicity and isoviscosity. Industrial production of saline, plasma-substituting and detoxification solutions. Nomenclature of industrially produced infusions.

Application of BFS (Blow-Fill-Seal) technology in the production of parenteral medicinal products. Features of industrial technology for manufacturing ampoules and vials. Technological flow chart for parenteral medicinal products using BFS technology.

Filling of powders into vials and ampoules.

Application of lyophilization technology in the production of parenteral medicinal products. Stages of the lyophilization process and equipment used.

Excipients, functions, nomenclature. Technological flow chart for the production of lyophilized powders.

Quality control of parenteral medicinal products. Preparation of regulatory documentation for parenteral medicinal products.

Modern nomenclature of parenteral medicinal products.

2.18. Industrial production of ophthalmic dosage forms

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

Industrial production of eye drops. Excipients. Stabilization and preservation of eye drops, characteristics of preservatives. Use of buffer solvents in the production of eye drops. Prolongation of action of eye drops. Technology features. Primary packaging: materials used, ways to improve primary packaging to maintain stability and sterility of eye drops. Sterilization of eye drops. Quality control. Nomenclature, labeling, storage of industrially produced eye drops.

Ophthalmic soft dosage forms. Requirements for eye ointments and bases for eye ointments. Sterility and stability of eye ointments. Technological flow chart for the production of eye ointments under aseptic conditions. Quality control. Packaging, labeling, storage of eye ointments. Nomenclature of industrially produced eye ointments.

Ophthalmic inserts: characteristics, classification and excipients. Film-forming agents in the production of ophthalmic inserts. Technological flow chart for the production of ophthalmic inserts. Quality control. Packaging, labeling, storage of ophthalmic inserts. Nomenclature of ophthalmic inserts.

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

Modern ophthalmic drug delivery systems (ocular implants, injectable ophthalmic forms in prefilled syringes).

2.19. Industrial production of medicinal products from natural raw materials. Basic principles of extraction. Characteristics of galenical preparations

Brief characteristics of plant raw materials and sources of their procurement. Features of plant cell structure. Characteristics of biologically active substances of medicinal plant raw materials. Characteristics of total (native or galenical) and total purified (neogalenical) medicinal products. Medicinal products from individual substances isolated from plants and from complex substances.

Extraction of plant, animal, microbiological raw materials and tissue culture in the «solid body – liquid» system, as one of the types of mass transfer processes.

Technological characteristics of phases: content of active substances, extractives and moisture in raw materials; quality of raw materials; rate and degree of swelling of raw materials; density, bulk density and tapped density of raw materials; porosity and void fraction of raw materials; degree of comminution of raw materials; particle surface area of raw materials; washout coefficient and absorption coefficient.

Characteristics of extractants. Requirements for extractants: dissolving capacity, selectivity, polarity, viscosity, surface tension, pH of the medium. Criteria for choosing extractants. Classification and modern range of extractants: water, ethyl alcohol,

chloroform, ether, acetone, etc. Use of liquefied gases in the production of extractive medicinal products.

Principles of extraction and stages of extraction: penetration of extractant into the raw material, dissolution and desorption, internal molecular diffusion, external molecular and convective diffusion. Diffusion equations (Fick's first and second laws and convective diffusion). Coefficients of internal, molecular and convective diffusion. Diffusion losses, calculation of diffusion losses. Factors influencing the reduction of diffusion losses (absorption of extractant by raw material, division of extractant and raw material into parts).

Kinetics of mass transfer during extraction with liquefied gases. Influence of various factors on the extraction process with liquefied gases, equipment design.

Methods of extracting animal and plant raw materials: static and dynamic, batch and continuous, equilibrium and non-equilibrium. Maceration, remaceration, percolation, repercolation, fast-flow repercolation, continuous extraction, circulation.

Equipment for extraction of animal and plant raw materials: maceration tanks, battery of extractors (percolators), continuous extractors, rotor-pulsation apparatus. Design and operating principle.

Ways to intensify the extraction process: changes in hydrodynamic conditions, grinding of raw materials in the extractant, ultrasound exposure, electromagnetic field, electro-pulse discharges, surface-active substances, etc.

Extraction in the «liquid – liquid» system. Characteristics of solvents, distribution coefficient.

Basic methods of extraction separation: single-stage and multi-stage extraction. Continuous countercurrent extraction.

Extractors, classification, design and operating principle.

2.20. Industrial production of tinctures

Tinctures, characteristics, classification. Methods of producing tinctures: extraction and dissolution of thick and dry extracts. Methods of obtaining extracts: maceration and its modifications, turboextraction, percolation. Purification of tinctures from ballast substances.

Technological and equipment flow charts. Quality control. Packaging, labeling, storage of tinctures. Preparation of regulatory documentation.

Nomenclature of industrially produced tinctures and prospects for its expansion.

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

Recovery of alcohol from exhausted raw materials by displacement with water and steam distillation. Rectification (concept, definition). Equipment used and its operating principle.

2.21. Industrial production of extracts

Extracts, classification by consistency and extractant used.

Liquid extracts, characteristics. Methods of obtaining extracts in the production of liquid extracts: percolation, repercolation with completed and incomplete cycles. Purification of extracts from ballast substances.

Technological flow chart for the production of liquid extracts. Quality control.

Packaging, labeling, storage of liquid extracts. Preparation of regulatory documentation.

Nomenclature of industrially produced liquid extracts (hawthorn, thyme, eleutherococcus, passion flower, etc.) and prospects for its expansion.

Thick and dry extracts, characteristics, classification. Methods of obtaining extracts in the production of thick and dry extracts: bismaceration, percolation, repercolation, countercurrent extraction, circulation extraction. Purification of aqueous and alcoholic extracts from ballast substances. Evaporation and drying of extracts.

Technological flow chart for the production of thick and dry extracts. Quality control. Packaging, labeling, storage of thick and dry extracts. Preparation of regulatory documentation.

Specific technology for the production of thick and dry ivy extract.

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

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

Oily extracts and CO_2 extracts. Characteristics and methods of their production. Specific technology for the production of rosehip, milk thistle and sea buckthorn oil. Quality control features.

Extract concentrates, characteristics, classification. Features of the production technology of extract concentrates. Nomenclature of liquid and dry extract concentrates.

2.22. Medicinal products from fresh plant raw materials

Principles of extraction of biologically active substances from fresh plant raw materials. Juices (not concentrated, concentrated, dry), tinctures and extracts, features of their production. Process flow schemes. Specific technology for obtaining plantain juice. Nomenclature of juices: plantain, echinacea, artichoke, celandine, etc. Tinctures from fresh medicinal plant raw materials.

2.23. Industrial production of neogalenical preparations, medicinal products from animal raw materials and biogenic stimulants

Neogalenical preparations, characteristics, classification. Total neogalenical preparations. Methods of obtaining primary extracts in production, characteristics of extractants used. Methods of purifying extracts from ballast and associated substances: fractional precipitation, solvent change, liquid extraction, chromatography, etc. Technology features (plantaglucide, mucaltin). Quality control.

Individual substance preparations, characteristics. Classification and production technology of medicinal products from individual substances of medicinal plant raw materials (digoxin).

Medicinal products from animal raw materials, characteristics, classifications of medicinal products (by medical use, nature of active substances and methods of production). Features of using animal raw materials in the production of medicinal products. Technological flow chart for the production of medicinal products from dried and defatted animal organs for internal and injectable use.

Biogenic stimulants, characteristics, classification, properties and conditions of production. Biogenic stimulants of plant origin (aloe extract), animal origin (vitreous body, actovegin, alflutop, diavitol, apilac, propolis, viprosal) and mineral origin (bischofite). Production features.

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

Syrups, characteristics, classification: flavoring and medicinal (based on plant raw materials and synthetic substances). Excipients used in syrup production. Technological flow charts for syrup production at pharmaceutical enterprises (based on flavoring syrups and based on synthetic sweeteners).

Quality control. Packaging, labeling, storage of syrups. Preparation of regulatory documentation for syrup production. Nomenclature of syrups.

Essential oils, characteristics. Production of essential oils. Equipment used. Quality control. General tests for essential oils: relative density, refractive index, optical rotation, fatty oils and mineral oils in essential oils. Additional tests for essential oils: solidification point; acid value; peroxide value; foreign esters; evaporation residue; water; solubility in alcohol. Packaging, labeling, storage.

Aromatic waters, characteristics, classification. Technological flow chart for the production of aromatic waters. Equipment for obtaining distilled aromatic waters. Quality evaluation of aromatic waters. Packaging, labeling, storage of aromatic waters.

2.25. Industrial production of aerosols and sprays

Aerosols: characteristics and classification. Characteristics of the inhalation route of administration of medicinal products. Excipients used in aerosol production: propellants, solvents, solubilizers, surface-active substances, film-forming agents, etc. Characteristics of aerosol cans, valve and spray systems. Requirements for medicinal products under pressure: particle size, dose delivered per actuation of the metering valve, etc.

Technological flow chart for aerosol production. Methods of filling aerosol cans. Quality evaluation of aerosol packaging. Quality control of aerosols. Aerodynamic testing of aerosols: methods, equipment used and its operating principle. Preparation of regulatory documentation. Labeling, storage of aerosols. Nomenclature of aerosols.

Safety precautions during production, transportation and storage of aerosol packaging. Environmental problems of aerosol production.

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

Sprays: characteristics and classification. Excipients. Technological flow chart for spray production. Features of primary packaging and spray devices. Quality control of sprays. Preparation of regulatory documentation. Labeling, storage, nomenclature.

Medicated foams: characteristics and classifications (dispersological, by application). Excipients. Features of production technology and spray devices. Quality control. Preparation of regulatory documentation. Labeling, storage, nomenclature.

2.26. Prolonged-release and targeted-action medicinal products. Nanotechnologies in pharmaceutics

Prolonged-release and targeted-action medicinal products. Characteristics and classifications (by duration of action and nature of distribution of active substances in the human body).

Methods of prolonging the action of medicinal products: reducing the rate of excretion from the body, slowing down biotransformation, delaying and prolonging absorption. Immobilization of medicinal products on inorganic and organic carriers.

Methods of immobilization of medicinal products: physical (adsorption, incorporation into gels, microencapsulation), physicochemical (formation of inclusion compounds, solid dispersions) and chemical (covalent binding of the drug to a polymer carrier, cross-linking of drug molecules with a polymer using bifunctional reagents, etc.).

Nanoparticles as drug delivery vehicles. Targeted drug design. Delivery systems used in nanotechnology: nanocrystals, liposomes, polymeric nanoparticles, micelles, dendrimers, etc.

Liposomes, characteristics, classification. Unilamellar and multilamellar liposomes. Thermosensitive and pH-sensitive liposomes. Excipients for liposome preparation. Natural phospholipids. Methods of liposome preparation. Preparation of liposomes using ultrasound. Incorporation of drugs into liposomes. Targeted 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 should 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 «INDUSTRIAL TECHNOLOGY OF DRUGS» 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**				
1.1, 1.2	Principles of organization of medicinal product manufacturing. Terminology. Basic processes of industrial technology, their role in the production of medicinal products. General concepts of machines and apparatuses	1,5	-	-	1, 2, 11, 13-15			
1.3	Mechanical processes and equipment	1,5	-	-	13, 14, 15			
1.4	Hydromechanical processes and equipment	-	-	1,5	1-3, 5, 15			Test
1.5	Heat-exchanging processes and equipment	1,5	-	-	1-4, 15			
1.6	Mass transfer processes and equipment	-	-	1,5	1-4, 15			Test
1.7	Good Manufacturing Practice (GMP). Rules of the Republic of Belarus and the EAEU. Regulatory documentation for manufacturing	-	-	1,5	1-4, 15			Test
1.8	Air and water preparation systems at pharmaceutical enterprises	1,5	-	-	1-4, 15			
2.1	Technology for industrial production of solid dosage forms. Production of powders and herbal mixtures. Study of pharmaceutical-technological properties of powders	1,5	-	-	1, 2, 11, 15			
2.2	Industrial production of granules. Study of pharmaceutical-technological properties of granules	1,5	-	1,5	1, 2, 12, 15			Test
2.3	Tablets. Methods of production. Theoretical basis of tableting. Excipients used in tablet production	1,5	-		1-3, 15			

2.4	Technological schemes for tablet production. Characteristics of tablet presses	-	-	1,5	1-3, 15			Test
2.5	Quality evaluation of tablets	1,5	-	-	1-3, 15			
2.6	Coating of tablets. Modern types of tablets	1,5	-	-	1 ,15			
2.7	Industrial production of dragees	-	-	1,5	1-3, 15			Test
2.8, 2.9	Industrial production of hard gelatin capsules. Industrial production of soft gelatin capsules. Microencapsulation of medicinal products	1,5	-	-	1-5, 15			
2.10	Industrial production of semi-solid dosage forms. production of ointments, creams, gels, pastes	1,5	-	-	1-3, 5, 15			
2.11	Industrial production of suppositories, pessaries and medical pencils	1,5	-	-	1-3, 5, 15			
	Laboratory classes	-	**64**	-				
1.1, 1.2	Principles of organization of medicinal product manufacturing. Terminology. Basic processes of industrial technology, their role in the production of medicinal products. General concepts of machines and apparatuses	-	4	-	1, 2, 11, 13, 14, 15			Interview, situational tasks
1.3, 1.4	Mechanical processes and equipment. Hydromechanical processes and equipment	-	4	-	1-3, 5, 13-15			Interview
1.5	Heat-exchanging processes and equipment	-	4	-	1-4, 15			Interview
1.6	Mass transfer processes and equipment							
1.7	Good Manufacturing Practice (GMP) Rules of the Republic of Belarus and the EAEU	-	4	-	1-4, 15	Organization of pharmaceutical manufacturing according to GMP requirements, virtual factory VR	Report on laboratory work	Interview, situational tasks
1.7	Regulatory documentation for manufacturing	-	4	-	1-4, 15	Organization of pharmaceutical manufacturing according to GMP requirements, virtual factory VR	Report on laboratory work	Interview, account of practical exercise
1.8	Air and water preparation systems at pharmaceutical enterprises	-	4	-	1-4, 15	Organization of pharmaceutical manufacturing according	Report on laboratory work	Interview, account of practical exercise

						to GMP requirements, virtual factory VR		
1.8	Final lesson on section «Principles of organization of medicinal product manufacturing»	-	4	-	1-4,11,13-15			Control work, situational tasks, test*
2.1	Technology for industrial production of solid dosage forms. Production of powders and herbal mixtures. Study of pharmaceutical-technological properties of powders	-	4	-	1, 2, 10, 15	Conducting pharmaceutical-technological tests of powders, preparation of regulatory documentation	Report on laboratory work	Interview, account of practical exercise
2.2	Industrial production of granules. Study of pharmaceutical-technological properties of granules	-	4	-	1, 2, 11, 15	Manufacturing of granules and conducting their pharmaceutical-technological tests, preparation of regulatory documentation	Report on laboratory work	Interview, account of practical exercise
2.3	Tablets. Methods of production. Theoretical basis of tableting. Excipients used in tablet production	-	4	-	1, 2, 12, 15	Analysis of tablet composition to determine the purpose of excipients, control of their content limits and selection of manufacturing technology	Report on laboratory work	Interview, test
2.4	Technological schemes for tablet production. Characteristics of tablet presses	-	4	-	1-3, 7, 15	Preparation of technological flow charts, organization of tablet production according to GMP requirements, equipment selection	Report on laboratory work	Interview, account of practical exercise
2.5	Quality evaluation of tablets	-	4	-	1-3, 7, 15	Conducting pharmaceutical-technological tests of tablets, preparation of regulatory documentation for tablets	Report on laboratory work	Interview, account of practical exercise, situational tasks
2.6, 2.7	Coating of tablets. Modern types of tablets. Industrial production of dragees	-	4	-	1-3, 7, 8 15	Analysis of tablet coating compositions	Report on laboratory work	Interview, situational tasks

2.8	Industrial production of hard gelatin capsules	-	4	-	1-8, 10-12, 15	Manufacturing of hard gelatin capsules and their quality control, preparation of regulatory documentation	Report on laboratory work	Interview, report on laboratory work with oral defense
2.9	Industrial production of soft gelatin capsules. Microencapsulation of medicinal products	-	4	-	1-8, 10-12, 15	Manufacturing of microcapsules, preparation of regulatory documentation	Report on laboratory work	Interview, report on laboratory work with oral defense
2.9	Final lesson on section «Industrial technology of solid drug forms». Practical skills	-	4	-	1-8, 10-14, 15			Control work, situational tasks, test* Credit
	8 semester							
	Lectures	**15**	**-**	**6**				
2.12	Industrial production of patches and mustard plasters	1,5	-	-	1, 3, 15			
2.13	Industrial production of liquid dosage forms for internal and external use	1,5	-	-	1, 5, 15			
2.14	Dilution and concentration of solutions in their industrial production	-	-	1,5	1, 2, 6, 15			Test
2.15	Industrial production of emulsions and suspensions. Drops. Medicated shampoos	1,5	-	-	1, 2, 6, 15			
2.16	Characteristics of parenteral dosage forms. sterilization. depyrogenation. Primary packaging – production and preparation	1,5	-	-	2, 5, 15			
2.17	Technology for production of parenteral dosage forms	1,5	-	-	2, 5, 15			
2.18	Industrial production of ophthalmic dosage forms	1,5	-	-	2, 3, 15			
2.19	Industrial production of medicinal products from natural raw materials. Basic principles of extraction. Characteristics of galenical preparations	1,5	-	-	2, 3, 15			
2.20, 2.21	Industrial production of tinctures. Industrial production of extracts	1,5	-	-	2, 3, 15			

2.22	Medicinal products from fresh plant raw materials	-	-	1,5	2, 3, 15			Test
2.23	Industrial production of neogalenical preparations, medicinal products from animal raw materials and biogenic stimulants	-	-	1,5	2, 3, 15			Test
2.24	Industrial production of syrups, essential oils, aromatic waters	-	-	1,5	1-4, 15			Test
2.25	Industrial production of aerosols and sprays	1,5	-	-	9, 15			
2.26	Prolonged-release and targeted-action medicinal products. nanotechnologies in pharmaceutics	1,5	-	-	1			
	Laboratory classes	-	**64**	-				
2.10	Industrial production of semi-solid dosage forms. production of ointments, creams, gels, pastes	-	4	-	1-4, 15	Manufacturing of a semi-solid dosage form and conducting its quality control	Report on laboratory work	Interview, account of practical exercise
2.11, 2.12	Industrial production of suppositories, pessaries and medical pencils. Industrial production of patches and mustard plasters	-	4	-	1-3, 5, 15	Manufacturing of suppositories and patches, evaluation of their quality	Report on laboratory work	Interview, account of practical exercise
2.13, 2.14	Industrial production of liquid dosage forms for internal and external use. Dilution and concentration of solutions in their industrial production	-	4	-	1, 2, 6, 15	Dilution and concentration of solutions to a given concentration	Report on laboratory work	Interview, account of practical exercise, situational tasks
2.15	Industrial production of emulsions and suspensions. Drops. Medicated shampoos	-	4	-	2, 5, 15	Manufacturing of emulsions and suspensions, evaluation of their quality	Report on laboratory work	Interview, report on laboratory work with oral defense
2.16	Characteristics of parenteral dosage forms. sterilization. depyrogenation. Primary packaging – production and preparation	-	4	-	2, 5, 15			Interview, test
2.17	Technology for production of parenteral dosage forms	-	4	-	1-6, 15	Determination of extractable volume of parenteral medicinal products	Report on laboratory work	Interview, situational tasks
2.18	Industrial production of ophthalmic dosage forms	-	4	-	2, 3, 15			Interview, situational tasks

2.18	Final lesson on sections «Industrial production of semi-solid dosage forms», «Industrial production of liquid dosage forms», «Industrial production of sterile dosage forms»	-	4	-	1-6,15			Control work, situational tasks, test*
2.19	Industrial production of medicinal products from natural raw materials. Basic principles of extraction. Characteristics of galenical preparations	-	4	-	2, 3, 15			Interview, situational tasks
2.20	Industrial production of tinctures	-	4	-	2, 3, 15	Manufacturing of tinctures and conducting quality control	Report on laboratory work	Interview, account of practical exercise, situational tasks
2.21	Industrial production of extracts	-	4	-	2, 3, 15	Alcohol recovery (alcohol recuperation)	Report on laboratory work	Interview, report on laboratory work with oral defense
2.22 2.23	Medicinal products from fresh plant raw materials. Industrial production of neogalenical preparations, medicinal products from animal raw materials and biogenic stimulants	-	4	-	1-4, 9, 15			Interview, situational tasks
2.24	Industrial production of syrups, essential oils, aromatic waters	-	4	-	2, 3, 15	Manufacturing of syrups and conducting quality control	Report on laboratory work	Interview, situational tasks
2.25	Industrial production of aerosols and sprays	-	4	-	1, 2			Interview, report on laboratory work with oral defense
2.25	Final lesson on sections «Industrial production of medicines from herbal raw materials», «Industrial production of aerosols and sprays»	-	4	-	1-4, 9, 15			Control work, situational tasks, test*
2.26	Prolonged-release and targeted-action medicinal products. nanotechnologies in pharmaceutics	-	4	-	1-4			Interview, report on laboratory work with oral defense
	Total hours	**33**	**128**	**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 / edited by R. I. Mahato, A. S. Narang, V. Kumar. – 4th ed. – Boca Raton : CRC Press, 2024. – 568 p.

Additional:

2. Allen, L. V., Jr. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems / L. V. Allen, Jr., T. B. McPherson. – 12th ed. – Philadelphia : Wolters Kluwer, 2023. – 656 p.

3. Aulton's Pharmaceutics. The Design and Manufacture of Medicines / ed. by Kevin M. G. Taylor, Michael E. Aulton. – 6th ed. – London : Elsevier, 2021. – 968 p.

4. Basics of Pharmaceutical Manufacturing and Quality Operations. A Comprehensive Guide / Erfan Syed Asif, Shahid Bader Usmani. – 1st ed. – Boca Raton : CRC Press, 2024. – 254 p.

5. Niazi, S. K. Handbook of Pharmaceutical Manufacturing Formulations : Third Edition. Volume 1. Compressed Solid Products / S. K. Niazi. – 3rd ed. – Boca Raton : CRC Press, 2024. – 646 p.

6. Lachman & Lieberman's Theory and Practice of Industrial Pharmacy / edited by Roop K. Khar, S. P. Vyas [et al.]. – 4th ed. – New Delhi : CBS Publishers & Distributors, 2017. – 1203 p.

7. Pharmaceutical Dosage Forms : Tablets / edited by Larry L. Augsburger, Stephen W. Hoag. – 3rd ed. – New Delhi : Taylor & Francis, 2024. – 570 p.

8. Pharmaceutical Dosage Forms : Capsules / edited by L. L. Augsburger, S. W. Hoag. – 1st ed. – Boca Raton : CRC Press, 2017. – 421 p.

9. Novel Drug Delivery System (NDDS) / P. K. Singh, R. Bhasin, A. Kumar, N. Rajan. – 1st ed. – New Delhi : IP Innovative Publication, 2024. – 372 p.

Normative regulatory acts:

10. European Pharmacopoeia. – 11th ed. – Strasbourg : European Directorate for the Quality of Medicines & HealthCare (EDQM) ; Council of Europe, 2022. – 3 vol.

11. Pharmacopoeia of the Eurasian Economic Union : Volume 1, part 1 / Eurasian Economic Commission. – Moscow : EEC, 2020. – 584 p.

12. Pharmacopoeia of the Eurasian Economic Union : Volume 1, part 2 / Eurasian Economic Commission. – Moscow : EEC, 2023. – 716 p.

13. EudraLex – Volume 4 : Good Manufacturing Practice (GMP) guidelines : Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use / European Commission. – Luxembourg : Publications Office of the European Union, 2018.

14. WHO Good Manufacturing Practices: main principles for pharmaceutical products. – Geneva : World Health Organization, 2016.

Electronic courseware for the academic 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 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:
test.

LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competence assessment:
defense of the abstract (report);
interview;
situational tasks;
test;
control work;
account of practical exercise;
report on laboratory work with oral defense.

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. Organization of pharmaceutical manufacturing according to GMP requirements, virtual factory VR	Report on laboratory work
2. Conducting pharmaceutical-technological tests of powders, preparation of regulatory documentation	Report on laboratory work
3. Manufacturing of granules and conducting their pharmaceutical-technological tests, preparation of regulatory documentation	Report on laboratory work
4. Analysis of tablet composition to determine the purpose of excipients, control of their content limits and selection of manufacturing technology	Report on laboratory work
5. Preparation of technological flow charts, organization of tablet production according to GMP requirements, equipment selection	Report on laboratory work
6. Conducting pharmaceutical-technological tests of tablets, preparation of regulatory documentation for tablets	Report on laboratory work
7. Analysis of tablet coating compositions	Report on laboratory work
8. Manufacturing of hard gelatin capsules and their quality control, preparation of regulatory documentation	Report on laboratory work
9. Manufacturing of microcapsules, preparation of regulatory documentation	Report on laboratory work
10. Manufacturing of suppositories and patches, evaluation of their quality	Report on laboratory work
11. Manufacturing of emulsions and suspensions, evaluation of their quality	Report on laboratory work
12. Dilution and concentration of solutions to a given concentration	Report on laboratory work
13. Determination of extractable volume of parenteral medicinal products	Report on laboratory work
14. Manufacturing of tinctures and conducting quality control	Report on laboratory work
15. Alcohol recovery (alcohol recuperation)	Report on laboratory work
16. Manufacturing of syrups and conducting quality control	Report on laboratory work
17. Manufacturing of a semi-solid dosage form and conducting its quality control	Report on laboratory work

LIST OF SIMULATION EQUIPMENT USED

1. A virtual factory VR «Production of solid dosage forms».
2. Simulators for equipment in the E-Learning system.

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	Recommended for use. Protocol # 14 of 16.05.2025
2. Pharmaceutical Ecology	Pharmaceutical Chemistry with advanced training and retraining course	There are no offers	Recommended for use. 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	Recommended for use. 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	Recommended for use. Protocol # 14 of 16.05.2025

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

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