MINISTRY OF HEALTH OF UKRAINE

ODESSA NATIONAL MEDICAL UNIVERSITY

Department of Pharmaceutical Chemistry and Drug Technology

APPROVED

Vice-rector for scientific and pedagogical work

_____ Eduard BURYACHKIVSKY

September 1st, 2025

WORKING PROGRAM IN THE DISCIPLINE «DRUG TECHNOLOGY»

Level of higher education: second (master's degree)

Area of Knowledge: 22 «Health care»

Specialty: 226 «Pharmacy, industrial pharmacy»

Specialization: 226.01 «Pharmacy»

Educational and professional program: Pharmacy, industrial pharmacy

2025

The work program is based on the educational and professional program "Pharmacy, Industrial Pharmacy" for the training of specialists of the second (master's) level of higher education in the specialty 226 "Pharmacy, Industrial Pharmacy" of the field of knowledge 22 "Health Care", approved by the Academic Council of ONMedU (protocol No. 10 dated June 27, 2024).

Developers:
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The work program was approved at the meeting of the Department of Pharmaceutical Chemistry and Drug Technology
Protocol No. 1 dated 08/29/2025.

Head of Department _____ Volodymyr GELMBOLDT

Agreed with the EPP guarantor _____ Liana UNHURIAN

Approved by the subject cycle methodical commission for pharmaceutical disciplines of ONMedU
Protocol No. 1 dated 08/29/2025

Head of the subject cycle methodical commission for pharmaceutical disciplines of ONMedU

_____ Natalia FIZOR

Reviewed and approved at the department meeting _____
Protocol No ___ from "___" _____ 20__ .

Head of the department _____ Volodymyr GELMBOLDT

Reviewed and approved at the department meeting _____
Protocol no ___ from "___" _____ 20__ .

Head of the department _____ Volodymyr GELMBOLDT

1. DESCRIPTION OF THE ACADEMIC DISCIPLINE

<table>
<tr><th>Name of indicators</th><th>Field of knowledge, specialty, specialization, level of higher education</th><th>Characteristics of the academic discipline</th></tr>
<tr><td rowspan="8">Total number:

Credits: 12

Hours: 360

Content modules: 2</td><td rowspan="8">Area of Knowledge
22 "Healthcare"

Specialty
226 "Pharmacy, Industrial Pharmacy"

Specialization
226.01 "Pharmacy"

Level of higher education
second (master's)</td><td>Full-time education
Mandatory discipline</td></tr>
<tr><td>Year of preparation: 3-4</td></tr>
<tr><td>Semesters V - VIII</td></tr>
<tr><td>Lectures (80 год.)</td></tr>
<tr><td>Practical (160 год.)</td></tr>
<tr><td>Independent work (120 год.)</td></tr>
<tr><td>Final control form –
Differential credit 3 course
Exam 4 course</td></tr>
</table>

2. GOALS AND OBJECTIVES OF THE ACADEMIC DISCIPLINE, COMPETENCES, PROGRAM LEARNING OUTCOMES

Goal: In-depth mastery of fundamental knowledge in the field of drug technology, in the field of pharmaceutical and industrial drug technology, acquisition and improvement of practical skills, abilities and competencies acquired while studying previous disciplines at the university, which will be widely used in practical work.

Task: mastering the requirements of current regulatory documents (SPhU, GPP and current orders) for the organization of production activities of pharmacies for the manufacture of medicines in various dosage forms; familiarization with the organization of production of medicines in pharmaceutical enterprises, in accordance with the requirements of Good Manufacturing Practice (GMP); use in professional activities of regulatory and legislative acts of Ukraine, the requirements of Good Pharmaceutical Practice (GPP) and Good Manufacturing Practice (GMP) for the manufacture of medicines in pharmacies and industrial enterprises; formation of knowledge among higher education applicants on: theoretical foundations of the technology for the manufacture of various types of dosage forms, conducting staged control, ways to improve the technology of dosage forms in pharmacy and industrial conditions; studying the influence of storage conditions and type of packaging on the stability of dosage forms; studying industrial equipment, including new ones, devices and automatic lines, modern requirements for the production of dosage forms, including the requirements of the World Health Organization (WHO) for the purity of starting materials, production facilities and personnel.

The process of studying the discipline is aimed at forming elements of the following competencies:

General (GC):

GC 1 – The ability to think abstractly, analyze and synthesize, learn and be up-to-date.
GC 2 – Knowledge and understanding of the subject area and understanding of professional activity.
GC 5 – Ability to evaluate and ensure the quality of work performed.
GC 6 – Ability to work in a team.

GC 9 – Ability to use information and communication technologies

Specialists (SC):

SC 12 – Ability to ensure proper storage of medicinal products of natural and synthetic origin and other pharmacy products in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in healthcare facilities.

SC 16 – The ability to organize and carry out the production activities of pharmacies for the manufacture of medicines in various dosage forms according to doctors' prescriptions and the requirements of medical and preventive institutions, including the justification of technology and the selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).

SC 19 – Ability to organize and carry out quality control of medicinal products of natural and synthetic origin in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QC), technological instructions, etc.; prevent the distribution of low-quality, falsified and unregistered medicinal products.

SC 20 – Ability to develop and evaluate quality control methods for medicinal products of natural and synthetic origin, including active pharmaceutical ingredients, medicinal plant raw materials and excipients using physical, chemical, physicochemical, biological, microbiological, pharmaco-technological methods; standardize medicinal products in accordance with current requirements.

Programmatic learning results (PLO):

PLO 3 – Have specialized knowledge and skills to solve professional problems and tasks, including for the purpose of further developing knowledge and procedures in the field of pharmacy.

PLO 15 – Predict and determine the impact of environmental factors on the quality and consumer characteristics of medicinal products of natural and synthetic origin and other pharmacy products, organize their storage in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP).

PLO 19 – Develop technological documentation for the manufacture of medicines, choose rational technology, manufacture medicines in various dosage forms according to doctors' prescriptions and the requirements of medical and preventive institutions, and prepare them for release.

PLO 20 – To carry out pharmaceutical development of medicinal products of natural and synthetic origin in industrial production conditions.

PLO 23 – Determine the main chemical and pharmaceutical characteristics of medicinal products of natural and synthetic origin; select and/or develop quality control methods for their standardization using physical, chemical, physicochemical, biological, microbiological and pharmaco-technological methods in accordance with current requirements.

As a result of studying the academic discipline, a higher education applicant must:

Know:

- the main stages of manufacturing, quality control and storage of medicines;
- classification of dosage forms, their structure, advantages and disadvantages;
- requirements of the State Pharmacopoeia of Ukraine and other regulatory documents for the manufacture of medicines;
- physicochemical, biopharmaceutical and technological properties of medicinal substances and excipients;
- methods of ensuring the stability and bioavailability of medicines;
- basic principles of operation of a pharmaceutical enterprise and pharmacy production in accordance with GMP requirements;
- modern methods of quality control, packaging and labeling of medicines;
- rules of labor protection, sanitary regime and safety precautions in the manufacture of medicines;
- basics of pharmaceutical technology of sterile, non-sterile, soft, liquid, solid and combined dosage forms;

- principles of calculating dosages, scaling technological processes and developing recipes.

Be able to:

- carry out the technological process of manufacturing medicines in a pharmacy and pharmaceutical enterprise;
- select the optimal excipients taking into account the physicochemical properties of medicinal substances and dosage form;
- calculate the quantitative composition of the formulation, make adjustments to the mass or volume when manufacturing various dosage forms;
- draw up technological documentation in accordance with the requirements of good manufacturing practice (GMP);
- control the quality of medicines at all stages of the technological process in accordance with the requirements of the State Pharmacopoeia of Ukraine;
- carry out operations for the preparation, purification and control of auxiliary materials, purified water and water for injection;
- use modern equipment and apparatus for the manufacture, filling and packaging of medicines;
- comply with the rules of asepsis and antiseptics during the manufacture of sterile dosage forms;
- assess the stability of medicines, determine shelf life and storage conditions;
- use regulatory and technical documentation, technological regulations and pharmacopoeial articles;
- analyze and eliminate deviations in the technological process;
- comply with labor protection requirements, sanitary and hygienic standards and environmental safety rules.

3. CONTENT OF THE COURSE

Subsection 1. Pharmacy technology of drugs

***Topic 1*. State regulation of the production of medicines in pharmacies. General issues of drug technology.**

- Basic pharmaceutical and technological terms: pharmacology, pharmacy, drug technology, medicinal product, medicinal raw material, dosage form, medicinal substance, medicinal product, etc..
- Types of regulatory documents (pharmacopoeia, orders, instructions, etc.).
- Provisions of good pharmacy practice (GPP) and good manufacturing practice (GMP).
- Stability of extemporaneous medicinal products.
- Classifications of dosage forms.
- Prescription, its meaning. Prescription structure. Rules for prescribing prescriptions according to regulatory documents (orders of the Ministry of Health of Ukraine). Rights and obligations of a pharmacist in relation to incorrectly prescribed prescriptions according to the requirements of the order of the Ministry of Health of Ukraine.

***Topic 2.* Solid dosage forms. Production in pharmacies of simple and complex powders with medicinal substances that differ in prescribed quantity, bulk density and particle structure.**

- Manufacturing of solid medicinal products in pharmacies in accordance with the requirements of the National Pharmaceutical Administration, orders of the Ministry of Health of Ukraine and other regulatory documents.
- Characteristics of powders as a dosage form, their classification. SFU requirements for powders.
- Methods of prescribing powders.
- General rules and stages of the technological process of manufacturing solid medicinal forms in

pharmacies. Grinding; basic physicochemical laws that affect the process of grinding powder ingredients. The degree of grinding of medicinal substances depending on the medical purpose of the medicinal product.

- Factors that affect the order of mixing components in the manufacture of complex powders.
- Rules for manufacturing complex powders with medicinal substances prescribed in equal and different quantities.
- Rules for introducing medicinal substances with different physicochemical properties into the composition of powders.
- Technology of powders with ingredients that differ in density, bulk density, particle structure (amorphous, fine-crystalline, coarse-crystalline) in pharmacy conditions.
- Rules for selecting packaging material in accordance with the physicochemical properties of powder components. Deviations permissible in the mass of individual doses of powders.
- Assessment of the quality of powders in accordance with the requirements of the SPhU and other regulatory documents. Packaging, registration before release, storage. Types of incompatibilities in powders.

Topic 3. **Manufacturing in pharmacies of complex powders with poisonous, narcotic and potent substances.**

- Rules for prescribing poisonous, narcotic and potent medicinal substances, the procedure for storage, dispensing and use in accordance with the requirements of the orders of the Ministry of Health of Ukraine.
- Verification of single and daily doses of poisonous and potent medicinal substances in powders.
- Narcotic and psychotropic substances used in powder technology and the norms of their single dispensing.
- Features of the manufacture of complex powders with poisonous, narcotic and potent medicinal substances prescribed in small (less than 0.05) quantities. Intra-pharmacy preparations (triturations).
- Characteristics, manufacture, storage, use for the manufacture of powders.
- Quality assessment, packaging, registration before dispensing, storage of powders in accordance with the requirements of the SPhU and other regulatory documents.

Topic 4. **Production of complex powders with colored, odorous and difficult-to-grind substances. Production of complex powders with extracts and semi-finished products.**

- List of coloring and odorous substances and their storage conditions according to the requirements of the order of the Ministry of Health of Ukraine.
- Features of the technology of powders with coloring substances.
- Rules for introducing odorous substances (menthol, thymol, camphor) into powders.
- Features of packaging powders with volatile substances.
- Substances that grind in the presence of an auxiliary liquid; reasons for using auxiliary liquids to improve their dispersion.
- Quality assessment, packaging, registration for release, storage of powders with coloring, odorous substances according to the requirements of the SPhU and other regulatory documents (orders of the Ministry of Health of Ukraine).
- Characteristics of extracts used in powders, their classification according to the SPhU.
- Production of solutions of thick extracts, conditions and shelf life.
- Features of the technology of complex powders with dry, thick and solutions of thick extracts.
- Use of semi-finished products for the production of complex powders, their advantages.
- Introduction of small mechanization tools in the process of manufacturing powders in pharmacies, mechanization of the processes of mixing and dosing powders in industrial conditions.

- Main signs of instability of solid dosage forms.

Topic 5. **Preparation of specieses in a pharmacy.**

- Specieses: characteristics, classification and methods of prescribing them.
- Stages of the technological process Production of specieses in pharmacies.
- Rules for introducing different groups of medicinal substances into the composition of specieses (water-soluble, water-insoluble, essential oils, substances soluble in ethanol).
- Technology of dosed specieses.
- Equipment used in the production of specieses in pharmacies.
- Quality assessment, packaging, registration before release, storage of specieses in accordance with the requirements of the State Pharmacopoeia and other regulatory documents (orders of the Ministry of Health of Ukraine).
- Medicinal herbal teas: definition, characteristics, application.
- Briquettes: definition, characteristics.

Topic 6. **Liquid dosage forms. Preparation of concentrated solutions.**

- Characteristics of solutions as dispersed systems, their classification.
- Obtaining purified water in a pharmacy.
- Requirements for purified water in accordance with the standards established by the State Pharmacopoeia, instructions to the orders of the Ministry of Health of Ukraine.
- Calculations of the amount of medicinal substances and water for the manufacture of concentrated solutions in various ways: using measuring vessels; taking into account the coefficient of volume increase; taking into account the density of the solution.
- Rules for the manufacture of concentrated solutions for the burette system according to the instructions to the order of the Ministry of Health of Ukraine.
- Quality control of concentrated solutions, their storage conditions and keeping records of prepared solutions according to the orders of the Ministry of Health of Ukraine.
- Dosage by volume. Factors affecting the accuracy of dosing.
- Structure of the burette system, rules for its care and use.
- Types of incompatibilities in liquid dosage forms.

Topic 7. **Production of liquid dosage forms by the mass-volume method by dissolving dry medicinal substances and using concentrated solutions.**

- Characteristics of liquid dosage forms as dispersed systems, their classification, requirements for them.
- Methods of prescribing and designating solution concentrations.
- Checking doses of poisonous and potent substances in mixtures.
- Rules for the manufacture of liquid medicinal products using concentrated solutions in accordance with the instructions for the preparation of liquid medicinal forms in pharmacies, approved by the order of the Ministry of Health of Ukraine.
- Manufacture of solutions containing up to 3% and more than 3% of dry medicinal substances, concentrated solutions of which are absent.
- Adding syrups, aromatic waters, galenic and novogalenic medicinal products, etc. to solutions.
- Assessment of the quality and storage of liquid medicinal products in accordance with the requirements of regulatory documents, sealing and registration before release (orders of the Ministry of Health of Ukraine).

Topic 8. **Special cases of making aqueous solutions. Drops.**

- Types of difficult cases of preparation of aqueous solutions, which are most often found in pharmacies: slow and difficult dissolution or insolubility of medicinal substances in the prescribed solvent; decomposition of substances that are easily oxidized; deterioration of solubility in the

presence of each other.

- Technological techniques that allow overcoming difficulties in the preparation of solutions: preliminary grinding of substances and use of a heated solvent; use of freshly distilled purified water and appropriate auxiliary materials; addition of auxiliary substances and use of complexation in the preparation of solutions; separate dissolution.
- Characteristics of drops as a dosage form, their classification by method of application.
- Checking the doses of poisonous and potent substances in drops.
- Rules for the preparation of drops using concentrated solutions and by dissolving dry substances.
- Technology of drops on non-aqueous solvents.
- Formation of eutectic mixtures.
- Assessment of the quality and storage of aqueous solutions and drops, sealing, registration before release in accordance with the requirements of regulatory documents (orders of the Ministry of Health of Ukraine).

Topic 9. **Preparation of liquid dosage forms by diluting standard pharmacopoeial liquids. Non-aqueous solutions.**

- Nomenclature of standard pharmacopoeial liquids; their concentrations, chemical and conventional names.
- Rules for calculating the amount of water and pharmacopoeial liquids depending on the method of prescription in accordance with the instructions to the order of the Ministry of Health of Ukraine.
- Preparation of solutions of pharmacopoeial liquids.
- Characteristics of non-aqueous solvents (ethyl alcohol, vegetable oils, vaseline oil, glycerin, chloroform, esilones, dimexide, polyethylene oxide-400), requirements for them.
- Calculations for the dilution of ethyl alcohol using the dilution formula and alcoholometric tables.
- Preparation of solutions in volatile and non-volatile solvents.
- Safety rules when working with flammable and explosive solvents.
- Assessment of the quality and storage of solutions in accordance with the requirements of regulatory documents, sealing and registration before release (orders of the Ministry of Health of Ukraine).

Topic 10. **HMC solutions. Colloidal solutions.**

- Characteristics of HMC, their classification and application in pharmacy.
- Influence of HMC structure on the dissolution process of limited and unlimited swelling substances.
- Features of manufacturing solutions of pepsin, gelatin, starch, methylcellulose, sodium carboxymethylcellulose, plant extracts.
- Characteristics and properties of colloidal solutions.
- Technology of solutions of protected colloids (collargol, protargol, ichthyol).
- Rules for adding medicinal substances to HMC solutions and protected colloids.
- Assessment of the quality and storage of HMC solutions and colloids, registration before release in accordance with the requirements of the orders of the Ministry of Health of Ukraine.

Topic 11. **Suspensions.**

- Characteristics of suspensions as a dosage form and a dispersed system; requirements for them.
- Factors affecting the stability of heterogeneous systems.
- Dispersion method of manufacturing suspensions with hydrophilic medicinal substances. Characteristics of stabilizers and the mechanism of their action.
- Features of the technology of suspensions of hydrophobic substances. Condensation method of manufacturing suspensions (chemical dispersion, solvent replacement).

- Opalescent and cloudy mixtures.
- Use of small-scale mechanization in the manufacture of suspensions in pharmacies.
- Assessment of the quality of suspensions, rules for sealing, design and storage in accordance with the requirements of the regulatory documents.

***Topic 12*. Emulsions.**

- Characteristics of emulsions as a dosage form and a dispersed system, their classification. Requirements of the State Pharmacopoeia for oil emulsions.
- Types of oil emulsions and methods for their determination.
- Characteristics of emulsifiers, their classification and mechanism of action.
- General rules and methods for the manufacture of oil emulsions.
- Stages of the technological process for the manufacture of emulsions.
- Introduction of medicinal substances with different physicochemical properties into the composition of oil emulsions.
- Features of the introduction of phenylsalicylate and sulfonamides.
- Assessment of the quality and storage of emulsions, capping, registration before release in accordance with the requirements of the SPhU and regulatory documents (orders of the Ministry of Health of Ukraine).
- Small-scale mechanization equipment for the production of emulsions in pharmacies.

***Topic 13*. Infusions and decoctions from medicinal plant raw materials.**

- Characteristics of infusions and decoctions as a dosage form and a dispersed system.
- Methods of prescribing infusions and decoctions.
- Theoretical foundations of the extraction process from herbal medicinal raw materials.
- Factors affecting the extraction process (ratio between the amount of raw material and extractant, standardization, histological structure and degree of grinding of raw materials, infuser material, temperature, duration of infusion and cooling, pH of the medium, chemical composition, etc.).
- Rules for the manufacture of infusions and decoctions from herbal raw materials and the addition of medicinal substances to them in accordance with the requirements of the State Drug Control Service.
- Equipment used in the technology of infusions and decoctions.
- Features of the production of aqueous extracts from herbal medicinal raw materials containing alkaloids, cardioglycosides, essential oils, tannins, anthracene derivatives, saponins, etc.
- Special cases of the production of infusions and decoctions (“double” infusions, decoctions from senna leaves, etc.).
- Author's recipes for aqueous extracts (Deryagin's, Kvater's, Ravkin's mixture, etc.).
- Quality assessment, storage of aqueous extracts, capping and their registration before release in accordance with the requirements of the State Pharmacopoeia and other regulatory documents (orders of the Ministry of Health of Ukraine).
- Types of incompatibilities in aqueous extracts.

***Topic 14.* Mucus. PMF technology using extract concentrates.**

- Characteristics of standardized extract concentrates for the manufacture of infusions and decoctions, their nomenclature.
- Advantages of their use in the technology of water extracts.
- Rules for the manufacture of water extracts using extract concentrates and the introduction of various medicinal agents into them.
- Features of the manufacture of extracts from raw materials containing mucus (marshmallow root, flax seeds, etc.) and the addition of various medicinal substances to them.
- Assessment of the quality and storage of water extracts in accordance with the requirements of

regulatory documents, sealing and registration before release (orders of the Ministry of Health of Ukraine).

- Improvement of the technology of water extracts.

Topic 15. **Soft dosage forms. Liniments and homogeneous ointments.**

- Characteristics of liniments as a dosage form and dispersed systems; their classification depending on the nature of the dispersion medium, physicochemical properties of the ingredients and medical purpose.
- Rules for the manufacture of liniments of various types of dispersed systems: solutions, suspensions, emulsions, combined.
- Pharmacopoeial regulations and difficult cases of the manufacture of liniments, their technology.
- Characteristics of ointments as a dosage form and dispersed systems, their classification (by medical purpose, place of application, consistency and physicochemical properties of medicinal substances included in the ointments), the requirements of the State Pharmacopoeia for them.
- Requirements for ointment bases, their classification.
- List of ointment bases recommended by the State Federal University of Health Sciences, principles of their selection.
- Characteristics of hydrophobic and hydrophilic bases.
- Main technological stages and rules for the manufacture of homogeneous ointments such as solutions, alloys.
- Pharmacopoeial prescriptions of ointment solutions.
- Assessment of the quality and storage of liniments and ointments in accordance with the requirements of regulatory documents, packaging and registration before release (orders of the Ministry of Health).

Topic 16. **Heterogeneous ointments.**

- Characteristics of diphilic (hydrophilic-lipophilic) ointment bases and emulsifiers for their production.
- Characteristics of suspension ointments and their technology.
- Official prescriptions of suspension ointments.
- Features of the introduction of resorcinol and zinc sulfate into dermatological ointments.
- Pastes, their classification.
- Features of the production of dermatological pastes.
- Characteristics of emulsion ointments of different types and their production depending on the properties of medicinal and auxiliary substances.
- Rules for the introduction of protargol, tannin and plant extracts of different consistencies into ointments.
- Assessment of the quality of two-phase ointments, storage and registration before release in accordance with the requirements of the State Pharmacopoeia, other regulatory documents (orders of the Ministry of Health of Ukraine).

Topic 17. **Combined ointments. Creams. Gels.**

- Characteristics of combined ointments and general rules for their manufacture.
- Stages of the technological process for the manufacture of multiphase ointments, taking into account the physicochemical properties of medicinal substances.
- Biopharmaceutical aspects of ointments.
- The principle of selecting bases taking into account the medical purpose of ointments.
- Basic rheological characteristics as indicators of the quality of ointments.
- Methods of quality control of combined ointments, their storage and registration before release according to the requirements of the State Pharmacopoeia, other regulatory documents (orders of

the Ministry of Health of Ukraine).
- Directions for improving extemporaneous ointments and liniments.
- Characteristics of gels and creams.
- Modern bases for their manufacture.
- Technology of creams and gels in pharmacies.
- Types of incompatibilities in soft dosage forms.

***Topic 18*. Suppositories. Suppository production by pumping. Sticks. Pills.**

- Characteristics of suppositories as a dosage form and as dispersed systems.
- Classification of suppositories.
- Requirements of the State Pharmacopoeia for them.
- Methods of prescribing suppositories; checking doses of poisonous and potent medicinal substances in them.
- Pharmacopoeial prescriptions and difficult cases of manufacturing liniments, their technology.
- Bases for suppositories; requirements for them, and a brief description.
- Features of prescribing sticks and calculating the base for them.
- Characteristics of technological stages of manufacturing suppositories by the rolling method.
- Rules for introducing medicinal substances with different physicochemical properties into bases; features of introducing protargol, collargol, tannin, dry and thick extracts.
- Methods for assessing the quality of suppositories, packaging, preparation for release, storage rules in accordance with the requirements of regulatory documents, relevant instructions (orders of the Ministry of Health of Ukraine).
- Characteristics of pills as a dosage form. Definition. Characteristics. Requirements for them.
- Excipients used in pill technology, their characteristics (thick and dry extracts, powders, starch-sugar mixture, bentonites, etc.).
- The principle of their selection depending on the chemical nature of medicinal substances.
- Stages of pill manufacturing.
- Determination of incompatibilities in pills.
- Assessment of pill quality: uniformity, disintegration, deviation from the average mass, etc.
- Packaging, storage conditions.
- Cases of incompatibilities in pills.

***Topic 19*. Suppository production by pouring method.**

- Composition and properties of official suppository bases used in the pouring method.
- Calculations of the amount of suppository bases for the manufacture of candles, balls and sticks by the pouring method.
- The concept of substitution coefficients.
- Bases for suppositories; requirements for them and a brief description.
- Characteristics of the technological stages of the manufacture of suppositories by the pouring method.
- Rules for introducing medicinal substances with different physicochemical properties into the bases when using the pouring method.
- Comparative assessment of suppository manufacturing methods (rolling, pouring, pressing).
- Biopharmaceutical aspects of suppositories, principles of selection of excipients for their manufacture.
- Assessment of the quality of suppositories, packaging, preparation for release, storage conditions according to the requirements of regulatory documents (orders of the Ministry of Health of Ukraine).

***Topic 20.* Requirements for the manufacture of sterile and aseptic medicinal products in**

pharmacies.

- Requirements of good pharmacy practice for the manufacture of sterile and aseptic dosage forms in pharmacies.
- Aseptic conditions for the manufacture of medicinal products.
- Procedure for monitoring compliance with the sanitary and anti-epidemic regime in pharmacies.
- Requirements for premises, equipment and sanitary and hygienic requirements for the manufacture of medicinal products in aseptic conditions.
- Requirements for personal hygiene of pharmacy personnel engaged in the manufacture of medicinal products in aseptic conditions.
- Characteristics of solvents used for the manufacture of injectable medicinal forms.
- Obtaining, storing and quality control of water for injection.
- Requirements for medicinal products and excipients used for the manufacture of medicinal products in aseptic conditions.
- Non-aqueous solvents. Fatty oils, requirements for them and preparation for use.
- Requirements for packaging and sealing materials used for the manufacture of medicines in aseptic conditions. Classification of sterilization methods.
- Thermal sterilization methods and equipment used for this.
- Procedure for controlling the temperature regimes of sterilizers.
- Sterilization regimes of individual objects and the procedure for registering sterilization results in the relevant journals.
- Requirements for quality control of sterile and aseptic dosage forms.
- Types of documentation maintained during the preparation of individual and serially manufactured medicines (general technological instructions, technological instructions for individual and serially manufactured medicines, production records).
- GMP requirements for the production of sterile products (preparation of the air environment, personnel, clothing, equipment, premises).

Topic 21. **Injection solutions.**

- Characteristics of injectable dosage forms; requirements imposed on them by the State Pharmacopoeia and their implementation.
- Aseptic conditions for the manufacture of medicinal products.
- Characteristics of solvents used for the manufacture of injectable dosage forms.
- Obtaining, storing and quality control of water for injection according to the requirements of the State Pharmacopoeia of Ukraine.
- Requirements for medicinal products and packaging and sealing materials used for the manufacture of injectable drugs.
- Technological stages of the manufacture of solutions for injections.
- Filtration of solutions and their testing for the absence of mechanical impurities.
- Sterilization methods and equipment used for this.
- Assessment of the quality of solutions for injections, sealing, preparation for release and storage in accordance with the requirements of the State Pharmacopoeia and relevant instructions (orders of the Ministry of Health of Ukraine).

Topic 22. **Injection solutions requiring stabilization.**

- Reasons that cause the destruction (decomposition) of medicinal substances in solutions for injections.
- Characteristics of stabilizers used for the manufacture of injection solutions; their classification.
- Principles of selection of stabilizers and calculation of their quantity.
- Stabilization of solutions of medicinal substances that are susceptible to hydrolysis and

saponification. Antioxidants, their classification.
- Stabilization of solutions of substances that are easily oxidized.
- Features of the manufacture of injection solutions of glucose and sodium bicarbonate.
- Assessment of the quality of injection solutions, their closure, registration before release and storage (orders of the Ministry of Health of Ukraine).

Topic 23. **Isotonic and infusion solutions. Injection solutions with thermolabile substances. Suspensions for injections.**
- The value of isotonization of solutions for injections.
- Methods for calculating isotonic concentrations using equivalents of sodium chloride, Raoult's laws (cryoscopic method), Van't Hoff's and the Mendeleev-Clapeyron equation.
- Principles of selection of isotonizing substances and general technological techniques Production of isotonic solutions. Infusion (physiological) solutions; requirements of the State Pharmacopoeia and other regulatory documents for them.
- Classification of infusion solutions according to their medical purpose and composition.
- Nomenclature of the most frequently used plasma-replacing and anti-shock solutions in the form of ready-made dosage forms.
- Features of the technology of infusion solutions depending on the composition of active substances.
- Rules for the manufacture of solutions for injections with thermolabile substances and suspensions for injections.
- Assessment of the quality of solutions, sealing, their registration for release and storage (orders of the Ministry of Health of Ukraine).
- Requirements for isotonicity, isohydricity, isoionicity, redox potential of solutions.
- Powders and tablets for sterile solutions, features of their technology, lyophilization.

Topic 24. **Ophthalmic dosage forms.**
- Characteristics of dosage forms used for the treatment of eye diseases (drops, lotions, rinses, ointments, suspensions, powders); requirements for them in accordance with the State Pharmacopoeia.
- Isotonization of eye drops, lotions, rinses.
- Prolongation of the action of eye drops.
- Features of the technology of eye drops depending on the physicochemical properties of medicinal substances.
- Rules for the manufacture of lotions and rinses.
- Modern types of ophthalmic dosage forms. Requirements of the State Federal University of Health Sciences and current orders for them.
- Ophthalmic medicinal inserts, characteristics, nomenclature, requirements for them.
- Characteristics of the bases used for the manufacture of eye ointments.
- Technology of eye ointments, features of the introduction of zinc sulfate and resorcinol into the composition of eye ointments.

Topic 25. **Dosage forms with antibiotics.**
- Characteristics of dosage forms with antibiotics; requirements for them and factors affecting their stability.
- Features of the technology of liquid and solid dosage forms with antibiotics (lotions, washes, rinses, eye and ear drops, powders, etc.).
- Technology of ointments and suppositories with antibiotics; characteristics of bases for their manufacture.
- Quality assessment of ophthalmic dosage forms and dosage forms with antibiotics, sealing,

preparation for release and storage.
- Characteristics of bases and solvents for dosage forms with antibiotics.
- Thermolabile and thermostable antibiotics.

Topic 26. **Pediatric and geriatric dosage forms.**
- Dosage forms for infants and children under 1 year.
- Characteristics of pediatric dosage forms. Requirements for them.
- Conditions for the manufacture of dosage forms for infants and children under 1 year in pharmacies.
- Features of drugs for the treatment of the elderly.
- Dosage forms that have advantages in geriatrics.

Subsection 2. Industrial technology of drugs.

Topic 27. **Regulatory documentation in the production of finished medicines.**
- The main activities of the Ministry of Health of Ukraine and the State Pharmacological Center. Regulatory documents in Ukraine.
- Basic principles of the registration system. Registration dossier.
- Production protocols, validation forms and cards. Categories of regulatory documentation in the industrial production of medicinal products according to GMP rules.
- Basic terms used in the production of medicinal products.
- Purpose and meaning of the material balance; rules for its compilation at each stage of production; calculation of its main indicators.

Topic 28. **Requirements for sterile products. Determination of the main quality indicators of ampoule glass.**
- Requirements for sterile products.
- Glass for the manufacture of ampoules and vials, its classes and grades.
- Basic requirements and quality indicators of ampoule glass.
- Preparation of glass wire, methods of washing ampoules, research on the stability of ampoules.

Topic 29. **Industrial production of injection solutions.**
- Basic principles of good manufacturing practice for medicinal products (GMP), requirements for the production of sterile products.
- Classification of clean rooms, cleanliness classes.
- Water for injection, requirements, equipment, control.
- Production of injectable drugs without and with stabilizers, aseptically manufactured, on non-aqueous solvents, etc.
- Methods of stabilization, isotonization, purification of solutions, types of filters.
- Methods of filling ampoules, modern methods of sealing ampoules and determining their tightness.
- Sterilization of injectable solutions, control of their sterility.
- Quality control of injectable solutions.
- Technological scheme of production; equipment used.

Topic 30. **Industrial production of infusion solutions.**
- Characteristics of infusion solutions, use. Classification and requirements for infusion solutions.
- Prospects for the development of infusion solutions, assortment of domestic and foreign medicines.
- Production of infusion solutions.
- Quality control.
- Technological scheme of production; equipment used.

***Topic 31*. Industrial production of ophthalmic, aural and nasal dosage forms.**

- Main characteristics of ophthalmic, aural and nasal dosage forms.
- Methods of their manufacture, equipment used.
- Physico-chemical and biological features of creation, prolongation.
- Quality control.
- Technological schemes for the production of ophthalmic, aural and nasal drugs.

***Topic 32*. Theoretical foundations of extraction.**

- Theoretical foundations of extraction.
- Extraction stages and their characteristics.
- Factors affecting the completeness and speed of extraction.
- Requirements for extractants.

***Topic 33*. Production of tinctures. Alcoholometry.**

- Characteristics and classification of tinctures.
- Methods of their manufacture and purification.
- Technological scheme of production, equipment used.
- Quality control of tinctures as a dosage form, packaging and storage conditions.
- Methods of ethanol production (from raw materials containing starch, carbohydrates, synthetically).
- Rules for determining alcohol concentration, dilution and accounting for alcohol use.
- Basic principles of ethanol recovery and rectification.

***Topic 34*. Production of liquid extracts.**

- Characteristics and classification of extracts.
- Main stages of production of liquid extracts.
- Technological scheme of production, equipment used.
- Quality control of liquid extracts.

***Topic 35*. Production of thick and dry extracts. Intensification of extraction processes.**

- Production of thick extracts.
- Theoretical foundations of the evaporation process, equipment and principle of its operation.
- Production of dry extracts.
- Theoretical foundations of the drying process, equipment used.
- Technological schemes for the production of thick and dry extracts.
- Standardization of extracts, packaging and storage conditions.
- Methods for intensification of the production of extracts from plant raw materials.

***Topic 36*. Production of drugs under pressure.**

- Classification of aerosols, advantages and disadvantages.
- Main components of aerosol packaging, types of valve-spraying system, classification of propellants and aerosol concentrates.
- Production of aerosols, quality control according to the SPhU.
- Technological scheme of production; equipment used.

***Topic 37*. Physico-chemical and technological properties of powders and granules.**

- Study of physicochemical and pharmaco-technological properties of powders and granules. Their influence on the technology of obtaining solid dosage forms.
- Theoretical foundations of tableting.

***Topic 38*. Production of tablets by direct compression and pre-granulation.**

- Industrial production of tablets using direct compression and pre-granulation.
- Study of equipment for grinding, sieving and mixing of raw materials, the principle of its

operation.
- Granulation methods; equipment used.
- Excipients in the production of tablets.
- Technological scheme of production.

***Topic 39*. Industrial production of film-coated tablets. Quality control.**

- Coating of tablets with shells.
- Types of coating and methods of application.
- Pressed, dragee and film shells.
- Technological scheme for the production of coated tablets; equipment used.
- Production of prolonged-release tablets, excipients to ensure prolongation. Quality control of tablets according to the requirements of the SPhU.

***Topic 40*. Production of medical capsules.**

- Definition of capsules, requirements of the SPhU.
- Types of capsules and their purpose. Excipients in the production of capsules.
- Methods of manufacturing soft and hard gelatin capsules, filling them with medicinal substances. Quality control according to the State Pharmaceutical Industry.
- Tubatins.
- Spansules.
- Rectal gelatin capsules.
- Technological aspects of manufacturing capsules with modified release of active ingredients.
- Technological scheme for the production of soft and hard gelatin capsules; equipment used.

***Topic 41*. Industrial production of soft drugs.**

- Ointments, gels, pastes, creams, liniments as dosage forms, their characteristics and classification. Advantages and disadvantages.
- Requirements for ointments, classification of bases and general requirements.
- Excipients in the production of soft dosage forms.
- Technological schemes for the production of soft dosage forms; equipment used.
- Structural and mechanical (rheological) characteristics of ointments.
- Quality control according to the SPhU.
- Packaging and labeling.

***Topic 42*. Industrial production of suppositories.**

- Suppositories, types and requirements for them.
- Characteristics of bases and excipients.
- Manufacturing methods.
- Technological scheme of production; equipment used.
- Quality control of suppositories according to the SPhU.

***Topic 43*. Production of patches and transdermal therapeutic systems.**

- Classification of patches.
- Excipients used in their production.
- Technological scheme of production; equipment used.
- Quality control of patches.
- Alternative method of drug administration - transdermal therapeutic systems (TTS).
- Types and categories of TTS.
- Requirements for active substances included in TTS.
- Structure of membrane and matrix TTS.
- Excipients used in the creation of TTS.

- TTS quality indicators.
- TTS improvement technology.

***Topic 44*. Production of nano- and radiopharmaceuticals.**

- Production and use of radiopharmaceuticals.
- Assortment and composition of radiopharmaceuticals on the pharmaceutical market of Ukraine.
- Features of their technology and quality control.
- Use of nanotechnologies in the production of medicines.
- Basic principles and directions of nanotechnology.
- Nanodrugs.
- Features of their production.
- Carriers for drug transport (liposomes, nanospheres, nanocapsules, colloidal carriers with monoclonal antibodies, etc.).

4. STRUCTURE OF THE ACADEMIC DISCIPLINE

Topic names	Number of hours of full-time study			
	Total	including		
		lectures	practical	IWS
Subsection 1. Pharmacy technology of drugs				
Topic 1. State regulation of the production of medicines in pharmacies. General issues of medicine technology.	6	2	2	2
Topic 2. Solid dosage forms. Production in pharmacies of simple and complex powders with medicinal substances that differ in prescribed quantity, bulk density and particle structure.	6	2	2	2
Topic 3. Production in pharmacies of complex powders with poisonous, narcotic and potent substances.	7	1	4	2
Topic 4. Production of complex powders with coloring, odorous and difficult-to-grind substances. Production of complex powders with extracts and semi-finished products.	5	1	2	2
Topic 5. Preparation of specieses in a pharmacy.	6	0	2	4
Topic 6. Liquid dosage forms. Preparation of concentrated solutions.	6	2	2	2
Topic 7. Production of liquid dosage forms by the mass-volume method by dissolving dry medicinal substances and using concentrated solutions.	6	2	2	2
Topic 8. Special cases of making aqueous solutions. Drops.	5	1	2	2
Topic 9. Preparation of liquid dosage forms by diluting standard pharmacopoeial liquids. Non-aqueous solutions.	5	1	2	2
Topic 10. HMC solutions. Colloidal solutions.	6	2	2	2
Topic 11. Suspensions.	8	2	4	2
Topic 12. Emulsions.	12	2	6	4
Topic 13. Infusions and decoctions from medicinal plant raw materials.	6	2	2	2
Topic 14. Slimes. HDF technology using extracts and concentrates.	6	2	2	2
Topic 15. Soft dosage forms. Liniments and homogeneous ointments.	8	2	4	2
Topic 16. Heterogeneous ointments.	7	1	4	2
Topic 17. Combined ointments. Creams. Gels.	7	1	4	2
Topic 18. Suppositories. Production of suppositories by pumping method. Sticks. Pills.	7	1	4	2
Topic 19. Production of suppositories by pouring method.	7	1	4	2
Topic 20. Requirements for the manufacture of sterile and aseptic medicines in pharmacies.	6	2	2	2
Topic 21. Injection solutions.	6	2	2	2
Topic 22. Injection solutions requiring stabilization.	6	0	4	2
Topic 23. Isotonic and infusion solutions. Injection solutions with thermolabile substances. Suspensions for injections.	12	4	4	4
Topic 24. Ophthalmic dosage forms.	8	2	4	2
Topic 25. Dosage forms with antibiotics.	5	1	2	2
Topic 26. Pediatric and geriatric dosage forms.	9	1	4	4
Differentiated credit	2	0	2	0
Total hours for content module 1:	180	40	80	60
Subsection 2. Industrial technology of drugs.				
Topic 27. Regulatory documentation in the production of finished medicines.	4	0	2	2
Topic 28. Requirements for sterile products. Determination of the main quality indicators of ampoule glass.	10	2	4	4
Topic 29. Industrial production of injection solutions.	11	2	6	3
Topic 30. Industrial production of infusion solutions.	8	2	4	2
Topic 31 Industrial production of ophthalmic, aural and nasal dosage forms.	9	2	4	3
Topic 32. Theoretical foundations of extraction.	4	2	0	2
Topic 33. Production of tinctures. Alcoholometry.	9	2	4	3
Topic 34. Production of liquid extracts.	9	1	6	2
Topic 35. Production of thick and dry extracts. Intensification of extraction processes.	7	1	4	2
Topic 36. Production of drugs under pressure.	11	4	4	3
Topic 37. Physicochemical and technological properties of powders and granules.	8	2	4	2
Topic 38. Production of tablets by direct compression and pre-granulation.	13	4	6	4
Topic 39. Industrial production of film-coated tablets. Quality control.	13	2	6	4
Topic 40. Production of medical capsules.	10	2	6	2
Topic 41. Industrial production of soft drugs.	14	4	6	4
Topic 42. Industrial production of suppositories.	10	2	4	4
Topic 43. Production of plasters and TTS.	10	4	4	4
Topic 44. Production of nano- and radiopharmaceuticals.	18	2	4	10

Total hours for content module 2:	180	40	80	60
Total hours:	360	80	160	120

5. TOPICS OF LECTURES / SEMINARS / PRACTICAL / LABORATORY CLASSES

5.1. Lecture topics

Topic name	Number of hours
Lecture 1. State regulation of the production of medicines in pharmacies. General issues of medicine technology.	**2**
Lecture 2. Solid dosage forms. Technology of powders with medicinal substances that differ in prescribed quantity, bulk density and particle structure.	2
Lecture 3. Solid dosage forms. Technology of powders with poisonous and potent substances. Technology of powders with coloring, odorous, difficult-to-grind substances and extracts.	2
Lecture 4. Liquid dosage forms. Classification. Solvents used for the preparation of liquid dosage forms. Technological stages of the manufacture of liquid dosage forms. Quality assessment and design of liquid dosage forms.	2
Lecture 5. Liquid dosage forms. Technology of concentrated solutions for burette installation. Preparation of liquid dosage forms from concentrated solutions.	2
Lecture 6. Liquid dosage forms. Technology of standard pharmacopoeial solutions, non-aqueous solutions. Special cases of manufacturing aqueous solutions. Technology of drops.	2
Lecture 7. Technology of HMC solutions. Technology of colloidal solutions.	2
Lecture 8. Suspension technology.	2
Lecture 9. Emulsion technology.	2
Lecture 10. Aqueous extracts from medicinal plant raw materials - infusions. Features of production.	2
Lecture 11. Decoctions from medicinal plant raw materials. Liquid drugs using extract concentrates. Mucus.	2
Lecture 12. Soft dosage forms. Liniments. Homogeneous ointments, manufacturing technology, features.	2
Lecture 13. Heterogeneous ointments – general rules for the manufacture of suspension, emulsion ointments; pastes; combined ointments.	2
Lecture 14. Suppositories by pumping and pouring method.	2
Lecture 15. Requirements for the manufacture of sterile and aseptic medicinal products in pharmacies. Organization of work in aseptic conditions. Technology of parenteral medicinal products.	2
Lecture 16. Requirements for the manufacture of sterile and aseptic medicinal products in pharmacies. Organization of work in aseptic conditions. Technology of parenteral medicinal products.	2
Lecture 17. Solutions for injections, isotonic and infusion solutions, manufacturing technology.	2
Lecture 18. Injection solutions with thermolabile substances. Suspensions for injections.	2
Lecture 19. Ophthalmic dosage forms: drops, ointments, eye lotions, rinses, suspensions, emulsions. Manufacturing technology	2
Lecture 20. Dosage forms with antibiotics. Pediatric and geriatric dosage forms. Incompatibilities.	2

Lecture 21. Medicinal products for parenteral use. Creation of conditions for sterile production. Preparation of containers and closures (ampoules, vials). Requirements for starting materials and solvents (obtaining water for injection in industrial conditions). Preparation of parenteral solutions (isotonization, stabilization).	2
Lecture 22. Industrial production of injection and infusion solutions.	2
Lecture 23. Filtration, sterilization of parenteral solutions. Quality control of these agents.	2
Lecture 24. Industrial production of ophthalmic dosage forms. Technology of manufacturing eye drops, lotions, sprays, soft drugs, inserts. Ear dosage forms.	2
Lecture 25. Extractive preparations. Stages of extraction. Requirements for extractants.	2
Lecture 26. Production of tinctures. Alcoholometry.	2
Lecture 27. Production of liquid, thick, dry extracts. Concentrated extracts.	2
Lecture 28. Production of drugs under pressure. Characteristics, structure of aerosol packaging. Propellants.	2
Lecture 29. Medical sprays. Technology of aerosol systems. Standardization of storage of drugs under pressure.	2
Lecture 30. Physico-chemical and technological properties of powders and granules.	2
Lecture 31. Tablets, characteristics and classification. Direct compression.	2
Lecture 32. Tablets Granulation. Types of tablet machines.	2
Lecture 33. Coating of tablets with shells. Granules. Pellets. Dragees.	2
Lecture 34. Production of medical microcapsules. Microencapsulation methods.	2
Lecture 35. Soft drugs. Characteristics, classification. Ointment bases, excipients.	2
Lecture 36. Soft drugs. Characteristics, classification. Ointment bases, excipients.	2
Lecture 37. Industrial production of suppositories.	2
Lecture 38. Production of medical plasters, characteristics, classification, industrial production. Mustard plasters.	2
Lecture 39. Transdermal therapeutic systems. General characteristics, classification, controlled release systems.	2
Lecture 40. Production of nano- and radiopharmaceuticals.	2
Number of lecture hours in the discipline	**80**

5.2. Seminar topics

Seminars are not provided

5.3. Topics of practical classes

Topic name	Number of hours
Topic 1. Practical lesson 1. State regulation of the production of medicines in pharmacies. General issues of medicine technology.	2

Topic 2. Practical lesson 2. Solid dosage forms. Production in pharmacies of simple and complex powders with medicinal substances that differ in the prescribed amount, bulk density and particle structure.	2
Topic 3. Practical lesson 3. Triturations. Making triturations, calculations.	2
Topic 3. Practical lesson 4. Production of complex powders with poisonous and potent substances.	2
Topic 4. Practical lesson 5. Production of complex powders with coloring, odorous and difficult-to-grind substances. Production of complex powders with extracts and semi-finished products.	2
Topic 5. Practical lesson 6. Making specieses in a pharmacy.	2
Topic 6. Practical lesson 7. Liquid dosage forms. Preparation of concentrated solutions.	2
Topic 7. Practical lesson 8. Manufacture of liquid dosage forms by the mass-volume method by dissolving dry medicinal substances and using concentrated solutions.	2
Topic 8. Practical lesson 9. Special cases of making aqueous solutions. Drops.	2
Topic 9. Practical lesson 10. Manufacture of liquid dosage forms by diluting standard pharmacopoeial liquids. Non-aqueous solutions.	2
Topic 10. Practical lesson 11. HMC solutions. Colloidal solutions.	2
Topic 11. Practical lesson 12. Suspensions.	2
Topic 11. Practical lesson 13. Suspensions.	2
Topic 12. Practical lesson 14. Emulsions.	2
Topic 12. Practical lesson 15. Solving situational and test tasks	2
Topic 12. Practical lesson 16. Emulsions.	2
Topic 13. Practical lesson 17. Infusions and decoctions from medicinal plant raw materials.	2
Topic 14. Practical lesson 18. Mucus. Technology of herbal dosage forms using extract concentrates.	2
Topic 15. Practical lesson 19. Soft dosage forms. Liniments.	2
Topic 15. Practical lesson 20. Soft dosage forms. Homogeneous ointments.	2
Topic 16. Practical lesson 21. Мазі гетерогенні	2
Topic 16. Practical lesson 22.	2

Heterogeneous ointments	
Topic 17. Practical lesson 23. Combined ointments.	2
Topic 17. Practical lesson 24. Creams. Gels.	2
Topic 18. Practical lesson 25. Suppositories. Making suppositories by the pumping method.	2
Topic 18. Practical lesson 26. Sticks. Pills.	2
Topic 19. Practical lesson 27. Manufacturing suppositories by the pouring method.	2
Topic 19. Practical lesson 28. Manufacturing suppositories by the pouring method.	2
Topic 20. Practical lesson 29. Requirements for the manufacture of sterile and aseptic medicines in pharmacies.	2
Topic 21. Practical lesson 30. Injection solutions.	2
Topic 22. Practical lesson 31. Injection solutions requiring stabilization.	2
Topic 22. Practical lesson 32. Injection solutions requiring stabilization.	2
Topic 23. Practical lesson 33. Isotonic and infusion solutions.	2
Topic 23. Practical lesson 34. Injection solutions with thermolabile substances. Suspensions for injections.	2
Topic 24. Practical lesson 35. Ophthalmic dosage forms. Drops.	2
Topic 24. Practical lesson 36. Ophthalmic dosage forms. Ointments.	2
Topic 25. Practical lesson 37. Dosage forms with antibiotics.	2
Topic 26. Practical lesson 38. Children's and geriatric dosage forms.	2
Topic 26. Practical lesson 39. Solving situational and test tasks	2
Differential credit	2
Topic 27. Practical lesson 41. Regulatory documentation in the production of finished medicines.	2
Topic 28. Practical lesson 42. Requirements for sterile products	2
Topic 28. Practical lesson 43. Determination of the main quality indicators of ampoule glass.	2
Topic 29. Practical lesson 44. Industrial production of injection solutions.	2
Topic 29. Practical lesson 45. Industrial production of injection solutions.	2
Topic 29. Practical lesson 46.	2

Industrial production of injection solutions.	
Topic 30. Practical lesson 47. Industrial production of infusion solutions.	2
Topic 30. Practical lesson 48. Industrial production of infusion solutions.	2
Topic 31. Practical lesson 49. Industrial production of ophthalmic dosage forms.	2
Topic 31. Practical lesson 50. Industrial production of ear and nasal dosage forms.	2
Topic 33. Practical lesson 51. Alcoholometry.	2
Topic 33. Practical lesson 52. Production of tinctures. Alcoholometry.	2
Topic 34. Practical lesson 53. Production of liquid extracts.	2
Topic 34. Practical lesson 54. Production of liquid extracts.	2
Topic 34. Practical lesson 55. Production of liquid extracts.	2
Topic 35. Practical lesson 56. Production of thick and dry extracts	2
Topic 35. Practical lesson 57. Intensification of extraction processes.	2
Topic 36. Practical lesson 58. Production of drugs under pressure.	2
Topic 36. Practical lesson 59. Production of drugs under pressure.	2
Topic 36. Practical lesson 60. Solution of situational and test tasks on the industrial production of injection solutions, infusion solutions, ophthalmic dosage forms, ear and nasal dosage forms; production of tinctures, liquid extracts, thick and dry extracts, preparations under pressure; alcoholometry.	2
Topic 37. Practical lesson 61. Physico-chemical and technological properties of powders.	2
Topic 37. Practical lesson 62. Physico-chemical and technological properties of granules.	2
Topic 38. Practical lesson 63. Production of tablets by direct compression method.	2
Topic 38. Practical lesson 64. Production of tablets with pre-granulation.	2
Topic 38. Practical lesson 65. Production of tablets by direct compression and with preliminary granulation.	2
Topic 39. Practical lesson 66. Industrial production of film-coated tablets.	2
Topic 39. Practical lesson 67. Industrial production of film-coated tablets.	2
Topic 39. Practical lesson 68.	2

Quality control of tablets	
Topic 40. Practical lesson 69. Production of medical capsules	2
Topic 40. Practical lesson 70. Production of medical capsules	2
Topic 40. Practical lesson 71. Production of medical capsules	2
Topic 41. Practical lesson 72. Industrial production of soft drugs.	2
Topic 41. Practical lesson 73. Industrial production of soft drugs.	2
Topic 41. Practical lesson 74. Industrial production of soft drugs.	2
Topic 42. Practical lesson 75. Industrial production of suppositories	2
Topic 42. Practical lesson 76. Industrial production of suppositories	2
Topic 43. Practical lesson 77. Production of plasters and TTS.	2
Topic 43. Practical lesson 78. Production of plasters and TTS.	2
Topic 44. Practical lesson 79 Production of nano- and radiopharmaceuticals.	2
Topic 44. Practical lesson 80. Solving situational and test tasks	2
Number of hours of practical classes in the discipline	**160**

5.4. Topics of laboratory classes

Laboratory classes are not provided

6. INDEPENDENT WORK OF A HIGHER EDUCATION STUDENT

Topic name / types of tasks	Number of hours
Topic 1. State regulation of the production of medicines in pharmacies. General issues of medicine technology.	**2**
Topic 2. Solid dosage forms. Production in pharmacies of simple and complex powders with medicinal substances that differ in prescribed quantity, bulk density and particle structure.	**2**
Topic 3. Production in pharmacies of complex powders with poisonous, narcotic and potent substances.	**2**
Topic 4. Production of complex powders with coloring, odorous and difficult-to-grind substances. Production of complex powders with extracts and semi-finished products.	**2**
Topic 5. Preparation of dressings in a pharmacy.	**4**
Topic 6. Liquid dosage forms. Preparation of concentrated solutions	**2**
Topic 7. Production of liquid dosage forms by the mass-volume method by dissolving dry medicinal substances and using concentrated solutions	**2**
Topic 8. Special cases of making aqueous solutions. Drops.	**2**

Topic 9. Preparation of liquid dosage forms by diluting standard pharmacopoeial liquids. Non-aqueous solutions	**2**
Topic 10. HMC solutions. Colloidal solutions.	**2**
Topic 11. Suspensions.	**2**
Topic 12. Emulsions.	**4**
Topic 13. Infusions and decoctions from medicinal plant raw materials.	**2**
Topic 14. Mucilages. Technology of herbal dosage forms using extract concentrates.	**2**
Topic 15. Soft dosage forms. Liniments and homogeneous ointments.	**2**
Topic 16. Heterogeneous ointments.	**2**
Topic 17. Combined ointments. Creams. Gels.	**2**
Topic 18. Suppositories. Making suppositories by pumping. Sticks. Pills	**2**
Topic 19. Production of suppositories by pouring method	**2**
Topic 20. Requirements for the manufacture of sterile and aseptic medicines in pharmacies.	**2**
Topic 21. Injection solutions.	**2**
Topic 22. Injection solutions requiring stabilization	**2**
Topic 23. Isotonic and infusion solutions. Injection solutions with thermolabile substances. Suspensions for injections.	**4**
Topic 24. Ophthalmic dosage forms.	**2**
Topic 25. Dosage forms with antibiotics.	**2**
Topic 26. Pediatric and geriatric dosage forms.	**4**
Topic 27. Regulatory documentation in the production of finished drugs.	**2**
Topic 28. Requirements for sterile products. Determination of the main quality indicators of ampoule glass.	**4**
Topic 29. Industrial production of injection solutions.	**3**
Topic 30. Industrial production of infusion solutions.	**2**
Topic 31. Industrial production of ophthalmic, aural and nasal dosage forms.	**3**
Topic 32. Theoretical foundations of extraction.	**2**
Topic 33. Production of tinctures. Alcoholometry.	**3**
Topic 34. Production of liquid extracts.	**2**
Topic 35. Production of thick and dry extracts. Intensification of extraction processes.	**2**
Topic 36. Production of drugs under pressure. Characteristics, structure of aerosol packaging. Propellants. Medical sprays. Technology of aerosol systems. Standardization of storage of drugs under pressure.	**3**
Topic 38. Physicochemical and technological properties of powders and granules.	**2**
Topic 39. Production of tablets by direct compression and pre-granulation.	**4**
Topic 40. Industrial production of film-coated tablets. Quality control.	**4**
Topic 41. Production of medical capsules.	**2**
Topic 42. Industrial production of soft drugs.	**4**
Topic 43. Industrial production of suppositories	**4**
Topic 44. Production of plasters and TTS.	**4**
Topic 45. Production of nano- and radiopharmaceuticals.	**10**
Total:	**120**

7. FORMS AND METHODS OF TEACHING

Forms of education:

The discipline is taught in the form of practical classes; organization of independent work of the applicant.

Methods of learning:

Practical classes: conversation, role-playing games, solving situational problems, solving test problems.

Independent work: independent work with the textbook, independent work with recommended basic and additional literature, with electronic information resources, independent solution of clinical tasks.

8. FORMS OF CONTROL AND CRITERIA FOR ASSESSING LEARNING OUTCOMES

Forms of current control: oral interview, testing, assessment of practical skills, assessment of communication skills during role-playing, solving situational tasks, assessment of activity in the lesson.

Final control form: exam.

Criteria for assessing the learning outcomes of higher education applicants during current control

Assessment	Assessment criteria
Excellent «5»	The applicant actively participates in the discussion of the most complex questions on the topic of the lesson, gives at least 90% correct answers to standardized test tasks, answers written tasks without errors, performs practical work and draws up a protocol.
Good «4»	The applicant participates in the discussion of the most complex questions on the topic, gives at least 75% of correct answers to standardized test tasks, makes some minor errors in answers to written tasks, performs practical work and draws up a protocol.
Satisfactory «3»	The applicant participates in the discussion of the most complex questions on the topic, gives at least 60% of correct answers to standardized test tasks, makes significant errors in answers to written tasks, performs practical work and draws up a protocol.
Unsatisfactory «2»	The applicant does not participate in the discussion of complex questions on the topic, gives less than 60% of correct answers to standardized test tasks, makes gross errors in answers to written tasks or does not give answers to them at all, does not perform practical work and does not draw up a protocol.

Only those applicants who have fulfilled the requirements of the curriculum in the discipline, have no academic debt, and their average score for current academic activity in the discipline is not less than 3.00 are allowed to take the final test.

The exam, as a form of final (semester) control, takes place as a separate control measure. Exams are taken by applicants: during the examination sessions at the end of the semester (autumn and spring) according to the schedule - with the tape system of training; according to the schedule of the educational process after studying the educational component according to the curriculum - with the cyclical schedule of classes.

The methodology for conducting final (semester) control of the educational component in the form of an exam is unified and involves the use of standardized forms. The number of questions that

are put on a standardized exam corresponds to the number of credits allocated for studying the academic discipline. The form of the examination ticket is standardized and consists of structural elements (components). The examination ticket may consist only of theoretical questions or with the addition of a situational task. Each ticket may contain from 3 to 5 questions. The questions are short, simple, understandable, clear and transparent, composed in such a way that a full answer to it takes no more than 5 minutes. The timing of the oral structured exam is standard - no more than 30 minutes. A checklist (answer template) is compiled for each question, which provides for key points that are mandatory for providing a full answer to the question posed. Each standard answer is accompanied by a literary source with pages. During an oral structured exam, the candidate sees the question, the teacher sees a checklist with standard answers and determines which components were or were not named by the candidate.

The overall score for the oral structured exam is calculated as the arithmetic average of all scores received for the answers to the questions (including situational tasks).

Criteria for assessing the learning outcomes of higher education applicants during final control

Assessment	Assessment criteria
Excellent «5»	The applicant worked systematically throughout the semester, demonstrated versatile and deep knowledge of the program material during the exam, is able to successfully complete the tasks provided for by the program, has mastered the content of the main and additional literature, has realized the interrelationship of individual sections of the discipline, their importance for the future profession, has demonstrated creative abilities in understanding and using the educational program material, has demonstrated the ability to independently update and replenish knowledge; the level of competence is high (creative);
Good «4»	The applicant has demonstrated full knowledge of the curriculum material, successfully performs the tasks provided for by the program, has mastered the basic literature recommended by the program, has shown a sufficient level of knowledge in the discipline and is capable of independently updating and renewing it in the course of further study and professional activity; the level of competence is sufficient (constructive-variative)
Satisfactory «3»	An applicant who has demonstrated knowledge of the basic curriculum material to the extent necessary for further study and subsequent work in the profession, copes with the tasks provided for by the program, made individual errors in the answers to the exam and when performing exam tasks, but has the necessary knowledge to overcome the errors made under the guidance of a scientific and pedagogical worker; the level of competence is average (reproductive)
Unsatisfactory «2»	The applicant did not demonstrate sufficient knowledge of the main educational and program material, made fundamental errors in performing the tasks provided for by the program, cannot use the knowledge in further study without the help of a teacher, and failed to master the skills of independent work; the level of competence is low (receptive-productive)

9. DISTRIBUTION OF POINTS RECEIVED BY HIGHER EDUCATION STUDENTS

Points in the academic discipline for applicants who have successfully completed the program are converted into a traditional four-point scale according to the absolute criteria given in the table:

National assessment for discipline	Total points for the discipline
Excellent («5»)	185 – 200
Good («4»)	151 – 184
Satisfactory («3»)	120 – 150
Unsatisfactory («2»)	Lower 120

A multi-point scale (200-point scale) characterizes the actual success of each applicant in mastering the academic discipline. The conversion of the traditional assessment into a 200-point one is performed by the University's information and technology department using the "Contingent" program according to the appropriate formula: Average score of success (current success in the discipline) x 40**.**

According ***to the ECTS rating scale***, the achievements of the students in the academic discipline who are studying in the same course of the same specialty are evaluated, according to the points they received, by means of ranking, namely:

ECTS grade	Statistical indicator
A	The best 10% of achievers
B	Next 25% of achievers
C	Next 30% of achievers
D	Next 25% of achievers
E	Next 10% of achievers

The ECTS scale establishes the applicant's belonging to the group of the best or worst among the reference group of fellow students (faculty, specialty), that is, his rating. When converting from a multi-point scale, as a rule, the boundaries of the grades "A", "B", "C", "D", "E" do not coincide with the boundaries of the grades "5", "4", "3" according to the traditional scale. The grade "A" on the ECTS scale cannot be equal to the grade "excellent", and the grade "B" - to the grade "good", etc. Applicants who received grades "FX" and "F" ("2") are not included in the list of ranked applicants. Such applicants automatically receive an "E" grade after retaking. The "FX" grade is given to applicants who have scored the minimum number of points for current educational activities, but who have not passed the final test. A grade of "F" is given to students who attended all classroom classes in the academic discipline, but did not achieve a grade point average (3.00) for current academic activities and were not admitted to the final examination.

10. METHODOLOGICAL SUPPORT

- Syllabus of the academic discipline;
- Work program of the academic discipline;
- Methodological recommendations for practical classes;
- Methodological recommendations for independent work of higher education applicants;
- Multimedia presentations;
- Illustrative materials;
- Situational tasks.

11. QUESTIONS FOR PREPARATION FOR THE FINAL TEST

Pharmacy technology:

1. Technology of dosage forms as a scientific discipline, its tasks and directions of development. Definition of technological terms: medicinal product, medicinal substance, dosage form,

medicinal product.

2. Classification of dosage forms: dispersive (physicochemical), by aggregate state, depending on the method of use and routes of administration.
3. Main directions of state standardization of the production of medicinal products. Regulatory documentation that regulates the quality, storage conditions and dispensing of medicinal products.
4. Prescription, its structure and rules for prescribing in accordance with the order of the Ministry of Health of Ukraine No. 360 dated 19.07.05.
5. Metrological characteristics of scales: accuracy (correctness), sensitivity, stability, constancy of readings.
6. Rules for weighing loose, viscous and liquid substances on pharmacy manual and technical scales. Indicate the minimum weight that can be weighed on manual one-gram scales of substances from lists A, B and the general list.
7. Definition of powders as a dosage form, their classification and requirements of the State Pharmaceutical University for them. Technological stages of preparation of complex powders and their characteristics.
8. Methods of prescribing powders. Preparation of complex powders, which include medicinal substances that differ in density, volumetric (bulk) mass, particle structure.
9. Rules for working with poisonous, potent and narcotic medicinal substances. Triturations, their purpose, storage and registration. Trituration technology using the example of 10.0 trituration of atropine sulfate (1:100); use of triturations in powders.
10. Preparation of complex powders with poisonous, narcotic, potent and other substances prescribed in different quantities. Rules for their registration before dispensing.
11. The degree of grinding of medicinal substances in powders depending on the medical application in accordance with the requirements of the State Pharmaceutical University. Difficult-to-grind medicinal substances. The purpose of auxiliary liquids and their quantity in the grinding process.
12. Examples of coloring and odorous substances and their storage conditions in accordance with the order of the Ministry of Health of Ukraine No. 44 dated 16.03.93. Features of the technology of powders with coloring and odorous substances.
13. Types of packaging material used in powder technology for substances with different physicochemical properties. Assessment of the quality of powders (particle size, homogeneity of mixing, accuracy of dosing, etc.).
14. Characteristics of liquid dosage forms, their classification. Methods of prescribing and designating the concentration of solutions; checking doses of poisonous and potent medicinal substances in mixtures.
15. Rules for preparing concentrated solutions for the burette system according to the instructions to the order of the Ministry of Health of Ukraine No. 197 of 07.09.93.
16. Burette device structure; rules for its care and use. Quality control of 29 concentrated solutions, correction of their concentrations; storage conditions.
17. Technology of mixtures containing dry medicinal substances in quantities up to 3% and more in accordance with the requirements of the Order of the Ministry of Health of Ukraine No. 197 dated 07.09.93. Quality assessment, registration before dispensing, storage conditions of liquid medicinal products in accordance with the State Pharmaceutical Federal Law.
18. Definition of a standard dropper. Factors affecting the accuracy of dosing. Rules for using a dropper; calibration of a non-standard dropper.
19. Features of the technology of aqueous solutions of slowly and poorly soluble substances (ethacridine lactate, copper sulfate, furacilin, boric acid, etc.).
20. Nomenclature of standard pharmacopoeial liquids, methods of prescribing them in recipes and

storage conditions. Preparation of ammonia and acetic acid solutions. Provide the appropriate calculations.

21. Features of the preparation of hydrochloric acid solutions for internal and external use (provide examples).
22. Preparation of solutions of hydrogen peroxide, formaldehyde, basic aluminum acetate, potassium acetate. Provide the necessary calculations using specific examples.
23. Features of the dilution of formalin, Burov's liquid, perhydrol, potassium acetate liquid.
24. Features of the technology and calculations for the dilution of ethyl alcohol using the dilution formula and alcoholometric tables. Rules for drawing up recipes that prescribe ethyl alcohol, and drawing up alcohol solutions before dispensing.
25. Characteristics of drops as a dosage form, their classification. Checking doses of poisonous and potent medicinal substances in drops. Rules for preparing drops using concentrated solutions and by dissolving dry substances.
26. Preparation of solutions of easily oxidizing substances (silver nitrate, potassium permanganate, iodine). Specify the concentration of iodine in solutions and Lugol for internal and external use.
27. Characteristics and classification of high molecular weight compounds (HMCs). The influence of the structure of the HMC molecule on the dissolution process of limited and unlimited swelling substances.
28. Application of HMCs in pharmacy. Preparation of solutions of unlimited swelling substances using the example of pepsin.
29. Features of the technology of solutions of limited swelling HMCs: gelatin, starch, methycellulose.
30. Characteristics and features of colloidal solutions. Factors determining their stability. The essence of colloidal protection. Name the preparations of protected colloids.
31. Definition of suspensions as a dosage form and as a dispersed system. Cases of suspension formation. Factors affecting the stability of suspensions. Assessment of the quality of suspensions and their registration before release in accordance with the requirements of the State Federal University.
32. Dispersion method for obtaining suspensions from hydrophilic substances. Use of the rule of B. V. Deryagin.
33. Preparation of suspensions from medicinal substances with sharply and not sharply expressed hydrophobic properties. Stabilizers, their quantitative selection. Technology of sulfur suspensions.
34. Condensation method for preparing suspensions. Opalescent and cloudy mixtures, conditions for their formation. Features of the technology of mixtures with ammonia-anis drops, extracts of different consistencies.
35. Definition of emulsions as a dosage form and dispersed system. Classification of emulsions, requirements for them. Emulsifiers, their brief characteristics.
36. Types of oil emulsions and methods for their determination. Stages of emulsion technology. Calculations of oil, emulsifier, water. Determination of the readiness of the primary emulsion.
37. Introduction of medicinal substances with different physicochemical properties into oil emulsions. Assessment of the quality of emulsions, their storage and design before release.
38. Characteristics of infusions and decoctions as disperse systems and dosage forms; requirements for them. Technology of decoctions from raw materials containing tannins, anthraglycosides, saponins.
39. The value of the ratio of the amount of medicinal plant raw materials and extractant, the coefficient of water absorption, temperature, duration of infusion and cooling when preparing infusions and decoctions.

40. Differences in the technology and rules for introducing medicinal substances into infusions and decoctions from medicinal raw materials and standardized extract concentrates. Ways to improve the technology of aqueous extracts. The value of enzymes and microflora in the technology of infusions and decoctions.
41. Characteristics of liniments as a dosage form and their classification depending on the nature of the base used, medical purpose and physicochemical properties of the ingredients. Assessment of the quality of liniments and their design before dispensing.
42. Features of the technology of homogeneous and heterogeneous liniments. Preparation of suspension, emulsion and combined liniments (give examples).
43. Characteristics of ointments as a dosage form and disperse systems. Features of the preparation of dermatological ointments with resorcinol, zinc sulfate, salicylic acid. The influence of bases on the bioavailability of medicinal substances from ointments.
44. Classification of ointments by medical purpose, place of application, consistency and physicochemical properties of medicinal substances. Pastes, their classification; features of the preparation of dermatological pastes.
45. Homogeneous ointments and their characteristics. Main technological stages of preparation and rules for introducing medicinal substances into homogeneous ointments.
46. Suspension (trituration) ointments; their classification and technology depending on the percentage of medicinal substances. Official prescriptions for suspension ointments.
47. Emulsion ointments; their characteristics and technology. Preparation of ointments with protargol, collargol, tannin, dry and thick extracts.
48. Combined-type ointments, their technology. Give examples. Preparation of ointments using in-pharmacy preparations (concentrates and semi-finished products). Assessment of the quality of ointments and their registration before dispensing, according to the State Federal University of Ukraine.
49. Characteristics of suppositories as a dosage form and disperse systems; their classification depending on the purpose. Suppository bases, their classification. Characteristics of hydrophilic bases.
50. State Federal University of Ukraine requirements for suppositories, the meaning of their geometric shape. Prescribing suppositories and checking the doses of poisonous and potent medicinal substances in them. Composition and preparation of gelatin-glycerol base for suppositories. Introduction of soluble and insoluble medicinal substances into water-soluble bases.
51. Stages of the technological process of suppositories by pumping. Introduction of medicinal substances soluble in water and other indifferent liquids into the composition of suppository masses, depending on the prescribed amount.
52. Stages of the technological process of preparing suppositories by pouring. What are direct and reverse substitution coefficients of medicinal substances and in what cases are they used?
53. Definition of dosage forms for injections and requirements of the State Federal University of Health Sciences for their publication. Routes of administration of injection solutions. List the stages of the technological process of preparing solutions for injections and give their brief characteristics.
54. Asepsis, its importance for ensuring sterility and pyrogen-freeness of injection solutions. Creation of aseptic conditions in the pharmacy in accordance with the order of the Ministry of Health of Ukraine No. 275 dated 15.05.06. The concept of pyrogenic substances and verification of pyrogenicity of drugs for injections in accordance with the requirements of the State Federal University of Medicine.
55. The concept of stabilization of injection solutions. The mechanism of stabilization of solutions of salts of weak bases and strong acids, salts of weak acids and strong bases (on specific

examples).

56. The value of isotonicity of injection solutions. Methods of calculating the isotonic concentration of medicinal substances. Give examples of calculations according to Raoult's law (cryoscopic method) and using the isotonic equivalent of sodium chloride.
57. Characteristics of dosage forms used in ophthalmology (drops, lotions, rinsing, emulsions, suspensions, ointments, powders). Requirements for ophthalmic dosage forms; their justification and implementation.
58. Features of the technology of eye drops depending on the solubility of the ingredients that make up their composition, and calculations of the isotonicity of drops.
59. Characteristics of the bases used for the preparation of eye ointments, and requirements for them. Assessment of the quality of eye dosage forms, registration before release, storage rules in accordance with the requirements.
60. Requirements of the State Federal University of Health Sciences for dosage forms with antibiotics. Conditions for their preparation. Features of the introduction of antibiotics into dosage forms.

Industrial technology:

1. Read prescriptions in Latin, analyze their components and evaluate the correctness of the prescription.
2. Identify physical, chemical and pharmacological incompatibilities. Resolve issues regarding the possibility of preparing and dispensing medications, taking into account the compatibility of the prescription components.
3. Work with tare and manual scales when weighing medicinal substances of different aggregate states.
4. Perform preparatory and basic technological operations when packaging medicinal substances (tare, weigh, measure).
5. Select packaging material when dosing loose, thick and viscous substances and liquids.
6. Calibrate a non-standard dropper and dose liquids drop by drop.
7. Calculate the number of prescription components, total volume or weight of the medicinal product.
8. Choose the optimal technology option and prepare a medicinal product in accordance with it with a staged quality assessment.
9. Perform basic technological operations for the preparation of simple and complex powders with medicinal substances prescribed in equal and different quantities, differing in particle structure, size and shape of crystals, aggregate state, bulk mass (weigh, grind, mix, dose).
10. Assess the quality of prepared powders and write a written control passport.
11. Check doses of poisonous and potent substances and the norms of a single release of narcotic and equivalent substances in powders.
12. Perform basic technological operations for the preparation of triturations and complex powders with poisonous and potent medicinal substances prescribed in small quantities (weigh, grind, mix, dose).
13. Perform basic technological operations for the preparation of complex powders with colored, odorous and difficult-to-grind medicinal substances (weigh, grind, mix, dose).
14. Perform basic technological operations for the preparation of powders with extracts (dry, thick, solutions of thick extracts) and semi-finished products (weigh, grind, mix, dose).
15. Use the State Pharmacopoeia, other regulatory documentation and reference literature to find the necessary information on the preparation of concentrated solutions.
16. Evaluate the correctness of prescriptions, check doses of poisonous and potent medicinal substances in liquid dosage forms.
17. Use the State Pharmacopoeia, other regulatory documentation and reference literature to find

the necessary information on the preparation of liquid dosage forms using concentrated solutions.

18. Perform basic technological operations for the preparation of liquid medicinal products using concentrated solutions and dissolving medicinal substances (weigh, measure, dissolve, filter).
19. Calculate the amount of water, medicinal and auxiliary substances for the preparation of solutions and drops.
20. Use the State Pharmacopoeia, other regulatory documentation and reference literature to find the necessary information on the preparation of solutions with standard pharmacopoeial liquids.
21. Calculate the amount of water and pharmacopoeial liquids depending on the method of their prescription.
22. Calculate the amount of alcohol and water for the preparation of alcohol of a given concentration, using the dilution formula and alcoholometric tables.
23. Calculate medicinal and auxiliary substances for the preparation of a dosage form.
24. Perform basic technological operations for the preparation of infusions and decoctions using concentrated extracts and aqueous extracts from raw materials containing mucus (grind, sift, weigh, extract, filter, dissolve).
25. Use the State Pharmacopoeia, other regulatory documentation and reference literature to find the necessary information on the preparation of liniments and ointments.
26. Calculate the percentage content of soluble medicinal substances in the base that are included in the ointment recipe and the number of auxiliary substances for the preparation of a medicinal product.
27. Perform basic technological operations for the preparation of suppositories by the pumping method (weigh, grind, dissolve, melt, pour into molds, cool, remove from molds).
28. Perform basic technological operations for the preparation of suppositories by the pouring method.
29. Perform basic technological operations for the preparation of injection solutions (weigh, dissolve, filter, check for the absence of mechanical impurities, hermetically seal, prepare for sterilization, sterilize).
30. Perform calculations of the isotonic concentration of medicinal substances using the isotonic equivalent of sodium chloride.

Exam questions (at the end of the 4th year of study).

List of theoretical questions for the exam:

1. General principles of production of finished dosage forms. Finished medicines, their role in providing the population. Expansion of the range of industrially produced medicines, organization of production of pharmaceutical enterprises.
2. Shop principle of production organization. Complex mechanization and aesthetics. Safety and labor protection. Technological process.
3. Maximum purified preparations and preparations of individual substances, obtaining new galenic preparations. Methods of purification of BAS.
4. Grinding. Types of grinding. Features of grinding of solids. Main methods of grinding. Grinding work (energy consumption).
5. Powders. Classification. Powder technology: grinding of the starting material, separation by particle size, mixing of individual components. Packaging and packaging. Biopharmaceutical aspects of powders.
6. Medical solutions. Classification (aqueous, alcoholic, glycerin, oily, aromatic waters, syrups). Methods of their preparation at chemical and pharmaceutical enterprises (dissolution, chemical interaction).
7. Standardization of solutions by the content of active substances and density. Solutions of

hydrogen peroxide, formaldehyde, Burov's solution, basic lead acetate solution. Alcoholic solutions of iodine. packaging. Packaging. Storage.

8. Extractive preparations. Theoretical foundations of extraction. Extraction of plant, animal, microbiological raw materials and tissue cultures.
9. Factors that affect the extraction process: histological structure, degree and nature of grinding, porosity, leaching and absorption coefficient, surface area of raw materials, concentration difference, temperature, extraction duration, effect of the extractant (extracting ability, selectivity, resorption, viscosity, surface tension and reaction of the medium to increase the speed and completeness of extraction). Viscosity. Surfactants. Hydrodynamics of the layer of plant raw materials.
10. Extraction methods: maceration and its modifications, percolation, repercolation with division of raw materials into equal parts and unequal parts, countercurrent extraction in a battery of extractors and continuous extractors, circulation extraction.
11. Intensification of the extraction process - turboextraction (vortex), extraction of raw materials on a rotary-pulsation apparatus RPA, extraction using ultrasound, variable pressure (four-body installation of the "carousel type"), extraction using electric charges, extraction using electroplasmolysis and electrodialysis.
12. Theoretical foundations of the extraction process: desorption, dissolution, leaching, diffusion, osmosis. Use of the basic principles of the theory of molecular and convective diffusion in the extraction process. 13. New technologies for the production of herbal medicines.
13. Extraction equipment: maceration tanks, communicated and non-communicated extractor batteries. Continuous extractors.
14. Alcohol recovery and rectification. Alcohol recovery from spent raw materials by water displacement and distillation with a water pore. Equipment.
15. Tinctures. Classification. Production. Maceration, possibilities of its intensification (partial, vortex, extraction using vibrators, pulsators, rotary-pulsation devices, ultrasound, extraction in a suspended layer of raw materials). Percolation.
16. Extracts. Characteristics. Classification by consistency and extractant used. Liquid extracts - methods of production (remaceration, percolation, repercolation, countercurrent extraction).
17. Purification. Standardization. Storage. Nomenclature of liquid extracts. Thick and dry extracts - methods of production (bismaceration, percolation, repercolation, countercurrent extraction, circulation extraction).
18. Purification of aqueous extracts. Purification of alcoholic extracts. Evaporation. Drying of extracts. Standardization. Nomenclature of aqueous thick extracts (wormwood, dandelion, licorice), dry (licorice).
19. Concentrated extracts. Characteristics. Classification. Methods of production of liquid concentrated extracts: percolation, repercolation, CANDI method. Methods for obtaining dry extract concentrates: rapid repercolation, maceration. Standardization. Polyextracts. Storage.
20. Production of enzyme preparations from animal raw materials with proteolytic action (pepsin, trypsin, chymotrypsin). Production of enzyme preparations from animal raw materials with hyaluronidase action (lidase, ronidase). Application. Storage.
21. Tablets. Definition. Characteristics. Types and nomenclature. Theoretical foundations of tableting.
22. Main groups of excipients used in the production of tablets: binders, disintegrants, antifriction agents, dyes, substances that prolong the action of medicinal products. Substances that are diluted. The influence of excipients on the therapeutic efficacy of drugs.
23. Stages of the technological process of obtaining tablets. Preparation of excipients and medicinal products, mixing of ingredients.
24. Features of the production of some parenteral dosage forms. Production of non-aqueous

solutions for injections.

25. Cultivation of cells and tissues in animals, humans and plants.
26. The value of granulation. Dry, wet granulation (by pressing, in a dragee boiler and plate granulators, suspended layer, spray drying), powdering of granulate. The influence of the type of granulation on the bioavailability of drugs. Granulate analysis: determination of physicochemical properties, granulometric composition, humidity, flowability, compressibility. Granulators and wiping machines, granulator dryers (SG-30).
27. Pressing. Tablet presses: impact and rotary. Comparative characteristics of tablet presses and the principle of their operation. The influence of pressing pressure on the therapeutic effectiveness of tablets. Direct pressing.
28. Methods of coating. Purpose of application. Coating technology: rolling, grinding, glossing, polishing. Obductors. Film coatings.
29. 29. Types and properties of film coatings. Assortment of film formers, plasticizers, solvents. Film coating technology. Equipment. Pressed coatings. Film coating technology. Equipment.
30. Pressed coating technology. Double and triple pressing machines. Extended-release tablets. Multilayer tablets. Durules. Magnetically controlled tablets.
31. Assessment of tablet quality: appearance, deviation from the average weight, dosage accuracy, quantitative content of active substances, disintegration, solubility, crushing and abrasion resistance. Control devices (rotating baskets, HNDKFI device, Stokes device, etc.).
32. Medical capsules. Microcapsules. Types of medical capsules. Assortment. Excipients in the production of gelatin capsules. Methods of obtaining: immersion ("wetting"), pressing, drop method.
33. Disintegration, solubility, strength and thickness of shells, speed and completeness of drug release from capsules. Factors affecting the bioavailability of medicinal substances. Rectal, vaginal capsules. Tubatins. Prospects for the development of capsules. Packaging.
34. Microencapsulation of medicinal products. Methods of obtaining microcapsules. Prospects for the development of technology Microencapsulation of drugs.
35. Plasters. Mustard plasters. Characteristics. Classification. Production technology. Equipment: reactors, USPL-I installations, chamber-loop dryer, etc. Lead, composite, epilin, resin-wax, rubber, elastic adhesive plaster, smeared, bactericidal, corn, pepper, liquid (cleol, collodion, BF-6 glue, colaplast, microplast, furoplast, Novikov liquid, corn liquid).
36. Features of the manufacture of ophthalmic, nasal and ear medicines, requirements for them, quality control according to the State Federal University and types of packaging.
37. Mustard plasters. Technology of mustard plasters. Packaging. Storage.
38. Rectal dosage forms. Characteristics of suppositories. Equipment for the production and packaging of suppositories: Franco-Crespi (Italy), line of the company "Haefliger and Karg", "Sarong200S" (Germany). Standardization. Nomenclature. Storage.
39. Aerosols. Characteristics. Classification. Inhalation aerosols. Composition and principle of operation of the aerosol can.
40. Types of aerosol systems. Characteristics of the contents of the aerosol can. Compositions released from the package in the form of foam (aqueous-alcoholic, non-aqueous foams). Excipients for obtaining aerosols (solvents, solubilizers, surfactants, film-forming agents, etc.), propellants.
41. Ways to improve aerosol packaging. Modern systems of aerosol preparations.
42. Methods of filling aerosol cans (under pressure and at low temperature). Quality assessment: strength and tightness of packaging. Accuracy of dosage of contents. Qualitative and quantitative composition. Prospects for the development of pharmaceutical aerosols. Nomenclature. Ingalipt. Cameton. Proposol. Legrazol. Nitazol. Neotizol. Lifuzol. Transportation and storage of medical aerosols.

43. Sterile and aseptically manufactured dosage forms. Injection solutions in ampoules. Factory-produced drugs prepared under aseptic conditions. Dosage forms for injections: solutions in ampoules, suspensions, emulsions, powders, tablets.
44. Requirements for dosage forms for injections: absence of mechanical inclusions, sterility, pyrogenicity, stability, etc. Sources of contamination of injection solutions. Cleanliness classes of premises. Requirements for personnel, overalls, equipment.
45. Solvents. Obtaining water for injection in factory conditions. Distillation devices. Demineralized water. Methods of obtaining: electrodialysis, ion exchange, reverse osmosis. Use of demineralized water. Factory devices for its obtaining. Non-aqueous solvents. Fatty oils and requirements for them. Preparation of vegetable oils. Alcohols, esters, amides.
46. Materials for the manufacture of ampoules and vials. Glass. Obtaining, technical requirements for it. Classes of glass. Research on the chemical and thermal stability of ampoules. Use of polymer packaging materials, syringe tubes.
47. Filtering materials. Filtering devices (fungus filters, KhNDKHFI, Salnikov, Seitz). Metal, ceramic, glass, fluoroplastic membrane filters. Sterilization by filtration.
48. Filling ampoules. Vacuum, syringe, steam condensation methods, their features and disadvantages. Filling devices. Sealing ampoules, linear and rotary machines. Sealing in a stream of inert gases. Sealing quality control.
49. Methods of sterilization of solutions in ampoules. Thermal sterilization. Steam sterilization under pressure. Radiation and cryoradiation sterilization. Control of sterilization mode. Checking tightness.
50. Quality assessment of finished products. Concept of sterile batch. Control of sterility and pyrogenicity, pH of the medium, quantitative content of active substances, purity. Labeling and packaging of ampoules. Automatic packaging machines. Problems of complex mechanization and automation of ampoule production. Creation of production lines.
51. Features of manufacturing in factory conditions of solutions of glucose, calcium chloride, magnesium sulfate, ascorbic acid, hexamethylenetetramine, ergot, euphylline, oil solutions of camphor, hormones, their analogues.
52. Ophthalmic dosage forms. Features of the technology of ophthalmic dosage forms of factory production. Eye drops. Aqueous solutions. Oil solutions. Suspensions. Nomenclature: solutions of atropine sulfate, sodium sulfacyl, pilocarpine hydrochloride, scopolamine hydrochloride, ascorbic acid, phosphacol and others.
53. Biotechnology in the manufacture of medicines. Biotechnology, its place in the development of scientific and technological progress in medicine and pharmacy. Modern directions of manufacturing medicines based on biotechnology.
54. Packaging of finished dosage forms. Packaging materials. Containers. Filling of dosage forms.
55. State standards for containers and packaging materials. Modern range of containers and packaging materials used in the pharmaceutical industry.
56. Prospects for the development of dosage form technology. Main directions of the development of dosage form technology. Systems with controlled release of active substances. Multilayer tablets, microcapsules, microdrages. Immobilized drugs: enzymes, hormones, mucopolysaccharides, iron-derived dextrans, albumins, γ-globulins, nucleic acids, interferons.
57. Suspensions. Emulsions. Ointments. Methods of industrial production of suspensions, emulsions, ointments. Mixing of phases. Grinding in a liquid medium. Grinding using ultrasound. Equipment.
58. Bases for ointments and excipients used in their industrial production. Prospects for the development of production and scientific research of ointments. Production of ointments in the conditions of pharmaceutical enterprises.
59. Features of obtaining modern nano- and radiopharmaceuticals, their role and place in modern

pharmacy and medicine.

List of practical skills, the mastery of which is monitored during the exam:

1. Determine the disintegration of tablets.
2. Make a working recipe to obtain a given number (20) of ampoules of a certain capacity (1 ml) of a 20% solution of camphor in oil.
3. Check the injection solution in ampoules for the absence of mechanical inclusions.
4. Make a working recipe to obtain a given number (1000 ampoules) and a given concentration (20%, ampoule 1 ml) of a solution of caffeine-sodium benzoate.
5. Prepare 250 ml of a solution of caffeine-sodium benzoate. The analysis showed that the solution contains 21% of the drug. How much water is needed to obtain a 20% solution?
6. Prepare 250 ml of a solution of caffeine-sodium benzoate. The analysis showed that the solution contains 19% of the drug. How much caffeine-sodium benzoate should be added to obtain a 20% solution?
7. Determine the content of ethyl alcohol in the alcohol-water mixture using a glass alcoholmeter.
8. Make a working recipe and prepare a solution of 36 sulfacyl-sodium 30% in 5 and 10 ml eye drops in bottles.
9. Prepare 5- and 10-ml drops of a 1% pilocarpine hydrochloride solution with methylcellulose in bottles.
10. Make and test a lily of the valley tincture.
11. Make and test a calendula tincture
12. Make 100 ml of coriander fruit water by steam distillation.
13. Prepare 20 kg of 52% alcohol from 96.6%.
14. Prepare and test sugar syrup.
15. Make a material balance equation, determine the yield, consumption, and consumption coefficient. To make the norms of consumption for obtaining 100 g of the finished product, if during the manufacture of sodium chloride salt instead of 100 g 99.7 g of the finished product were obtained.
16. Protocol for grinding solids in a ball mill.
17. Prepare a complex licorice powder. 18. Grind 10 kg of rowan berries and fill in the working recipe. 19. Determine the shape, size, nature of the surface of the powder.
18. Determine the fractional composition of the powder.
19. Calculate the working recipe for the manufacture of 100 kg of acetylsalicylic acid tablets of 0.5, the average weight of the tablets is 0.55. K(vitr) = 1.05.
20. Determine the amount of starch for the production of 200,000 phenobarbital tablets of 0.1 g each, with an average weight of 0.2 g (sugar 0.08, talc 0.0036).
21. Determine the compression of tablets.
22. Determine the force of pushing tablets out of the matrix.
23. Draw up a production schedule for the production of streptocide tablets.
24. Coat amitriptyline tablets by the suspension dragee method.
25. Produce Hexavit dragees.
26. Apply an enteric-coated film coating to the tablets.
27. Produce plantaglucid granules.
28. Determine the abrasion resistance of tablets.

12. RECOMMENDED LITERATURE

Basic:

1. Zujkina S.S. The pharmacotechnological studies of the phytopecies composition for the complex therapy of mastopathy / S.S. Zujkina, L.I. Vishnevska // Вісник фармації. – 2017. – № 2 (90). – С. 43- 47.

2. Industrial technology of medicines: a basic textbook for students. Higher. uch. pharmacy. institutions (pharmac. f-tiv) / E.V. Gladuh, A.A. Ruban, I.V. Saiko and others. - H .: NUPh: Original, 2016. - 632p. : To them. - (National Textbook Series).
3. Excipients in the manufacture of drugs: textbook. way. for students. higher pharmacy. textbook lock / OA Ruban, IM Pertsev, SA Kutsenko, YS Masliy; for order. IM Pertsev. - H .: Golden Pages, 2016. - 720 p.
4. Modern pharmaceutical technologies: textbook. way. to laboratory classes of full-time, part-time and part-time undergraduates majoring in 8.110201 "Pharmacy" / ed. O. A. Ruban. - H .: NUPh Publishing House, 2016. - 256 p.

Additional:

1. Guidelines to prepare for the final module control and state attestation on the discipline "Chemist's Teclmology of Drugs": for English students of specialty “Pharmacy”: Reference edition. For individual student's work. Yamykh. T. G. Rukhmakova O. A.. Buryak M. V. and otliers. - Kliarkiv: NUPh. 2014. - p 48.
2. Industrial Drug Technology : Tutorial for Laboratory Classes for Students of Speciality “Pharm acy” / Yu. V. Yudina, Yu. V. Shmyrova, S. V. Stepanenko [et al].— Kharkiv : NUPh : Original, 2012. — 254 p.
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