MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Faculty pharmaceutical
Department pharmaceutical technology of drugs

PHARMACEUTICAL DRUG TECHNOLOGY

(the name of educational component)

WORK PROGRAM
of educational component

training __second master's level_____
(name of higher education level)

in specialty __ 226 Pharmacy, industrial pharmacy_____
(code and specialty name)

field of knowledge __ 22 Public Health_____
(code and name of field of knowledge)

of educational program_ Pharmacy (for foreign students)_____
(name of educational program)

in specialization(s)_____
(name of specialization, if available)

Kharkiv-2023
(Year of creation)

The work program of the educational component «Pharmaceutical Drug Technology» in specialty 226 Pharmacy, industrial pharmacy of the educational program Pharmacy (for foreign students) Phm (4,10d) engl. for applicants for higher education 3rd year.

EDUCATIONAL COURSE TEAM:

VYSHNEVSKA Liliia, head of the pharmaceutical technology of drugs department, doctor of pharm. sc., prof. of a higher education institution
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(specify the LAST NAME, first name of the authors, their positions, scientific degrees and academic titles)

Work program has been considered and approved at the Department meeting Technology of Drugs
Record from of September 1, 2023 No. 1

Head of the department_____ prof. Liliia VYSHNEVSKA

Work program has been approved at the meeting of the Methodical Commission of technological disciplines
Record from of September 1, 2023 No. 1

/Head of the specialized commission _____ prof. Olena RUBAN

1. Description of the educational component

Language of study: English

Status of the educational component: obligatory

Prerequisites for studying the educational component: The educational component is based on the study of physics, general and inorganic chemistry, physical and colloidal chemistry, biology with the basics of genetics.

Educational component is the basis for the study of medical and pharmaceutical commodity science, good practices in pharmacy, pharmaceutical chemistry, management and marketing in pharmacy, biopharmacy, standardization of medicines, what foresees integration of teaching with these educational components and forming of abilities to apply knowledge from «Pharmaceutical Drug Technology» in the process of subsequent studies and in professional activity; educational component lays the foundation for vocational training, promotes the formation of the technical and pharmaceutical thinking required for the pharmaceutical specialty; together with other pharmaceutical educational components and social sciences, drug technology plays an important role in providing special technological training for professional activities.

The subject of educational component study of compulsory educational component «Pharmaceutical Drug Technology» is the main ideas and trends of the development of pharmaceutical technology in the countries of the world and in Ukraine; retention of modern principles of normative documentation and technologies of pharmaceutical production in various forms with the use of new groups of auxiliary substances and modern types of equipment in pharmacy conditions.

Information content of the educational component. 270 hours of 9.0 ECTS credits are allocated to the study of the educational component .

2. Objectives and tasks of the educational component

The purpose of teaching the educational component «Pharmaceutical Drug Technology» is to acquire higher education students theoretical foundations and practical abilities and skills of manufacturing drugs in the conditions of pharmacies, taking into account the requirements of proper pharmacy practice; rules for drawing up technological documentation for the manufacture of medicinal products, rules for their storage and packaging; acquisition of knowledge on the characteristics, classification and assortment of ready-made medicinal forms; the formation of theoretical knowledge and professional skills among students of higher education by studying the influence of excipients on the quality of medicinal products, which makes it possible to more fully realize the scientific and creative potential of future specialists. Mastering the theory and practice of manufacturing medicinal forms is necessary for a specialist to perform the duties of a specialist, which is provided for by the legal and procedural legislation and the relevant order of the Ministry of Health of Ukraine.

The main tasks of the educational component «Pharmaceutical Drug Technology» are:

- retention of the requirements of the current normative documents (State Pharmacopoeia of Ukraine, Good Pharmacy Practice (GPP) and current Orders) to the organization of production activities of pharmacy in the manufacture of medicinal products in various pharmaceutical forms;
- use in the professional activity of normative and legal acts of Ukraine, requirements of GPP for the manufacture of medicines in pharmacy;
- formation of knowledge by applicants of higher education from: the theoretical foundations of the technology various types of medical forms, the conduct of stage-by-stage control, ways of improving the technology of medical forms in the pharmacy conditions;
- studying the effects of storage conditions and the type of packaging on the stability of the dosage forms.

3. Competence and planned educational outcomes

Educational component «Pharmaceutical Drug Technology» ensures the acquisition of applicants for higher education the following **competences**:

• *integral:*

the ability to solve typical and complex specialized tasks and practical problems in professional pharmaceutical activity with the application of provisions, theories and methods of fundamental, chemical, technological, biomedical and socio-economic sciences; integrate knowledge and solve complex issues, formulate judgments based on insufficient or limited information; clearly and unambiguously convey their conclusions and knowledge, rationally justifying them, to a professional and non-specialist audience.

• *general competences:*

GC 6. Knowledge and understanding of the subject area and understanding of professional activity.

GC 11. Ability to evaluate and ensure the quality of performed works.

• *professional competences:*

PC 14. The ability to organize and carry out the production activities of pharmacies for the manufacture of medicinal products in various dosage forms according to the prescriptions of doctors and orders of medical institutions, including the justification of technology and the selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).

Integrative final *program learning outcomes* (PLO), the formation of which is facilitated by the educational component:

PLO 2. To apply knowledge of general and professional disciplines in professional activities.

PLO 3. To adhere to the norms of sanitary and hygienic regime and safety requirements in carrying out professional activities.

PLO 4. To demonstrate the ability to independently search, analyze and synthesize information from various sources and use these results to solve typical and complex specialized tasks of professional activity.

PLO 26. To choose rational technology, to make medicines in various dosage forms according to the prescriptions of doctors and orders of medical institutions, to issue them before release. To perform technological operations: weigh, measure, dose a variety of medications by weight, volume, etc. To develop and draw up technological documentation for the manufacture of medicines in pharmacies.

As a result of studying the educational component, the applicant for higher education will be

know:

• modern requirements of normative documentation which regulating technology and quality control of extemporal drugs in Ukraine and abroad;

• characteristics and classification of dosage forms as disperse systems;

• theoretical base of technology by various medical forms;

• rules of rational technology of solid, liquid, soft, sterile and aseptic medicinal forms;

• the influence of physical and chemical properties of medicinal substances on the technology of extemporal solid, liquid, soft, sterile and aseptic medicinal forms,

• assortment and characteristic of the auxiliary substances and it used in the technology of extemporal drugs;

• assortment and principles of the use of modern labour saving tools;

• control of the quality of medical forms;

• stability of extemporal drugs (types, factors influencing the stability of medicinal products);

• types and tasks of documentation for the preparation of medicines in pharmacies;

• the procedure for working with computer programs on the technology of extemporal formulation.

be able to:

• use regulatory documents for regulating technology and quality control of extemporal drugs in Ukraine and abroad;

• choose the rational technology of preparation of solid, liquid, soft, aseptic medicinal forms, using the necessary equipment, computer programs on the technology of the extemporal formulation;

• to determine the modes of sterilization of medicinal forms taking into account the physical and chemical properties and stability of medicinal substances;

• to conduct production documentation of the technological process;

• to making out technological instructions on extemporal prescriptions of medicines, taking into account the physical and chemical properties of the ingredients.

possess:

- *practical skills in the preparation of solid, liquid, soft, aseptic medicinal forms, using the necessary equipment, computer programs on the technology of extemporal medicines.*

4. The educational component structure

Names of content modules and topics	The amount of hours					
	Ph(4,10d)engl					
	the whole amount	including				
		l.	sem	Practical lessons	lab	self-study
1	*2*	*3*	*4*	*5*	*6*	*7*
Module 1. General questions of drug technology. Solid and liquid dosage forms.						
Content module 1. General questions of drug technology. Powders. Species.						
Topic 1. General questions of drug technology. State control over the production of drugs.	9	1			4	4
Topic 2. Preparation of simple and complex powders with drugs, different in prescribed quantity, bulk weight and structure of the particles in pharmacy conditions.	8.25	0.25			4	4
Topic. 3. Preparation of complex powders with poisonous and strong-effective substances. Triturations.	8.25	0.25			4	4
Topic 4. Preparation of complex powders with dyeing, aromatic and poorly powdered substances.	8.25	0.25			4	4
Topic 5. Preparation of complex powders with extracts and semi-finished products.	8.25	0.25			4	4
Topic 6. Preparation of species in pharmacies.	4					4
Topic 7. Module control CM 1 on the topic “General questions of drug technology. Powders. Species”.	8				4	4
The whole amount of hours for the content module 1	54	2			24	28
Content module 2. Liquid dosage forms.						
Topic 8. Preparation of concentrated solutions.	8.5	0.5			4	4
Topic 9. Preparation of liquid dosage forms by mass-volume method by dissolution of dry medicinal substances and use of concentrated solutions.	8.5	0.5			4	4
Topic 10. Special cases of preparation aqueous solutions. Drops.	8.5	0.5			4	4
Topic 11. Preparation of liquid dosage forms by diluting of the standard pharmacopoeian liquids. Non-aqueous solutions.	8.5	0.5			4	4
Topic 12. Solutions of HMC. Colloidal solutions.	9	1			4	4
Topic 13. Suspensions.	13	1			8	4
Topic 14. Emulsions.	13	1			8	4
Topic 15. Infusions and decoctions of medicinal plant raw material.	8.5	0.5			4	4
Topic 16. Infusions and decoctions from extracts concentrates. Mucilages.	8.5	0.5			4	4
Topic 17. Module control of CM 2 on the topic "Liquid dosage forms".	6				2	4
The whole amount of hours for the content module 2	90	6			44	40
Semester credit of module 1.	4				2	2
The whole amount of hours module 1.	150	8			72	70

Module 2. Soft dosage forms. Suppositories. Medicinal forms requiring aseptic preparation conditions						
Content module 3. Soft dosage forms. Suppositories.						
Topic 18. Liniments and homogeneous ointments.	6.5	0.5			3	3
Topic 19. Ointments suspension and ointment-emulsion.	9.5	0.5			6	3
Topic 20. Combined ointments. Creams. Gels.	7	1			3	3
Topic 21. Preparation of suppositories by rolling method.	6.5	0.5			3	3
Topic 22. Preparation of suppositories by casting method.	9.5	0.5			6	3
Topic 23. Module control CM 3 on the topic «Soft dosage forms and suppositories».	7	-			3	4
The whole amount of hours for the content module 3	46	3			24	19
Content module 4. Dosage forms required aseptic conditions of preparation.						
Topic 24. Requirements for the preparation of sterile and aseptic medicines in pharmacy conditions.	5.5	0.5			3	2
Topic 25. Solutions for injections.	5.5	0.5			3	2
Topic 26. Solutions for injections required stabilization.	5.5	0.5			3	2
Topic 27. Isotonic and infusion solutions. Solutions for injections with thermolabile substances. Suspensions for injection.	5.5	0.5			3	2
Topic 28. Ophthalmic dosage forms. Dosage forms with antibiotics.	7	2			3	2
Topic 29. Medicinal forms for infants and children under 1 year of age. Radiopharmaceuticals. Geriatric drugs.	2,5	0,5			-	2
Topic 30. Difficult cases of medicines preparation. Incompatibilities.	8.5	0.5			6	2
Topic 31. Module control CM 4 on the topic «Dosage forms required aseptic conditions of preparation»	4	-			3	1
The whole amount of hours for the content module 4	44	5			24	15
Semester credit of module 2.	7,5	-			3	4,5
The whole amount of hours module 2	97.5	8			51	38.5
Semester exam	22.5	-				22.5
The whole amount of hours	270	16			123	131

5. Contents of the educational component

Module 1. General questions of drug technology. Solid and liquid dosage forms.

Content module 1. *«General questions of drug technology. Powders. Species»*

Topic 1. General questions of drug technology. State control over the production of drugs. Dosing in pharmaceutical practice.

Basic pharmaceutical concepts: medicine, pharmacy, biopharmacy, pharmacist, etc. Definition of drug technology as a scientific discipline, its tasks at the modern stage and directions of development. Technological terms: medicinal product, medicinal raw material, medicinal form, medicinal substance, medicinal preparation, etc.

Types of pharmacy regulatory documents (pharmacopoeia, orders, instructions, etc.).

Provisions of good pharmacy practice (GPP)) regarding the manufacture of medicinal products in pharmacy conditions. Requirements of the general article of SPU 5.N.1 "Extemporaneous medicinal products": definition, manufacture, internal pharmacy quality control, packaging, labeling, conditions and storage periods. Requirements of the US Pharmacopoeia and the international PIC/S convention for the preparation of drugs in pharmacies: manufacturing conditions, equipment, stability of drugs, primary packaging.

Requirements of proper pharmacy practice regarding the preparation of non-sterile dosage forms in pharmacies (requirements regarding the technological process, documentation; medicinal and auxiliary substances; packaging; intra-pharmacy quality control of extemporaneous medicinal products).

Stability of extemporaneous medicinal products: definitions, types, factors affecting the stability of medicinal products.

Documentation when preparing drugs in pharmacies, its types and tasks.

Classification of dosage forms: dispersological, by aggregate state, depending on the method of use and routes of administration.

The recipe, its meaning. Recipe structure. Rules for prescribing prescriptions according to regulatory documents (orders of the Ministry of Health of Ukraine). Cases of incorrect prescribing of prescriptions received by pharmacies. Rights and obligations of a pharmacist in relation to incorrectly written prescriptions in accordance with the requirements of the order of the Ministry of Health of Ukraine.

Topic 2. Preparation of simple and complex powders with drugs, different in prescribed quantity, bulk weight and structure of the particles in pharmacy conditions.

Preparation of solid medicinal products in pharmacies in accordance with the requirements of the National Health Service, orders of the Ministry of Health of Ukraine and other regulatory documents (DFU, American pharmacopoeia, PIC/S documents, etc.).

Characteristics of powders as a dosage form, their classification. SPU requirements for powders. Ways of prescribing powders.

General rules and stages of the technological process of preparation of solid dosage forms in pharmacies. Detailing; the main physico-chemical laws that affect the process of refining powder ingredients. The degree of grinding of medicinal substances depends on the medical purpose of the medicinal product.

Factors affecting the order of mixing components in the preparation of complex powders. Rules for preparing complex powders with medicinal substances prescribed in equal and different amounts. Rules for the introduction of medicinal substances with different physical and chemical properties into powders. Technology of powders with ingredients that differ in density, bulk mass, particle structure (amorphous, fine-crystalline, coarse-crystalline) in pharmacies and at enterprises. Rules for the selection of packaging material in accordance with the physical and chemical properties of the powder components. Permissible deviations in the mass of individual doses of powders. Evaluation of the quality of powders in accordance with the requirements of the State Pharmacopoeia and other National Standards for packaging, registration before release, and storage (orders of the Ministry of Health of Ukraine).

Topic. 3. Preparation of complex powders with poisonous and strong-effective substances. Triturations.

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 substances used in the technology of powders and norms of their one-time release. Preparation of complex powders with poisonous, narcotic and potent medicinal substances prescribed in small (less than 0.05) quantities. Characteristics of triturations, their preparation, storage, use for preparation of powders. Quality assessment, packaging, preparation for

release, storage of powders in accordance with the requirements of the State Pharmacopoeia and other NDs (orders of the Ministry of Health of Ukraine).

Topic 4. Preparation of complex powders with dyeing, aromatic and poorly powdered substances.

A list of dyeing and aromatic substances and condition of their storage in obedience to the requirements of order of MH of Ukraine. Peculiarities of powders technology with dyeing substances and sanitary terms of their preparation. Rules of introduction of aromatic substances to the medical forms. List of medicinal substances, which grind down in presence of an auxiliary liquid.

Characteristics of hard gelatine capsules; use cases for packaging powders. Quality control, packaging design to delivery, storage of powders with colouring, aromatic substances and substances that ate ground in dyeing presence of an auxiliary liquid in accordance with - die requirements of State Pharmacopoeia and other regulations (orders of the Ministry of Health of Ukraine).

Topic 5. Preparation of complex powders with extracts and semi-finished products.

Characteristics of the extracts used in powders, their classification according to the SPU. Preparation of solutions of thick extracts, conditions and term of their storage. Features of the technology of complex powders with dry, thick and solutions of thick extracts. The use of semi-finished products for the preparation of complex powders, their advantages. Areas of improvement of powder technology: expansion of the range of semi-finished products; introduction of small mechanization in the process of preparation of powders in pharmacies and mechanization of the processes of mixing and dosing of powders in industrial conditions. Quality assessment, packaging, preparation for release, storage of powders with extracts and semi-finished products in accordance with the requirements of the State Pharmacopoeia and other ND (orders of the Ministry of Health of Ukraine). The main signs of instability of powders.

Topic 6. Preparation of species in pharmacies.

Species: characteristics, classification and methods of their prescription. Stages of the technological process of assembly preparation. Rules for the introduction of different groups of medicinal substances (water-soluble, water-insoluble, essential oils, substances soluble in ethanol) into the composition of the assembly. Technology of metered species. Equipment used in assembly production. Quality assessment, packaging, preparation for release, storage of collections in accordance with the requirements of the State Pharmacopoeia and other ND (orders of the Ministry of Health of Ukraine).

Topic 7. Module control CM 1 on the topic "General questions of drug technology. Powders. Species".

The module control of the CM 1 is carried out in order to verify the level of assimilation of theoretical material. Theoretical knowledge is controlled through a test questionnaire and work on individual cards.

Content module 2. *«Liquid dosage forms»*

Topic 8. Preparation of concentrated solutions.

Characteristics of solutions, as disperse systems, their classification. Obtaining of purified water in pharmacies and at enterprises. Requirements relating to purified water in accordance with the norms 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 preparation of concentrated solutions in different ways: using the measuring tableware; taking into account the coefficient of volume increase (CVI); taking into account the density of the solution. Rules for the preparation of concentrated solutions for the burette system in accordance with the order of the Ministry of Health of Ukraine. Deviations permissible in the total volume of liquid dosage forms. Control of quality of concentrated solutions, conditions of their storage and keeping records of

prepared solutions according to orders of the Ministry of Health of Ukraine. The structure of the burette system, the rules of care and use of it.

Topic 9. Preparation of liquid dosage forms by mass-volume method by dissolution of dry medicinal substances and use of concentrated solutions.

Characteristics of liquid dosage forms as disperse systems, their classification, requirements to them. Solubility of medicinal substances as one of the basic physical and chemical characteristics necessary for the preparation of solutions. Ways of prescribing and indicating concentration of solutions. Checking of doses of poisonous and strong-effective substances in medicines. Rules for the preparation of liquid medicinal forms using concentrated solutions in accordance with the instruction on the preparation of liquid dosage forms in pharmacies, approved by the order of the Ministry of Health of Ukraine. Preparation of solutions containing up to 3 % and more than 3 % of dry medicinal substances, concentrated solutions of which are absent. Adding to solutions of syrups, aromatic waters, galenic medicines, etc. Evaluation of quality, packaging, preparation for dispensing, storage of liquid medicines in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 10. Special cases of preparation aqueous solutions. Drops.

Definition of difficult prescriptions and ways to eliminate difficulties. Types of difficult cases of preparation of aqueous solutions, which are most often encountered in pharmacies: slow and heavy dissolution or insolubility of medicinal substances in the prescribed solvent; decomposition of substances that are easily oxidized; deterioration of solubility in a coherent presence. Special technological techniques to overcome the difficulty in preparing solutions: preliminary grinding of substances and the use of a heated solvent; the use of crossed-out purified water and the corresponding auxiliary materials; addition of adjuvants and use of complex formation in the preparation of solutions; soluble dissolution.

Characteristics of drops as dosage forms, their classification by method of application. Checking of doses of poisonous and strong-effective substances in drops. Rules for preparing drops using concentrated solutions and by dissolving dry substances. Creation of eutectic mixes. Preparation of drops in non-aqueous solvents in pharmacies and at enterprises. Evaluation of quality, packaging, preparation for dispensing, storage of aqueous solutions and drops in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 11. Preparation of liquid dosage forms by diluting of the standard pharmacopoeian liquids. Non-aqueous solutions.

Nomenclature of standard pharmacopoeian liquids; their concentrations, chemical and conventional names. Preparation of solutions of pharmacopoeian liquids (the rules for calculating the amount of water and pharmacopoeian liquids depending on the prescribing method), according to the order of the Ministry of Health of Ukraine.

Characteristics of non-aqueous solvents (ethyl alcohol, vegetable oils, vaseline oil, glycerol, chloroform, polyethylene oxide-400, etc.), requirements to them. Calculations for the dilution of ethyl alcohol using the formula for dilution and alcohol test tables. Preparation of solutions on volatile and non-volatile solvents in pharmacies. Safety rules for work with flammable and explosive solvents. Evaluation of quality, packaging, preparation for dispensing, storage of non-aqueous solutions in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 12. Solutions of HMC. Colloidal solutions.

Characteristics of HMC, their classification and application in pharmacy. Influence of the structure of HMC on the dissolution process of limited and unlimited swollen substances. Features

of preparation of solutions of pepsin, gelatine, starch, methylcellulose, sodium carboxymethylcellulose, plant extracts. Characteristics and properties of colloidal solutions. Technology of solutions of protected colloids (collargol, protargol, ichthyol). Rules for the addition of medicinal substances to solutions of HMC and protected colloids. The main signs of instability of solutions of HMC and colloidal solutions. Evaluation of quality and storage of solutions of HMC and colloids, registration for dispensing in accordance with the requirements of orders of the Ministry of Health of Ukraine.

Topic 13. Suspensions.

Characteristics of suspensions as dosage form and disperse system; requirements for them. Cases of formation of suspensions. Factors influencing the stability of heterogeneous systems. The Stokes law. Solubilisation, its use in pharmaceutical technology. The technology of suspensions of hydrophilic and hydrophobic substances: the use of the effect of P. A. Rebinder and the rule of B. V. Deryagin. Dispersion method for preparing suspensions with hydrophilic medicinal substances. The essence of method of taking muddy. Characteristics of stabilizers and the mechanism of their action. Condensation method for the preparation of suspensions (chemical dispersion, solvent exchange). Opalescent and turbid mixtures. The main signs of instability of suspensions. Evaluation of quality, packaging, preparation for dispensing, storage of suspensions in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 14. Emulsions.

Characteristics of emulsions as dosage forms and disperse system, their classification. Requirements of the State Pharmacopoeia to oil emulsions. Types of oil emulsions and methods of their determination. Characteristics of emulsifiers, their classification and the mechanism of action. General rules and methods for preparation oil emulsions. Calculation of the amount of emulsifier, water and oil. Stages of the process of preparation emulsions. Introduction of medicinal substances with different physical and chemical properties to the composition of oil emulsions. Features of the introduction of phenyl salicylate and sulfanilamide's. Main signs of instability of emulsions. Evaluation of quality and storage of emulsions, packaging, preparation for dispensing in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 15. Infusions and decoctions of medicinal plant raw material.

Characteristics of infusions and decoctionsas a dosage form and disperse system. Ways of prescribing infusions and decoctions. Theoretical bases of the process of extraction from medicinal plant raw materials. Factors influencing the extraction process (the relation between the quantity of raw material and the extractant, standardity, the histological structure and the degree of substrate of the raw material, the material of the infuser, the temperature, the duration of infusing and cooling, the pH of the medium, the chemical composition, etc.). Rules for the preparation of infusions and decoctionsfrom plant raw materials and the addition of medicinal substances to them in accordance with the requirements of the State Pharmacopoeia. Equipment used for the preparation of infusions and decoctions. Features of preparation of water extracts from medicinal plant raw materials containing alkaloids, cardio glycosides, essential oils, tannins, anthracene derivatives, saponins, etc. Special cases of preparation of infusions and decoctions("double" infusions, decoctionsof Senna leaves, etc.). Authors' prescriptions of water extracts (Deryagin, Qvater, Ravkin's mixtures, etc.). Evaluation of quality, storage of water extracts, storage and registration of them for dispensing in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 16. Infusions and decoctions from extracts concentrates. Mucilages.

Characteristics of standardized extracts-concentrates for the preparation of infusions and decoctions, their nomenclature. Advantages of their application in the technology of water extracts. Rules for the preparation of water extracts with the use of extracts-concentrates and the introduction of various therapeutic agents in them. Features of the preparation of water extracts from raw materials containing mucus (althea root, flaxseed, etc.) and the addition of various medicinal substances to them. Evaluation of quality and storage of water extracts in accordance with the requirements of regulatory documents, packaging and registration for dispensing (orders of the Ministry of Health of Ukraine). Areas of improvement of technology of water extracts.

Topic 17. Module control of CM 2 on the topic "Liquid dosage forms".

The module control of the CM 2 is carried out in order to verify the level of assimilation of theoretical material. Theoretical knowledge is controlled through a test questionnaire and work on individual cards.

Semester credit of module 1.

Summarizing the results of studying the module, increasing the rating if desired, and filling out reporting documentation.

Module 2. Soft dosage forms and suppositories. Medicinal forms requiring aseptic preparation conditions

Content module 3. *«Soft dosage forms and suppositories»*

Topic 18. Liniments and homogeneous ointments.

Characteristics of liniments as dosage forms and disperse systems; their classification depending on the nature of the dispersion medium, the physical and chemical properties of the ingredients and medical purpose. Rules for preparation liniments of various types of disperse systems: solutions, suspensions, emulsions, combined. Pharmacopoeia prescriptions and difficult cases of preparation liniments, their technology. Characteristics of ointments as dosage forms and disperse systems, their classification (by medical purpose, place of application, consistency and physical and chemical properties of medicinal substances that are part of ointments), requirements of the State Pharmacopoeia to them. Requirements for ointment bases, their classification. List of ointment bases that are recommended by SPU, principles of their selection. Characteristics of hydrophobic and hydrophilic bases. The main technological steps and rules for the preparation of homogeneous ointments such as solutions, alloys. Pharmacopoeian prescriptions of ointment-solutions. Evaluation of quality and storage of liniments and ointments in accordance with the requirements of normative documents, packaging and preparation for dispensing (orders of the Ministry of Health of Ukraine).

Topic 19. Ointments suspension and ointment-emulsion.

Characteristics of diphilic (hydrophilic-lipophilic) ointment bases and emulsifiers for their preparation. Characteristics of ointments-suspension (triturational) and their technology depending on the percentage of medicinal substances. Officinal prescriptions of ointments-suspensions. Features of introduction in dermatological ointment resorcinol and zinc sulfate. Pastes, their classification. Features of preparation dermatological pastes. Characteristics of ointments-emulsions of different types and their preparation, depending on the properties of medicinal and auxiliary substances. Features of the composition and technology of cooling ointments. Rules for introducing protargol, tannin and vegetable extracts of different consistency in the ointment. Evaluation of quality of diphilic ointments, storage and preparation for dispensing in accordance with the requirements of the State Pharmacopoeia, other normative documents (orders of the Ministry of Health of Ukraine).

Topic 20. Combined ointments. Creams. Gels.

Characteristics of combined ointments and general rules of their preparation. Stages of technological process of preparation of combined ointments taking into account physical and

chemical properties of medicinal substances. Preparation of ointments using intra-pharmacy products (concentrates and semi-finished products). Methods of quality control of combined ointments, their storage and preparation for dispensing according to the requirements of the State Pharmacopoeia, other normative documents (orders of the Ministry of Health of Ukraine). The main signs of instability in ointments. Directions of perfection of ointments and liniments of extemporaneous preparation. Characteristics of creams and gels, general rules for its preparation.

Topic 21. Preparation of suppositories by rolling method.

Characteristics of suppositories as dosage forms and as disperse systems. Classification of suppositories. Requirements of the State Pharmacopoeia to them. Methods of prescribing suppositories; checking of doses of poisonous and strong-effective medicinal substances in them. Pharmacopoeian prescriptions and difficult cases of preparation of suppositories, their technology. Bases for suppositories; the requirements imposed on them, and a brief description. Features of prescribing sticks and calculating the base for them. Characteristics of technological stages of preparation of suppositories by the rolling method. Rules for the introduction of medicinal substances with different physical and chemical properties in the bases; features of the administration of protargol, collargol, tannin, dry and dense extracts. Methods of evaluating the quality of suppositories, packaging, registration for dispensing, rules for storage in compliance with the requirements of normative documents, relevant instructions (orders of the Ministry of Health of Ukraine).

Topic 22. Preparation of suppositories by casting method.

Bases for suppositories used in the preparation of suppositories by the casting method; the requirements put forward to them, and a brief description. Calculations of the quantity of suppository bases for the preparation of suppositories by the pouring method. The notion of replacement coefficient. Characteristics of technological stages of preparation of suppositories by the pouring method. Rules for the introduction of medicinal substances with different physical and chemical properties in the bases when using the pouring method. Main signs of instabilities of suppositories. Evaluation of quality of suppositories, packaging, preparation for dispensing, storage conditions in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

Topic 23. Module control CM 3 on the topic «Soft dosage forms and suppositories».

The module control of the CM 3 is carried out in order to verify the level of assimilation of theoretical material. Theoretical knowledge is controlled through a test questionnaire and work on individual cards.

Content module 4. «*Dosage forms required aseptic conditions of preparation.»*

Topic 24. Requirements for the preparation of sterile and aseptic medicines in pharmacy conditions.

Requirements of GPP for preparation of sterile and aseptic dosage forms in pharmacies. Aseptic conditions for the preparation of medicines. The procedure for monitoring compliance with the sanitary-and-epidemic regime in pharmacies. Requirements for premises, equipment and sanitary-hygienic requirements for the preparation of medicinal products in aseptic conditions. Requirements for personal hygiene of the staff of pharmacy establishments, which prepare medicines in aseptic conditions. Characteristics of solvents used for the preparation of injectable dosage forms. Obtaining, storing and controlling quality of water for injection. Requirements for medicinal and auxiliary substances used for preparation medicines in aseptic conditions. Non-aqueous solvents. Fatty oils, requirements for them and preparation for use.

Requirements for packaging materials used for the preparation of medicines in aseptic conditions. Classification of sterilization methods. Thermal sterilization methods and equipment used for this purpose. The procedure for controlling the temperature regimes of sterilizers. Sterilization modes of individual objects and the order of registration of results of sterilization in corresponding journals. Requirements for quality control of sterile and aseptic dosage forms. Types of documentation that is being prepared for the preparation of individual and serially prepared medicines (general technological instructions, technological instructions for individual and serial medicines, production records).

Topic 25. Solutions for injections.

Characteristics of injectable dosage forms; the requirements put forward to them by the State Pharmacopoeia and their realization. Technological stages of preparation of solutions for injections. Filtration of solutions and check them for no mechanical impurities. Progressive quality control of solutions for injection, corking, registration for dispensing and storage in accordance with the requirements of the State Pharmacopoeia and in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

Topic 26. Solutions for injections required stabilization.

Causes of destruction (decomposition) of medicinal substances in solutions for injections. Characteristics of stabilizers used for the preparation of solutionsfor injections; their classification. The principles of the selection of stabilizers and the calculation of their quantity. Stabilization of solutions of medicinal substances, which are supported by hydrolysis. Antioxidants, their classification. Stabilization of solutions of substances that are easily oxidized. Features of preparation of solutions for injections of glucose and sodium hydrocarbonate. Evaluation of quality of solutions for injections, corking, registration for dispensing and storage in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

Topic 27. Isotonic and infusion solutions. Solutions for injections with thermolabile substances. Suspensions for injection.

The value of isotonating of solutions for injections. Methods for calculating isotonic concentrations (using equivalents for sodium chloride). Principles of choosing of isotonating substances. Infusion (physiological) solutions; requirements of the State Pharmacopoeia and other normative documents to them. Classification of solutions for infusion for their medical purpose and composition. The nomenclature of the most commonly used plasma replacement and anti-shock solutions in the form of ready-prepared dosage forms of industrial production. Features of the technology of solutions for infusion, depending on the composition of active substances. Rules for preparing solutions for injections with thermolabile substances and suspensions for injections. Emulsions for parenteral nutrition. The main signs of instability of solutions, suspensions and emulsions for injections. Evaluation of quality of solutions, suspensions and emulsions for injection, corking, registration for dispensing and storage in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

Topic 28. Ophthalmic dosage forms. Dosage forms with antibiotics.

Characteristics of medical forms used for the treatment of ophthalmic diseases; requirements to them in accordance with the state control system. Isotonating of eye drops, lotions, and washes. Prolonging the effect of eye drops. Ensuring the stability of eye drops, assortment of preservatives. Features of the technology of eye drops, depending on the physical and chemical properties of medicinal substances. Rules for preparation lotions and washings. Characteristics of the bases used for the preparation of eye ointments. The technology of eye ointments and the peculiarities of introducing zinc sulfate and resorcinol in it. Characteristics of dosage forms with antibiotics; the requirements put forward to them and factors influencing their stability. Features of the technology

of liquid and solid dosage forms with antibiotics (lotions, washes, rinses, eye and ears drops, etc.). Technology of ointments and suppositories with antibiotics; characteristics of the bases for their preparation. Evaluation of quality of ophthalmic dosage forms and dosageforms with antibiotics, corking, registration for dispensing and storage in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

Topic 29. Medicinal forms for infants and children under 1 year of age. Radiopharmaceuticals. Geriatric drugs.

Characteristics of dosage forms for infants and children under 1 year of age; requirements for them. Features of preparation of liquid dosage forms, powders, suppositories, ointments for infants and children under 1 year of age, capping, preparation for release and storage in accordance with the requirements of the ND. Assessment of the quality of dosage forms for newborns and children under 1 year of age.

Topic 30. Internal pharmacy preparations. medicines made "for stock". Incompatibilities.

Definition and types of in-pharmacy preparations (IPP) according to the Federal Drug Administration. Application of IPP in the technology of solid, liquid, soft, sterile and aseptic dosage forms. Semi-finished products. Definition, preparation conditions. Testing, labeling, terms and conditions of storage. Medicinal products manufactured "for stock". Definition, nomenclature, labeling, storage terms and conditions. Functions and duties of a pharmacist for preparing IPP. Technological instruction. Requirements of the SPU to its structure. Cases of incorrect prescribing of prescriptions received by pharmacies (overdosing, lack of seals, prescribing in a non-Latin language, incorrect medical purpose, etc.). Rights and obligations of a pharmacist in relation to incorrectly written prescriptions in accordance with the requirements of the order of the Ministry of Health of Ukraine. Causes of physical and physicochemical incompatibilities. Classification of chemical incompatibilities according to the types of reactions taking place and their manifestation during the interaction of the ingredients of dosage forms. Characteristics of pharmacological incompatibilities. Types of antagonism. "Conditional" incompatibilities, their medical application.

Topic 31. Module control CM 4 on the topic «Dosage forms required aseptic conditions of preparation»

The module control of the CM 4 is carried out in order to verify the level of assimilation of theoretical material. Theoretical knowledge is controlled through a test questionnaire and work on individual cards.

Semester credit of module 2

Summarizing the results of studying the module, increasing the rating if desired, and filling out reporting documentation.

Semester exam

Exam is conducted with the aim of verification of level of mastering of theoretical material from educational component. Conducted in the volume of educational material certain an on-line tutorial, and in the terms set by a curriculum. Examination is conducted in writing. Every student gets a card with 60 test questions of theoretical orientation and to 1 situational tasks.

6. Topics of lectures

№ s/n	Name of topic	Volume in hours
		Ph(4,10d)engl
1	General issues of drug technology. State control over the production of medicinal products.	1
2	Preparation in the conditions of pharmacies of simple and complex powders with medicinal substances that differ in the prescribed amount, bulk mass and structure	0.25

3	Preparation of complex powders with poisonous and potent substances. Trituration.	0.25
4	Technology of powders with dyeing, aromatic and poorly powdered substances	0.25
5	Preparation of complex powders with extracts and semi-finished products. Preparation of species in pharmacies.	0.25
6	Preparation of concentrated solutions.	0.5
7	Technology of mixtures by dissolving dry medicinal substances and use of concentrated solutions.	0.5
8	Special cases of aqueous solutions preparation. Drops.	0.5
9	Preparation of liquid dosage forms by diluting standard pharmacopeia liquids. Pharmacy preparation of non-aqueous solutions.	0.5
10	Technology of high molecular compounds (HMC) solutions and colloidal solutions.	1
11	Suspensions	1
12	Emulsions	1
13	Technology of aqueous extracts from medicinal plant raw material.	0.5
14	Technology of aqueous extracts from extracts – concentrates. Mucus.	0.5
15	Technology of liniments and homogeneous ointments.	0.5
16	Technology of heterogeneous ointments.	0.5
17	Technology of combined ointments.	1
18	Technology of suppositories by rolling method	0.5
19	Technology of suppositories by casting method.	0.5
20	Modern requirements to the preparation medicines for parenteral application in pharmacies.	0.5
21	Technology of solutions for injections.	0.5
22	Technology of solutions for injections required stabilization.	0.5
23	Technology of isotonic solutions. Technology of infusion solutions. Technology of solutions for injections with thermolabile substances. Suspensions for injections.	0.5
24	Ophthalmological dosage forms. Medicinal forms with antibiotics.	2
25	Medicinal forms for infants and children under 1 year of age.	0.5
26	Internal pharmacy preparations. Medicines made "for stock". Incompatibilities.	0.5
	Total hours	**16**

7. Topics of seminars

Not provided by the curriculum**.**

8. Topics of practical lessons

Not provided by the curriculum**.**

9. Topics of laboratorial lessons

№ s/n	**Name of topic**	**Volume in hours**
		Ph(4,10d)engl
1	General questions of drug technology. State control over the production of drugs.	4
2	Preparation of simple and complex powders with drugs, different in prescribed quantity, bulk weight and structure of the particles in pharmacy conditions.	4
3	Preparation of complex powders with poisonous and strong-effective substances. Triturations.	4
4	Preparation of complex powders with dyeing, aromatic and poorly powdered substances.	4

5	Preparation of complex powders with extracts and semi-finished products.	4
6	Module control CM 1 on the topic “General questions of drug technology. Powders. Species”.	4
7	Preparation of concentrated solutions.	4
8	Preparation of liquid dosage forms by mass-volume method by dissolution of dry medicinal substances and use of concentrated solutions.	4
9	Special cases of preparation aqueous solutions. Drops.	4
10	Preparation of liquid dosage forms by diluting of the standard pharmacopoeian liquids. Non-aqueous solutions.	4
11	Technology of HMC solution and colloidal solutions.	4
12	Suspensions	8
13	Emulsions	8
14	Technology of aqueous extracts from medicinal plant raw material.	4
15	Technology of aqueous extracts from extracts – concentrates. Mucus.	4
16	Module control of CM 2 on the topic "Liquid dosage forms".	2
17	Semester credit of module 1.	2
18	Technology of liniments and homogeneous ointments.	3
19	Technology of heterogeneous ointments.	6
20	Technology of combined ointments.	3
21	Technology of suppositories by rolling method	3
22	Technology of suppositories by casting method.	6
23	Module control CM 3 on the topic «Soft dosage forms and suppositories».	3
24	Modern requirements to the preparation medicines for parenteral application in pharmacies.	3
25	Technology of solutions for injections.	3
26	Technology of solutions for injections required stabilization.	3
27	Isotonic and infusion solutions. Solutions for injections with thermolabile substances. Suspensions for injection.	3
28	Technology of ophthalmic medicines. Technology of medicinal forms with antibiotics.	3
29	Internal pharmacy preparations. Medicines made "for stock". Incompatibilities.	6
30	Module control CM 4 on the topic «Dosage forms required aseptic conditions of preparation»	3
31	Semester credit of module 2.	3
	The whole amount of hours	123

10. Self-study work

№ s/n	**Name of topic**	**Volume in hours** **Ph(4,10d)engl**
1	**General issues of drug technology. State control over the production of medicinal products.** Types of pharmacy regulatory documents (pharmacopoeia, orders, instructions, etc.). Requirements of proper pharmacy practice regarding the preparation of non-sterile dosage forms in pharmacies (requirements regarding the technological process, documentation; medicinal and auxiliary substances; packaging; intra-pharmacy quality control of extemporaneous medicinal products). Classification of dosage forms: dispersological, by aggregate state, depending on the method of use and routes of administration. The recipe, its meaning. Recipe structure. Rules for prescribing prescriptions according to regulatory documents (orders of the Ministry of Health of Ukraine).	4

2	**Preparation in the conditions of pharmacies of simple and complex powders with medicinal substances that differ in the prescribed amount, bulk mass and structure of particles.** Detailing; the main physico-chemical laws that affect the process of refining powder ingredients. The degree of grinding of medicinal substances depends on the medical purpose of the medicinal product. Modern means of small mechanization in the preparation of solid dosage forms in pharmacies.	4
3	**Preparation of complex powders with poisonous and potent substances. Triturations.** 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.	4
4	**Preparation of complex powders with colored, fragrant and hard-to-grind substances.** The list of coloring and odorous substances and their storage conditions according to the requirements of the order of the Ministry of Health of Ukraine. Characteristics of hard gelatin capsules; cases of their use for packaging powders.	8
5	**Preparation of complex powders with extracts and semi-finished products.** Characteristics of the extracts used in powders, their classification according to the DFU. Preparation of solutions of thick extracts, conditions and term of its storage.	4
6	**Preparation of species in pharmacies.** Medicinal herbal teas: definition, characteristics, application. Briquettes: definition, characteristics	4
7	**Control of content module 1 on the topic: "General issues of drug technology. Powders. Species".** Preparation for modular control on the topic: "General issues of drug technology. Powders. Species".	4
8	**Preparation of concentrated solutions.** Obtaining purified water in pharmacies and enterprises. Requirements for purified water in accordance with the norms established by the State Pharmacopoeia, instructions for the orders of the Ministry of Health of Ukraine Structure of the burette system, rules for its care and use	4
9	**Preparation of liquid medicinal forms by mass-volume method by dissolving dry medicinal substances and using concentrated solutions.** Solubility of medicinal substances as one of the main physico-chemical characteristics necessary for the preparation of solutions. Methods of prescribing and indicating concentrations of solutions.	4
10	**Special cases of preparation of aqueous solutions. Drops.** Preparation of drops using non-aqueous solvents in pharmacies and enterprises.	4
11	**Preparation of liquid dosage forms by diluting standard pharmacopoeial liquids. Non-aqueous solutions.** Production of standard pharmacopoeial liquids in industrial conditions. Characteristics of non-aqueous solvents (ethyl alcohol, vegetable oils, petroleum jelly, glycerin, chloroform, esilones, dimexide, polyethylene oxide-400), requirements for them. Safety rules for working with flammable and explosive solvents.	4
12	**Solutions of high molecular compounds (HMC), colloidal solutions.**	4

	Fields of application of HMC in pharmacy. Sedimentation, aggregative and thermodynamic stability characterizing the physicochemical stability of solutions of protected colloids	
13	**Suspensions**. A modern assortment of suspension stabilizers. Sedimentation, aggregative and thermodynamic stability characterizing the physico-chemical suspension. Stokes formula. Factors affecting the bioavailability of medicinal substances from suspensions.	4
14	**Emulsions**. Evaluation of the quality of emulsions: absence of mechanical impurities, delamination, deviation in the total mass, etc. Packaging and storage conditions Prospects for the development and improvement of emulsion technology: expansion of the range of emulsifiers, introduction of small mechanization tools, instrumental methods of quality assessment, etc.	4
15	**Infusions and decoctions from medicinal plant raw materials.** Theoretical bases of the extraction process: desorption, dissolution, leaching, diffusion, osmosis. Use of the basic provisions of the theory of molecular and convective diffusion in the extraction process. Factors affecting the quality of water extracts.	4
16	**Infusions and decoctions from extracts-concentrates. Mucus.** Nomenclature of thick, dry and liquid extracts. Production methods (remaceration, percolation, repercolation, countercurrent and circulation extraction, ultrasonic and turboextraction).	4
17	**Control of content module 2 on the topic "Liquid dosage forms".** Preparation for modular control on the topic "Liquid dosage forms".	4
18	**Semester evaluation of module 1** Preparation for the semester assessment of module 1	2
19	**Liniments and ointments are homogeneous.** Requirements for ointment bases, their classification. The list of ointment bases recommended by the SPU, the principles of their selection. Characteristics of hydrophobic and hydrophilic bases.	3
20	**Suspension and emulsion ointments.** Characteristics of diphilic (hydrophilic-lipophilic) ointment bases and emulsifiers for their preparation. Official prescriptions for suspension ointments. Features of the composition and technology of cooling ointments (cold creams).	3
21	**Combined ointments. Creams. Gels.** The principle of selection of bases taking into account the medical purpose of ointments. Methods of quality control of combined ointments, their storage and preparation before release in accordance with the requirements of the State Pharmacopoeia, other regulatory documents (orders of the Ministry of Health of Ukraine). Directions for improvement of ointments and liniments of extemporaneous preparation. Features of the technology of creams and gels.	3
22	**Preparation of suppositories by pumping method** Bases for suppositories; requirements for them and a brief description. Peculiarities of prescribing sticks and calculating the base for them. Methods of 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).	3
23	**Preparation of suppositories by pouring method.** Comparative assessment of suppository preparation methods (pumping, pouring, pressing). Biopharmaceutical aspects of suppositories, principles of selection of excipients for their	4

	preparation. Assessment of the quality of suppositories, packaging, registration before release, storage conditions in accordance with the requirements of regulatory documents (orders of the Ministry of Health of Ukraine). Excipients used in pill technology, their characteristics (thick and dry extracts, powders, starch-sugar mixture, bentonites, etc.). The principle of their selection depends on the chemical nature of medicinal substances	
24	**Control of content module 3 on the topics "Soft dosage forms. Suppositories".** Preparation for modular control. Requirements for the manufacture of sterile and aseptic medicinal products in pharmacies.	2
25	**Obtaining, storing and quality control of water for injections.** Classification of sterilization methods. Thermal methods of sterilization and the equipment used for this purpose. The procedure for controlling the temperature regimes of sterilizers	2
26	**Solutions for injections** Filtering solutions and checking them for the absence of mechanical impurities.	2
27	**Solutions for injections that require stabilization.** Characteristics of stabilizers used for the preparation of injection solutions; their classification. Antioxidants, their classification.	2
28	**Isotonic and infusion solutions. Solutions for injections with thermolabile substances. Suspensions for injections.** Principles of selection of isotonic substances and general technological methods of preparation of isotonic solutions. Nomenclature of the most frequently used plasma-substituting and anti-shock solutions in the form of ready-made medicinal forms.	4
29	**Ophthalmological dosage forms. Medicinal forms with antibiotics.** Prolongation of the effect of eye drops. Rules for preparing eye lotions and washes. Assessment of the quality of ophthalmic dosage forms and dosage forms with antibiotics, capping, preparation for release and storage.	2
30	**Medicinal forms for newborns and children under 1 year of age. Radiopharmaceuticals. Geriatric drugs.** Characteristics of medicinal forms for children. Requirements for dosage forms for newborns. Features of the technology of geriatric and radiopharmaceutical drugs.	2
31	**Internal pharmacy preparations. Medicines made "for stock". Incompatibilities.** Semi-finished products. Definition, preparation conditions. Testing, labeling, terms and conditions of storage.	2
32	**Control of content module 4 on the topic "Medicinal forms requiring aseptic preparation conditions".** Preparation for modular control	2
33	**Semester evaluation of module 2.** Preparation for the semester assessment of module 2.	1
34	Exam Preparation for the exam (theoretical questions).	22,5
	The whole amount of hours	131

Tasks for Self-study work

1. To learn the modern requirements of regulatory documentation regulating the technology and quality control of extemporaneous medicinal products in Ukraine and abroad.
2. Learn the influence of the physicochemical properties of medicinal substances on the technology of extemporaneous solid, liquid, soft, sterile and aseptic medicinal forms, as well as suppositories.

3. Learn the rules of rational technology of solid, liquid, soft, aseptic dosage forms, suppositories, using the necessary equipment.
4. Learn how to work with computer programs on the technology of extemporaneous formulation;
5. Learn the rules for selecting auxiliary substances (stabilizers, emulsifiers, extenders, ointment and suppository bases, etc.) for the preparation and extension of the shelf life of medicinal products.
6. To master the definition of sterilization modes of medicinal products, taking into account the physical and chemical properties of medicinal substances.
7. Learn the procedure for keeping production documentation of the technological process.
8. Compile technological instructions for extemporaneous prescriptions of drugs and prescriptions of "reserve" drugs, taking into account the physical and chemical properties of the ingredients and the available equipment.

11. Criteria and evaluation order of educational outcomes

Criteria for assessing the knowledge and skills of higher education graduates from the educational component "Pharmaceutical Drug Technology" are developed in accordance with the "Regulations on the procedure for assessing students' knowledge in the credit-module organization of the educational process at NUPh".

Assessment of the student's progress in the educational component is a rating, exhibited on a 100-points scale and has a definition for the ECTS system and according to the traditional scale adopted in Ukraine.

Assessments (in points) are reflected in the calendar-thematic plans of laboratory classes.

The number of points that a student receives in a laboratory session ranges from 2.5 to 4.0.

Evaluation criteria	**Points**
theoretical training: • showed comprehensive and profound knowledge of theoretical material on the subject of the lesson, as set forth in the textbook, lectures and additional literature; • flawlessly fulfilled a written homework; • correctly responded to 5 test questions with the entrance control knowledge; • gave comprehensive answers to the teacher's theoretical questions; ***practical training:*** • without making mistakes, he wrote a prescription in accordance with the current NTD; • gave a detailed description of the medicinal form taking into account the physical-chemical properties of the medicinal substances; • properly prepared a workplace (picking up, weight, measuring devices, utensils, auxiliary material, etc.); • without errors made calculations on the reverse side of the written control passport (WCP); • correctly prepared the medicinal product, following the pharmaceutical procedure and sanitary regime in his workplace; • packaged and dispatched a medicinal product in accordance with applicable requirements; • handed over to the teacher for inspection the flawlessly prescribed medical form with the necessary documentation (WCP).	3,6–4,0
theoretical training: • showed complete knowledge of the theoretical material on the subject of	3,0–3,5

• the lesson laid down in the textbook and lectures; • has done a written homework without errors; • answered a theoretical questions of the teacher with minor disadvantages; • correctly responded to 4 test questions at the entrance control of • knowledge; ***practical training:*** • without making mistakes, he wrote a prescription in accordance with the • current one; • gave the incomplete characteristic of the medicinal form; • prepared his workplace with errors (for example, dishwashing	
theoretical training: • showed the knowledge of theoretical material on the topic of the classroom in the amount that is considered necessary and sufficient for the implementation of the practical part of the class; • completed a written homework with errors; • answered theoretical questions with errors that were eliminated with the help of a teacher; • correctly responded to 3 test questions at the entrance control of knowledge; ***practical training:*** • mistakes were made when prescribing the prescription form in accordance with the current NTD; • gave a description of a medicinal form that does not reflect the characteristics of medicinal substances; • prepared a workplace with errors (for example, dishwashing • inappropriately selected, etc.); • without errors made calculations on the reverse side of the control passport; properly prepared the drug, but the technology is irrational and without theoretical substantiation; • suggests errors in the compliance with the pharmaceutical procedures and sanitary regimes in their workplace (for example, they do not lose ground before work, etc.); • packaged and issued a misplaced drug for delivery (the technological order of ingredients in the control passport is not up to date, not all the labels are glued, etc.); • handed out to the teacher a checked dosses with the necessary documentation (a prescription and a passport of written control).	2,6–2,9
theoretical training: did not fulfil a written homework; did not get acquainted with the theoretical material on the subject of the lesson laid down in the textbook and lectures; did not answer the teacher's theoretical questions; answered correctly on 1-2 test questions, or did not respond at all at the entrance control of knowledge; ***practical training:*** made gross mistakes in prescribing of the prescription; did not give a description of the drug; prepared his workplace with errors; calculations on the back of the control panel are made with errors; chose the wrong technology of the drug and did not give her theoretical substantiation.	0–2,5

Independent work of the applicants of higher education is monitored during each laboratory lesson, during the control of the content module.

In the event that the AHE came to the class unprepared, he must be present at the class. After working with the electronic study guide for independent work on the Technology of pharmaceutical production drugs and an individual conversation with the teacher on the topic of the lesson, the student is admitted to practical work.

Control of mastering content modules is carried out in the last classes of studying the topics of content modules. The means of diagnosing students' knowledge are test control with the help of a computer program, 2 calculation problems and a recipe prescription. Only those students who have completed all types of work provided by the curriculum (worked out, missed practical classes, etc.)

Control of CM 1 is carried out in order to check the level of assimilation of theoretical material and practical skills. Theoretical knowledge is monitored by means of a test control using a computer program, solving 2 calculation problems and a recipe prescription. Control of practical skills is carried out by preparing medicines according to an individual prescription and drawing up the relevant documentation.

Control of CM 2 is carried out in order to check the level of assimilation of theoretical material and practical skills. Theoretical knowledge is monitored by means of a test control using a computer program, solving 2 calculation problems and a recipe prescription. Control of practical skills is carried out by preparing medicines according to an individual prescription and drawing up the relevant documentation.

Control of CM 3 is carried out in order to check the level of assimilation of theoretical material and practical skills. Theoretical knowledge is monitored by means of a test control using a computer program, solving 2 calculation problems and a recipe prescription. Control of practical skills is carried out by preparing medicines according to an individual prescription and drawing up the relevant documentation.

Control of CM 4 is carried out in order to check the level of assimilation of theoretical material and practical skills. Theoretical knowledge is monitored by means of a test control using a computer program, solving 2 calculation problems and a recipe prescription. Control of practical skills is carried out by preparing medicines according to an individual prescription and drawing up the relevant documentation.

Ticket structure:

• an individual prescription, according to which the ZVO must describe and produce an extemporaneous medicinal product;

• 2 calculation tasks;

• 60 tests using a computer program.

Evaluation criteria	**Points**
	10,0–16,0
Individual prescription, according to which ZVO must describe and manufacture an extemporaneous medicinal product; • wrote out a prescription without errors according to the current ND; • gave a detailed description of the medicinal product taking into account the physico-chemical properties of medicinal substances; • correctly prepared his workplace (picked up weighing devices, utensils, auxiliary material, etc.); • performed calculations on the reverse side of the written control passport without	15,0 –16,0

errors; • correctly prepared the medicinal product, observing the pharmaceutical order and sanitary regime in his workplace; • packaged and processed the medicinal product before release in accordance with current requirements; handed over to the teacher for inspection an impeccably prepared medicinal product with the necessary documentation (prescription and WCP). **Calculation tasks** • Correctly solved calculation problems with an explanation of the sequence of actions **Tests** Answered 90-100% of test questions	
Individual prescription, according to which AHE must describe and manufacture an extemporaneous medicinal product; • issued a prescription without errors according to the current one; • gave an incomplete description of the medicinal product; • prepared his workplace with errors (for example, irrationally selected dishes, etc.); • performed calculations on the reverse side of the WCP without errors; • correctly prepared the medicinal product with minor errors in compliance with the pharmaceutical order and sanitary regime in his workplace (for example, he did not wipe the scales before work, etc.); • packaged and issued a medicinal product with minor errors (carelessly pasted labels or signature, etc.); handed over the prepared medicinal product with the necessary documentation (prescription and WCP) to the teacher for verification. **Calculation tasks** • Correctly solved calculation problems without explaining the sequence of actions **Tests** • Answered 82-89% of test questions	13,0-14,0
Individual prescription, according to which ZVO must describe and manufacture an extemporaneous medicinal product; • mistakes were made when writing a prescription according to the current ND; • gave a description of the medicinal product that does not reflect the characteristics of the medicinal product; • prepared his workplace with errors (for example, irrationally selected dishes, etc.); • performed calculations on the reverse side of the PPK without errors; • correctly prepared the medicinal product, but the technology is irrational and without theoretical justification; • made mistakes in compliance with the pharmaceutical order and sanitary regime in his workplace (for example, did not wipe the scales before work, etc.); • packaged and processed a medicinal product with errors before release (the technological order of the ingredients in the PPK was not met, not all labels were pasted, etc.); • submitted the prepared medicinal product with the necessary documentation (prescription and passport of written control) to the teacher for verification. **Calculation tasks** • Solved one of the two calculation problems incompletely without explaining the sequence of actions **Tests** Answered 64-81% of test questions	12,0–13,0
Individual prescription, according to which ZVO must describe and manufacture an extemporaneous medicinal product; • mistakes were made when writing a prescription according to the current ND; • did not give a description of the medicinal product; • prepared his workplace with errors (for example, irrationally selected dishes, etc.); • performed calculations on the reverse side of the PPK without errors; • correctly prepared the medicinal product, but the technology is irrational and without theoretical justification; • made mistakes in compliance with the pharmaceutical order and sanitary regime	10,0–12,0

in his workplace (for example, did not wipe the scales before work, etc.); • packaged and processed a medicinal product with errors before release (the technological order of the ingredients in the PPK was not met, not all labels were pasted, etc.); • submitted the prepared medicinal product with the necessary documentation (prescription and passport of written control) to the teacher for verification. **Calculation tasks** Solved one of the two calculation problems incompletely without explaining the sequence of actions **Tests** Answered 60-63% of test questions	
Individual prescription, according to which AHE must describe and produce an extemporaneous medicinal product; • made gross mistakes when writing a prescription; • did not give a description of the medicinal product; • prepared his workplace with errors; • calculations on the reverse side of the PPK are made with errors; • chose the wrong drug technology and did not provide its theoretical justification. **Calculation tasks** • Did not solve any of the proposed calculation problems **Tests** • Answered less than 60% of test questions	lesser 10

The sum of points for the study of CM is the sum of the points received by the student during the study of all topics of the content module.

Semester evaluation of module is conducted by summarizing the module study results, increasing the rating if desired and filling out the reporting documentation.

The semester exam is conducted in writing. Each student must answer 60 test problems of a theoretical orientation, 1 situational problem and a calculation problem. The situational task is estimated at 50 points, the calculation task - 20 points, each correct answer to the test - 0.5 points.

The evaluation of the student's success in the discipline is a rating, is presented on a one-point scale and is defined according to the ECTS system and the traditional scale adopted in Ukraine.

12. Forms of current and final control of study success.

Evaluation of the current educational activity (carried out during each class) - test control, control of theoretical knowledge (survey), control of practical skills and abilities. When mastering each topic of the content modules for the current educational activity of the ZVO, points are awarded for all types of activities, which are summed up at the end of studying the content module.

Control of mastering content modules is carried out in the last classes of studying the topics of content modules. The means of diagnosing students' knowledge are test control with the help of a computer program, the solution of calculation problems and the manufacture of extemporaneous medicinal products according to an individual prescription.

Semester control is carried out in the form of a semester credit in the last classes.

The semester exam is conducted in order to check the level of assimilation of the theoretical material of the discipline. It is carried out in the amount of educational material determined by the educational program and in the terms established by the educational plan. The exam is conducted in writing.

13. Methodological support

1. Educational work program.
2.Calendar plan of lectures and practical classes
3.Textbook
4.Tutorials
5. Electronic study guide
6. Distance course
7. Multimedia texts of lectures
8. Video films
9.Methodical recommendations for AHE classwork.
10.Methodical recommendations for individual and out of class work of students.
11. Methodological recommendations for preparation for the final module control.
12.Methodological support from the control of students' knowledge (control tasks and tests), criteria and evaluation order of educational, reference of answers:

- Examination papers pack to the control thematic modules;
- Examination papers pack to the comprehensive test.
- Semester exam papers pack

13. Tests to determine the basic, current and final level of knowledge. A set of situational problems for classes.
14. Educational equipment, technical teaching aids.

14. Reading suggestions

The main reading suggestions

1.Pharmacy — based technology of drugs : the manual for applicants of higher education / O. I. Tykhonov , T. G. Yarnykh, O. A. Rukhmakova, G. B. Yuryeva; ed. by O. I. Tykhonov and T. G. Yarnykh. - Kharkiv : NUPh : Golden Pages, 2019. - 488 p.

2.Workbook for Pharmacy-based Technology of Drugs: A tutorial for the 3-rd year English-speaking applicants of higher education of "Pharmacy" specialty / T. G. Yarnykh, O. I. Tykhonov, O. A. Rukhmakova, M. V. Buryak, V. V. Kovalyov, I. V. Herasymova – Kh.: NUPh, 2019. – 149 p.

3.Workbook for preparation to the licensed examination "KROK-2" in pharmacy-based technology of drugs: for English-speaking applicants of higher education of specialty "Pharmacy": Practical aids. For individual work / T. G. Yarnykh, O. A. Rukhmakova, V. V. Kovalyov, M. V. Buryak – Kh.: NUPh, 2017. – 56 p.

4.Tests. Pharmacy-based technology of drugs: A handbook for the out-of-classwork of English applicants/ T. G. Yarnykh, O. I. Tykhonov, O. A. Rukhmakova, G. B. Yuryeva, M. V. Buryak, V.V.; ed. by T.G. Yarnykh. – Kh.: NUPh, 2019. – 156 p.

5. Аптечна технологія ліків : підруч. для студентів вищ. навч. закл. О. І. Тихонов, Т. Г. Ярних. 5-е вид. Вінниця : Нова кн., 2016. 536 с., іл.

6. Аптечна технологія ліків: метод. рек. для самостійної роботи здобувачів вищої освіти спеціальності «Фармація, промислова фармація» денної та заочної форми навчання / Половко Н. П. [та ін.]. – Х.: Вид-во НФаУ, 2018. – 72 с.

7. Аптечна технологія ліків: метод. рек. до лабораторних занять з дисципліни «Технологія ліків». Модуль «Аптечна технологія ліків» для здобувачів вищої освіти спеціальності «Фармація» денної та заочної форми навчання / Н. П. Половко [та ін.]. – Х.: Вид-во НФаУ, 2018. – 224 с.

8. Еволюція лікарських форм і їх виготовлення: навч. посібник для студентів фармац. фотов вузів МОЗ України / Л.І. Вишневська, Н.П. Половко, Е.В. Семченко, І.В. Герасимова; під ред. Л.І. Вишневської - Х .: Оригінал, 2019. - 336 с.

9. Методичні рекомендації з підготовки до комплексного практично орієнтованого кваліфікаційного іспиту з фармації : метод. рек. Для здобувачів вищої освіти спеціальності 226 Фармація, промислова фармація освітніх програм Фармація, клінічна

фармація / за ред. А. А. Котвіцької. – 2-ге видання, переробл. та доп. Х. : НФаУ, 2022. 38 с.
10. Навчальний посібник з аптечної технології ліків: навч. посібник для здобувачів вищ. освіти спеціальності «226 Фармація, промислова фармація» / Т. Г. Ярних, Л. І. Вишневська, Т. М. Ковальова та ін; під ред. проф. Л. І. Вишневської, Т. Г. Ярних – Х.: Оригінал, 2021. – 119 с. : іл.
11. Практикум для навчальних занять з аптечної технології ліків [Электронный ресурс] : навч. посібник для здобувачів вищої освіти фармацевт. вишів і ф-тів / Л. І. Вишневська [та ін.] ; НФаУ, Каф. АТЛ. - Електрон. текстові дан. - Харків : НФаУ, 2021. - 345 с.
12. Технологія гомогенних рідких лікарських засобів в умовах аптек [Электронный ресурс] : лекція для здобувачів вищої освіти спец."Фармація" : навч. посібник для позааудит. роботи / Л. І. Вишневська [та ін.] ; за ред.: Л. І. Вишневської, Н. П. Половко ; НФаУ, Каф. АТЛ. - Електрон. текстові дан. - Харків : НФаУ, 2021. - 122 с.
13. Технологія лікарських препаратів для парентерального застосування в умовах аптек [Электронный ресурс] : навч. посібник для здобувачів вищої освіти спец."Фармація, промислова фармація" [денної і заоч. форми навчання] / Л. І. Вишневська, Н. П. Половко, К. П. Ромась ; під ред. проф.: Л. І. Вишневської, Н. П. Половко ; НФаУ, Каф. АТЛ. - Електрон. текстові дан. - Харків : НФаУ, 2021. - 124 с.
14. Технологія рідких лікарських засобів на основі гетерогенних систем. Колоїдні розчини. Суспензії: навч. посібник для шукачів вищ. освіти спеціальності «Фармація» фак. по підготовці іноземних громадян / Л. І. Вишневська, Н.П. Половко, Т.Н. Ковальова; під ред. Л. І. Вишневської та Н.П. Половко - Х .: Вид-во НФаУ, 2019. - 40 с .: іл. - (Серія «Бібліотека АТЛ»).
15. Технологія рідких лікарських засобів на основі гетерогенних систем: колоїдні розчини, суспензії: навч. посібник для здобувачів вищ. освіти спеціальності «Фармація» / Л. І. Вишневська, Н.П. Половко, Т.Н. Ковальова; за ред. Л. І. Вишневської та Н.П. Половко - Х.: Вид-во НФаУ, 2022. 80 с.

Supplementary reading suggestions

1. Державна Фармакопея України / ДП «Український науковий фармакопейний центр якості лікарських засобів». 2-ге вид. Харків : ДП «Український науковий фармакопейний центр якості лікарських засобів», 2015. Т. 1. 1128 с.
2. Державна Фармакопея України / ДП «Український науковий фармакопейний центр якості лікарських засобів». 2-ге вид. Харків : ДП «Український науковий фармакопейний центр якості лікарських засобів», 2014. Т. 2. 724 с.
3. Державна Фармакопея України / ДП «Український науковий фармакопейний центр якості лікарських засобів». 2-ге вид. Харків : ДП «Український науковий фармакопейний центр якості лікарських засобів», 2015. Т. 3. 732 с.
4. Про затвердження правил виробництва (виготовлення) лікарських засобів в умовах аптеки : наказ МОЗ України від 17.10.12 р. № 812. Офіційний вісник України. 2012. № 87. 28 с.
5. Стандарт МОЗ України «Вимоги до виготовлення нестерильних лікарськіх ЗАСОБІВ в условиях аптек» СТ-Н МОЗУ 42 - 4.5 до: 2015 // За ред. проф. О. І. Тихонова и проф. Т.Г. Ярних. - Київ, 2015. - 109 с. (Затверджено наказом МОЗ Украіні № 398 від 01.07.2015 р.).
6. Стандарт МОЗ України «Вимоги до виготовлення стерильних и асептичних лікарськіх ЗАСОБІВ в условиях аптек» СТ-Н МОЗУ 42 - 4.6 до: 2015 // За ред. проф. О.І. Тихонова и проф. Т.Г. Ярних. - Київ, 2015. - 76 с. (Затверджено наказом МОЗ України № 398 від 01.07.2015 р.).
7. Вишневська, Л. І. Мистецтво фармацевтичної справи: від витоків до сьогодення. Art of pharmaceutical business: from the origins to the present : [монографія] /Л. І.

Вишневська, Н. П. Половко, К. В. Толочко ; за ред. Л. І. Вишневської. Харків : НФаУ, 2021. 116 с.
8. John F Marriott, Keith A Wilson, Christopher A Langleyv, Dawn Belcher Pharmaceutical Compounding and Dispensing. - Published by the Pharmaceutical Press. – 2010. – 288 p.
9. USP Pharmacists' Pharmacopeia. – II ed. – Rockville. The United State Pharmacopeial, Inc., 2008. – 1519 p.

15. Electronic resources, including the Internet

1. atl.nuph.edu.ua - сайт кафедри аптечної технології ліків
2. Наукова бібліотека НФаУ: Режим доступу:http://dspace.ukrfa.kharkov.ua; http://lib.nuph.edu.ua
3. www.moz.gov.ua - офіційний сайт Міністерства охорони здоров'я України
4. nuph.edu.ua - офіційний сайт Національного фармацевтичного університету
5. library@nuph.edu.ua - сайт бібліотеки НФаУ
6. fp.com.ua - сайт журналу «Фармацевт практик»
7. www.provisor.com.ua - офіційний сайт журналу «Провізор»
8. Компендіум: лікарські препарати. - [Електронний ресурс]. Режим доступу: http://compendium.com.ua/ станом на 10.10.2022 р .
9. Державний реєстр лікарських засобів України. - [Електронний ресурс]. - Режим доступу:http://www.drlz.com.ua/ - станом на 10.09.2022 р