MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Department Technologies of pharmaceutical preparations

INDUSTRIAL TECHNOLOGY OF DRUGS

(the name of educational component)

WORK PROGRAM

of educational component

training for ____**master**_____
(Higher Educational Level Name)
in specialty ____**22 Health**_____
(Code and Specialty Name)
field of knowledge «_**226 Pharmacy for foreign students**_____
(Code and Knowledge Field Name)
of educational program ___**Pharmacy**_____
(Educational Program Name)
in specialization(s)_____
(name of specialization, if available)

Kharkiv-2023
(year of creation)

The work program of the educational component Industrial Technology of Drugs in specialty 226 Pharmacy for foreign students educational program Pharmacy in specialization(s)_____ for applicants for higher education 4th year of study.

EDUCATIONAL COURSE TEAM:

SOLDATOV Dmytro, associate professor, PhD_____

KUKHTENKO Oleksandr, professor, Doctor of Pharmacy_____

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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
Technologies of pharmaceutical preparations

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Record from « 25»_August 2023_____№ 1

Head of the Department _____ prof. Oleksandr KUKHTENKO

(sig.) (first name LAST NAME)

Work program has been approved at the meeting of the Methodical Commission of technological educational components

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Record from « 01»__September 2023_____№ 1

Head of Specialized Committee _____ prof. Olena_RUBAN

(sig) (first name LAST NAME)

1. Description of the educational component

Language of study: English

Status of the educational component: compulsory

Prerequisites for studying the educational component: The teaching of this discipline is preceded by almost all fundamental and professionally oriented general education disciplines (philosophy, general biology with the basics of human physiology, physical and colloidal chemistry, medical botany, pharmacognosy with the basics of biochemistry of medicinal plants, pharmacy drug technology), on the knowledge of which the educational component is based.

The educational component is the basis for the study of medical and pharmaceutical merchandising, proper practices in pharmacy, pharmaceutical chemistry, management and marketing in pharmacy, biopharmacy, standardization of medicinal products, technology of medicinal cosmetics, which involves the integration of teaching with the above-mentioned disciplines for the formation of skills to apply knowledge in the process further education and professional activities.

The educational component lays the foundations of professional training, contributes to the formation of technical and pharmaceutical thinking necessary 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 «Industrial Technology of Drugs» is the main provisions and trends in the development of pharmaceutical technology in the countries of the world and in Ukraine; assimilation of modern principles of regulatory documentation and production technologies of pharmaceuticals in various dosage forms with the use of new groups of excipients and modern types of equipment in industrial conditions.

Information content of the educational component. _7.25_ECTS credit _217.5__hours are assigned to the study of the educational component.

2. Objectives and tasks of the educational component

The purpose of teaching the educational component «Industrial Technology of Drugs**»** is to acquire higher education students the theoretical foundations and practical abilities and skills of manufacturing drugs in the conditions of pharmaceutical enterprises, taking into account the requirements of good manufacturing 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 «Industrial Technology of Drugs» are:

• familiarization with the organization of the production of medicinal products in the conditions of pharmaceutical enterprises, in accordance with the requirements of Good Manufacturing Practice (GMP);

• formation of students of higher education knowledge on: theoretical foundations of the technology of manufacturing various types of dosage forms, conducting step-by-step control, ways of improving the technology of dosage forms in pharmacy and industrial conditions;
• study of the influence of storage conditions and type of packaging on the stability of dosage forms;
• study of industrial equipment, including new 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 raw materials, production facilities and personnel.

3. Competence and planned educational outcomes

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

Soft- skills / General competences (GC):

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

Hard-skills / Professional (special) competences (PC):

PC 15. Ability to organize and participate in the production of medications in the context of pharmaceutical companies, including the selection and justification of the technological process, equipment in accordance with the requirements of Good Manufacturing Practice (GMP) with the appropriate development and design of the necessary documentation. Determine the stability of medications

PC 18. Ability to develop and implement a quality management system for pharmaceutical companies in accordance with the requirements of current Standards, perform quality audits and risk management for the quality of pharmaceutical products.

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

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 5. To position your professional activities and personal qualities in the pharmaceutical labor market; to formulate the purposes of own activity taking into account public and industrial interests.

PLO 7. To perform professional activities using creative methods and approaches.

PLO 27. To substantiate the technology and organize the production of medicines at pharmaceutical enterprises and draw up technological documentation for the production of medicines at pharmaceutical enterprises.

As a result of studying the educational component, the applicant for higher education will be
know:
• basic regulatory and technological documents and GMP requirements for the production of finished medicinal products;
• sections of the technological regulations for the production of pharmaceutical products, production recipes, dossiers of the production site, etc.;
• requirements for the design of technological schemes for the production of medicinal products;
• methods of industrial preparation of medicines in various dosage forms;
• sequence and phasing of the technological process;
• methods of stabilization of medicines;
• technological factors affecting the quality of drugs;

• rules and sequence of drug control, ensuring the release of quality drugs;
• definition, characteristics, requirements for medicinal products, auxiliary substances and materials;
• technological equipment for carrying out operations and stages of the technological process of pharmaceutical production;
• modern appearance of packaging, quality assessment and prospects for further improvement of its manufacturing technology.
be able to:
• draw up technological schemes for the production of medicinal products in accordance with the chosen technology and the requirements of regulatory documentation;
• work independently with special literature;
• conduct scientific research to solve professional tasks;
• work on equipment and apparatus for obtaining finished and intermediate products;
• taking into account the properties of medicinal substances and auxiliary materials, find the optimal version of the technology of preparation of medicinal products;
• to resolve the question of the expediency of using auxiliary substances in the composition of the medicinal product;
• determine the main critical parameters and quality control points of semi-finished products, the most important technological parameters that ensure compliance with the established technological regime;
• taking into account the properties of medicinal substances, find the optimal option for primary packaging;
• draw up the finished medicinal form, intermediate products and product quality results;
• calculate the material balance of individual operations and stages of the technological process of pharmaceutical production;
• navigate in regulatory and production documentation (technological regulations, recipes, technological instructions, protocols, etc.);
• document the implementation of the technological process in relevant journals and documents and formulate conclusions;
• choose the optimal method of packaging medicinal forms;
• determine the causes of defects, based on technological control data, and implement measures to prevent and eliminate defects in accordance with the requirements of technological regulatory documentation.
possess:

• drawing up technological schemes for the production of medicinal products in accordance with the selected technology and the requirements of regulatory documentation;
• independent study of special literature;
• skills of conducting scientific research to solve professional tasks;
• skills to work on equipment and apparatus for obtaining finished and intermediate products;
• taking into account the properties of medicinal substances and auxiliary materials, to have the skills to find the optimal version of the technology of preparation of medicinal products;
• to resolve the question of the expediency of using auxiliary substances in the composition of the medicinal product;
• have the skills to determine the main critical parameters and quality control points of semi-finished products, the most important technological parameters that ensure compliance with the established technological regime;
• taking into account the properties of medicinal substances, to have the skills to find the optimal option of primary packaging;
• to have the skills to design the finished dosage form, intermediate products and product quality results;
• have skills in calculating the material balance of individual operations and stages of the technological process of pharmaceutical production;

• navigate in regulatory and production documentation (technological regulations, recipes, technological instructions, protocols, standards etc.);
• document the implementation of the technological process in relevant journals and documents and formulate conclusions;
• choosing the optimal method of packaging medicinal forms;
• determining the cause of the defect, based on technological control data, and implementing measures to prevent and eliminate the defect in accordance with the requirements of technological regulatory documentation.

4. The educational component structure

Names of content modules and topics	**The amount of hours**											
	full time study						**part time study**					
	the whole amount	**including**					**the whole amount**	**including**				
		l.	**sem**	**Practical lessons**	**lab**	**self-study**		**l.**	**sem.**	**Practical lessons**	**lab.**	**self-study**
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*
Content module 1. Regulatory and technical documentation and production according to GMP. Material balance at the stages of the technological process. Alcoholometry. Production of extraction preparations.												
Topic 1. Regulatory and technical documentation in the production of drugs.	7	1			3	3						
Topic 2. Alcohol measurement. Determination of concentration, dilution and accounting of alcohol use.	8	2			3	3						
Topic 3. The main indicators of the material balance. Grinding, sifting, mixing. Preparation of powders and collections.	7	1			3	3						
Topic 4. Industrial production of tinctures. Intensification of extraction processes.	12	2			6	4						
Topic 5. Production of extraction preparations. Industrial production of liquid extracts.	7	1			3	3						
Topic 6. Production of thick and dry extracts.	11	1			6	4						
Control of CM 1	8				3	5						
The whole amount of hours for the	60	8			27	25						

content module 1												
Content module 2. Industrial production of dosage forms and sterile drugs for parenteral and ophthalmic use												
Topic 7. Basic principles of good manufacturing practice of medicinal products (GMP), requirements for the production of sterile products.	8	2			3	3						
Topic 8. Glass for making ampoules and vials, classes, brands.	7	1			3	3						
Topic 9. Industrial production of solutions for injections. Methods of production of injection solutions and methods of filling ampoules.	8	2			3	3						
Topic 10. Features of the production of solutions for injections that require stabilization.	7	1			3	3						
Topic 11. Production of infusion solutions. Eye medicines.	11	1			6	4						
Topic 12. Control of independent work. Industrial production of nasal and ear medicines.	7	1			3	3						
Control of CM 2	6				3	3						
Semester credit of the module 1: "Production of extractives. Production of parenterals"	6				3	3						
The whole amount of hours for the content module 2	60	8			27	25						
Content module 3. Physico-chemical and pharmaco-technological properties of powders, granules. Production of tablets by the method of direct pressing and with preliminary granulation. Production of coated tablets. Production of medical capsules.												
Topic 13. Physico-chemical and technological properties of powders and granules.	9	1			4	4						

Topic 14. Industrial production of tablets. Industrial production of tablets using preliminary granulation and direct pressing.	9	1			4	4						
Topic 15. Covering tablets with a shell. Types of coating and methods of application. Production of long-acting tablets, excipients.	9	1			4	4						
Topic 16. Production of medical capsules.	9	1			4	4						
Topic 17. Quality control of solid dosage forms.	7	1			4	2						
Control of CM 3	8				4	4						
The whole amount of hours for the content module 3	51	5			24	22						
Content module 4. Production of soft medicines. Ointment Gels. Liniments. Industrial production of suppositories. Medicines under pressure.												
Topic 18. Production of soft medicines. Ointment Gels. Liniments. Ointments, pastes, creams, liniments as a medicinal form.	10	2			4	4						
Topic 19. Industrial production of suppositories. Mustard seeds. Plasters. Skin adhesives. The influence of excipients on the quality of soft drugs. Transdermal therapeutic systems. Suppositories, types and requirements for them.	9	1			4	4						
Topic 20. Production of medicinal products under pressure. Classification of aerosols, advantages and disadvantages.	7	1			2	4						
Topic 21. Industrial production of non-sterile dosage forms. Pharmaceutical solutions. Syrups. Aromatic waters.	7	1			2	4						

Control of CM 4	6				2	4						
Semester credit of the module 2: "Production of solids. Production of semisolids, suppositories, aerosols"	7.5				2	5.5						
The whole amount of hours for the content module 2	46.5	5			16	25.5						
Semester exam	**22.5**					**22.5**						
The whole amount of hours for the course	**240**	**26**			**94**	**120**						

5. Contents of the educational component

Content module 1. Regulatory and technical documentation and production according to GMP. Material balance at the stages of the technological process. Alcoholometry. Production of extraction preparations.

Topic 1. Regulatory and technical documentation in the production of drugs. Packaging and labeling of pharmaceuticals according to GMP. The main activity of the Ministry of Health of Ukraine. Regulatory documents in Ukraine. Basic principles of the registration system. Registration file. Production protocols, validation forms and maps. Pharmaceutical development.

Topic 2. Alcohol measurement. Determination of concentration, dilution and accounting of alcohol use. Methods of ethanol production (from raw materials containing starch, carbohydrates, synthetically). Methods of obtaining absolute ethanol. Basic chemical and physicochemical properties of ethyl alcohol. Determination of concentration, dilution and accounting of alcohol use.

Topic 3. The main indicators of the material balance. Grinding, sifting, mixing. Preparation of powders and collections. The main methods of crushing solid bodies. The degree of crushing of solids. Classification of solid bodies according to the degree of grinding. The influence of the size of particles of solid bodies on the quality of medicinal products. Sifting and mixing of powdered materials.

Topic 4. Industrial production of tinctures. Intensification of extraction processes. Scheme of production, equipment. Description of the technological process. Standardization of tinctures. Theoretical foundations of the extraction process. Recovery of extractants from spent raw materials

Topic 5. Production of extraction preparations. Industrial production of liquid extracts. Methods of intensification of obtaining extracts from plant raw materials. Scheme of production, equipment. Description of the technological process. Standardization of extracts, packaging and storage conditions. Quality control according to SPhU Modern trends in the production of medicines based on biotechnology. . Preparations of biogenic stimulants. Preparations from fresh plants. Medicines from animal raw materials

Topic 6. Production of thick and dry extracts. Methods of purification of thick and dry extracts. Scheme of production, equipment. Description of the technological process. Standardization of extracts, packaging and storage conditions. Problems and tasks of the production of phytochemical preparations and prospects for their development. Concentrated extracts, oil extracts.

Content module 2. Industrial production of dosage forms and sterile drugs for parenteral and ophthalmic use

Topic 7. Basic principles of good manufacturing practice of medicinal products (GMP), requirements for the production of sterile products. Classification of clean rooms, cleanliness classes. The characteristics of injection solutions in ampoules, the requirements of the DFU for them.

Topic 8. Glass for making ampoules and vials, classes, brands. Basic requirements and quality indicators of ampoule glass. Preparation of ampoules for filling.

Topic 9. Industrial production of solutions for injections. Methods of production of injection solutions and methods of filling ampoules. Method of sealing ampoules and determination of tightness. Sterilization of injection solutions, control of their sterility. Quality control of injection solutions, production scheme. The problem of complex mechanization and automation of ampoule production.

Topic 10. Features of the production of solutions for injections that require stabilization. Peculiarities of manufacturing solutions for injections using non-aqueous solvents. Solutions for injections, which are produced in aseptic conditions. Block diagram of production. Description of the technological process. Equipment. Standardization.

Topic 11. Production of infusion solutions. Eye medicines. Classification and requirements for infusion solutions. Prospects for the development of infusion solutions, an assortment of domestic and foreign medicines. Structure of ophthalmic dosage forms. Physico-chemical and biological features of creation, prolongation. The main characteristics of dosage forms for ophthalmology, production methods, equipment, quality control, production schemes of ophthalmic preparations.

Topic 12. Control of independent work. Industrial production of nasal and ear medicines. Characteristics, classification, features of production and application. Excipients, types of packaging.

Content module 3. Physico-chemical and pharmaco-technological properties of powders, granules. Production of tablets by the method of direct pressing and with preliminary granulation. Production of coated tablets. Production of medical capsules.

Topic 13. Physico-chemical and technological properties of powders and granules. Study of physico-chemical and pharmaco-technological properties of powders and granules. Influence of the properties of excipients on the technology of obtaining solid dosage forms.

Topic 14. Industrial production of tablets. Industrial production of tablets using preliminary granulation and direct pressing. Granulation methods. Excipients in the production of tablets. Block diagram of production, equipment.

Topic 15. Covering tablets with a shell. Types of coating and methods of application. Production of long-acting tablets, excipients. Block diagram of the production of coated tablets, equipment.

Topic 16. Production of medical capsules. Definition of capsules as drugs, SPhU requirements for capsules. Types of capsules and their purpose. Auxiliary substances in the production of capsules. Methods of manufacturing soft and hard gelatin capsules, filling them with medicinal substances. Tubatyn Rectal gelatin capsules.

Topic 17. Quality control of solid dosage forms. Quality control of finished products in accordance with the requirements of the SPhU.

Content module 4. Production of soft medicines. Ointment Gels. Liniments. Industrial production of suppositories. Medicines under pressure.

Topic 18. Production of soft medicines. Ointment Gels. Liniments. Ointments, pastes, creams, liniments as a medicinal form. Requirements for ointments, classification of bases and general

requirements. Excipients in the production of soft dosage forms. Quality assessment, packaging and labeling. Advantages and disadvantages gels Block diagrams of the production of soft dosage forms, equipment. Quality control according to SPhU.

Topic 19. Industrial production of suppositories. Mustard seeds. Plasters. Skin adhesives. The influence of excipients on the quality of soft drugs. Transdermal therapeutic systems. Suppositories, types and requirements for them. Characteristics of bases and auxiliary substances. Manufacturing methods. Block diagram of production, equipment, product quality control in accordance with the SPhU.

Topic 20. Production of medicinal products under pressure. Classification of aerosols, advantages and disadvantages. The main components of aerosol packages, types of valve-spraying system, classification of propellants. Production of aerosols, equipment, quality control according to the SPhU.

Topic 21. Industrial production of non-sterile dosage forms. Pharmaceutical solutions. Syrups. Aromatic waters. Characteristic. Classification. Methods of their preparation and cleaning. Apparatus. Radiopharmaceuticals. The main directions of development of the technology of medicinal forms.

Semester credit from the module

Semester exam

6. Topics of lectures

№	Name of topic	The amount of hour	
		full time study	part time study
1	Theoretical basics of grinding, sieving, mixing. Concept of material balance	2	
2	Theoretical foundations of the extraction process. Intensification of extraction processes. Industrial production of tinctures. Recovery of extractants from spent raw materials	2	
3	Industrial production of extracts. Extracts are liquid, thick and dry. Methods of purification of thick and dry extracts. Standardization. Problems and tasks of the production of phytochemical preparations and prospects for their development.	2	
4	Modern requirements for the organization of the production of sterile preparations. Determination of the main indicators of the quality of ampoule glass.	2	
5	Industrial production of solutions for injections. Features of the production of solutions for injections that require stabilization. Peculiarities of manufacturing solutions for injections using non-aqueous solvents. Solutions for injections, which are produced in aseptic conditions.	2	
6	Industrial production of solutions for infusions. Industrial production of eye medicines.	1	
7	Nasal and ear medication/s. Ways of improving the technology of dosage forms for ophthalmology and otolaryngology.	1	
8	Tablets. Classification according to DFU. Definition. Biopharmaceutical aspects of drugs in tablets. theoretical foundations of tableting. Pharmaco-technological properties of powders and granules. Production of tablets by the method of direct pressing. Block diagram of production. Description of the technological process. Equipment. Standardization.	2	
9	Production of tablets with preliminary granulation. Block diagram of production. Description of the technological process. Equipment. Standardization. Excipients. Features of production technology. Marking.	2	

	Packaging.		
10	Production of coated tablets. Gradual control. Trial. Ways of improving the technology of production of prolonged-release tablets.	2	
11	Capsules. Classification of capsules. Definition. Optimization of the composition of capsule shells. Production. Intermediate control. Trial. Improvement of technology. Trial. Improvement of the production of long-acting capsules. Quality control of solid dosage forms. The influence of various factors on the release and bioavailability of medicinal substances from solid medicinal products. Production of microcapsules. Production of microcapsules and medicinal preparations based on microcapsules.	2	
12	Soft medicines for local use. Definition. Classification. Specific requirements. Production. Intermediate control. Trial. Mustard seeds. Plasters. Skin adhesives. The influence of excipients on the quality of soft drugs	2	
13	Rectal drugs. Classification. Production. Intermediate control. Trial. Marking. The main areas of improvement of the technology of rectal products.	2	
14	Theoretical and practical aspects of drug production. Problems of drug improvement and new pharmaceutical technologies. Therapeutic systems and prospects for their development. Industrial production of liposomal preparations. The main directions of development of the technology of medicinal forms.	2	
	The whole amount of hourн	**26**	

7. Topics of seminars

Not provided for in the working curriculum

8. Topics of practical lessons

Not provided for in the working curriculum

9. Topics of laboratorial lessons

№	**Name of topic**	**The amount of hour**	
		full time study	**part time study**
1	Regulatory and technical documentation in the production of GLZ. Packaging and labeling of pharmaceuticals according to GMP. Compilation of the material balance by stages of the technological process. Grinding, sieving, mixing. Technological scheme of production	4	
2	Spiritometry. Methods and devices for determining ethanol concentration. Recovery of extractants from spent raw materials	4	
3	Industrial production of tinctures. Block diagram of production, equipment. Description of the technological process. Standardization of tinctures	4	
4	Extracts. Industrial production of liquid extracts. Block diagram of production, equipment. Description of the technological process. Standardization	4	
5	The extracts are thick and dry. Block diagram of production, equipment.	4	

	Description of the technological process. Methods of purification of thick and dry extracts. Standardization		
6	The extracts are thick and dry. Block diagram of production, equipment. Description of the technological process. Methods of purification of thick and dry extracts. *Control of acquisition of CM 1*	6	
7	Modern requirements for the organization of the production of sterile preparations. Characteristics of the stages of production preparation.	4	
8	Determination of the main indicators of the quality of ampoule glass. Preparation of ampoules for filling.	4	
9	Water treatment. Industrial production of solutions for injections. Description of the technological process. Equipment. Standardization Industrial production of solutions for injections. Features of the production of solutions for injections that require stabilization. Description of the technological process. Equipment. Standardization	6	
10	Peculiarities of manufacturing solutions for injections using non-aqueous solvents. Solutions for injections, which are produced in aseptic conditions. Description of the technological process. Equipment. Standardization	6	
11	Industrial production of solutions for infusions. Features of the industrial technology of ophthalmic dosage forms. Production of eye drops. Block diagram of production. Description of the technological process. Equipment. Standardization.	4	
12	Production of eye drops. Block diagram of production. Description of the technological process. Equipment. Standardization. Ways of improving the technology of dosage forms for ophthalmology and otolaryngology. *Control of acquisition of CM 2* *Control of practical skills*	4	
13	Determination of physico-chemical and technological properties of powders and granules.	4	
14	Production of tablets by the method of direct pressing and with preliminary granulation. Block diagram of production. Description of the technological process. Equipment.	4	
15	Industrial production of coated tablets. Equipment. Production scheme	4	
16	Production of medical capsules. Block diagram of production. Equipment	4	
17	Quality control of solid dosage forms in accordance with RD *Control of acquisition of CM 3*	4	
18	Production of semi-solids. Block diagram of production. Equipment.	4	
19	Mustard seeds. Plasters. Skin adhesives. Manufacturing technology. Requirements for excipients. Equipment. Packaging. Storage conditions.	8	
20	Industrial production of suppositories. Characteristics of bases and auxiliary substances. Block diagram of production. Equipment	4	
21	Production of medicinal products under pressure Industrial production of non-sterile medicinal forms. The main directions of development of the technology of medicinal forms. *Control of the acquisition of CM 4*	4	
	The whole amount of hour	**94**	

10.Self-study work

№	Name of topic	The amount of hours

		full time study	**part time study**
1	The history of the development of industrial production of medicines in Ukraine. Stages of development. Characteristics of ready medicines produced by domestic pharmaceutical enterprises. Creation of new areas of production of ready medicines.	4	
2	Characteristics of the main technological processes and devices for the industrial production of pharmaceuticals. General concepts about machines and devices, automatic lines. Thermal processes in pharmaceutical production. Heating. Evaporation. Drying. Equipment.	4	
3	Concentrated extracts, oil extracts. Manufacturing technology. Equipment. Standardization.	4	
4	Preparations of biogenic stimulants. Chemical nature of biogenic stimulants. Classification. Standardization.	4	
5	Preparations from fresh plants. Methods of obtaining juices from fresh vegetable raw materials. Concentrated juices. Dry juices. Extraction preparations from fresh plants.	4	
6	Medicines from animal raw materials. Assortment. Manufacturing technology. Standardization. Application.	4	
7	Modern trends in the production of medicines based on biotechnology. Microbiological synthesis. Isolation of products of biosynthesis. Methods of purification, concentration. Crystallization and drying of biosynthesis products. Equipment. Standardization.	6	
8	Radiopharmaceuticals.	4	
9	The problem of complex mechanization and automation of ampoule production. Creation of current lines and isolated technologies in the production of parenteral drugs. Prospects for the development of production and scientific research of sterile dosage forms.	4	
10	Promising dosage forms for eye treatment. Eye inserts.	4	
11	Industrial production of nasal and ear medicines. Characteristics, classification, features of production and application. Excipients, types of packaging.	4	
12	Container and packaging of medicines. Classification of containers and packages.	4	
13	Briquetting fees, briquetting technology. Technology of preparation of instant teas. Technological and hardware schemes of production. Types of packing and packing. Prospects for the development of production and scientific research of collections.	7	
14	The effect of excipients on the therapeutic activity of medicinal substances in solid dosage forms.	7	
15	Pharmaceutical solutions. Syrups. Aromatic waters. Characteristic. Classification. Methods of their preparation and cleaning. Apparatus.	7	
16	Medicinal forms of prolonged action. Methods of localization and management of BAR release processes from medicinal products.	7	
17	Emulsions and suspensions. General characteristics and classification of emulsions. Classification of surfactants. Technology of emulsions. Quality assessment. Characteristics and properties of suspensions. Production technology of suspensions. Ways of improving suspension technology.	7	
18	Transdermal therapeutic systems. Technological scheme of production.	7	
19	Production of microcapsules. Production of microcapsules and medicinal preparations based on microcapsules.	7	
20	Industrial production of liposomal preparations. Forecasting the development of the technology of manufacturing medicinal forms.	5,5 2,5	
21	Industrial production of non-sterile dosage forms. Pharmaceutical	7	

	solutions. Syrups. Aromatic waters. Characteristic. Classification. Methods of their preparation and cleaning. Apparatus. Therapeutic systems and prospects for their development. The main directions of development of the technology of medicinal forms.		
	Усього годин	**97,5**	

Tasks for Self-study work

- Master the types of regulatory documents in pharmacy (State Pharmacopoeia of Ukraine, orders of the Ministry of Health of Ukraine, European Pharmacopoeia, standards, instructions, etc.).
- Master the processes of detailing; the main physico-chemical laws that affect the grinding process.
- Learn the nomenclature of dry, thick and liquid extracts. Biopharmaceutical aspects of powders and capsules. The main signs of instability of solid dosage forms.
- To acquire knowledge about medicinal herbal teas: definition, characteristics, requirements of DFU, application. Briquettes: definition, characteristics.
- To learn the concept of solubility of medicinal substances as one of the main physico-chemical characteristics necessary for the preparation of solutions. Solubility parameters of substances in accordance with the requirements of the Federal State of Ukraine.
- To master the modern nomenclature of non-aqueous solvents, the requirements of ND for them.
- To master the characteristics of non-aqueous solvents (ethyl alcohol, vegetable oils, petroleum jelly, glycerin, chloroform, esilones, dimexide, polyethylene oxide-400), requirements for them.
- Master the fields of application of the Navy in pharmacy. The influence of the structure of the Navy on the dissolution process of limited and unlimited swelling substances.
- Learn the modern assortment of suspension stabilizers. Factors affecting the bioavailability of medicinal substances in suspensions.
- Learn the nomenclature and classification of emulsifiers. Selection of emulsifiers and emulsion stabilizers.
- To master the theoretical foundations 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.
- Master the list of ointment bases recommended by the DFU, the principles of their selection.
- Learn the characteristics of emulsion ointments of various types and their production depending on the properties of medicinal and auxiliary substances.
- To master the biopharmaceutical aspects of ointments. The principle of selection of bases taking into account the medical purpose of ointments.
- Learn the peculiarities of manufacturing suppositories.
- Master the assessment of suppository manufacturing methods (pouring, pressing). Biopharmaceutical aspects of suppositories, principles of selection of excipients.
- Master the GRP requirements for the production of sterile products (preparation of the air environment, personnel, clothing, equipment, premises).
- To master the concept of pyrogenicity and methods of achieving it.
- To master the causes of instability of solutions for injections.
- Learn the requirements of isotonicity, isohydry, isoionicity, oxidation-reduction potential of solutions.
- To acquire knowledge about modern types of ophthalmic medicinal forms.
- Learn the characteristics of bases and solvents for dosage forms with antibiotics.
- To acquire knowledge about dosage forms for newborns and children up to 1 year and dosage forms that have advantages in geriatrics.

- To learn general concepts about machines, devices, automatic lines of pharmaceutical technology, their main processes.
- Consider the theoretical foundations of extraction, stages of extraction and their characteristics.
- Familiarize yourself with the factors that affect the completeness and speed of extraction. Types of extractants and their requirements.
- To master the raw materials and methods of ethanol production, the equipment used, requirements for medical ethanol.
- To analyze methods of intensification of the LRS extraction process.
- To master new technologies for the production of phytopreparations.
- Get acquainted with the industrial production of biogenic stimulants. Consider their chemical nature, classification, sources of production and standardization.
- Get acquainted with the industrial production of maximally purified (new galenic) preparations. Consider their classification, production features, equipment and standardization.
- Consider the classification and process of obtaining preparations from fresh plant materials, juices, balms and elixirs.
- Get acquainted with the classification and features of the technology of preparations from animal raw materials (organ preparations), hormones, enzymes.
- Learn information about the characteristics, classification, production process and standardization of extracts-concentrates and oil extracts.
- To master the composition and methods of obtaining essential oils, determining their quality, storage and use in pharmacy.
- To study the GMP requirements and basic regulations for the production of preparations for parenteral use.
- Consider new types of packaging for sterile medicinal products: PVC containers, bags for irrigation solutions, pre-filled syringes, etc.
- Master the technologies of obtaining injection, infusion drugs, emulsions for parenteral use and carpules.
- Learn the specifics of the production of ophthalmic, nasal and ear medicines, requirements for them, their quality control according to the Federal Drug Administration and types of packaging.
- To analyze the bottlepack technology ("blowing-filling-sealing") in the production of sterile medicines, its advantages, main stages.
- Consider types of equipment for grinding, sieving, mixing, pressing and coating tablets. Types and principle of their operation.
- Understand the main factors affecting the bioavailability of medicinal substances in tablets.
- To master modern types of excipients and the basic principles of obtaining dragees, granules, solid dosage forms with prolonged release of active substances, confectionary dosage forms.
- Familiarize yourself with the main groups of auxiliary substances and modern equipment used in the production of suspensions, emulsions, ointments, and suppositories.
- Learn the biopharmaceutical aspects of ointments and suppositories.
- Consider and characterize modern rectal dosage forms (capsules, tampons, ointments, rectiols, aerosols, etc.).
- To analyze the structural and mechanical properties of soft drugs and the factors affecting them.
- Master the industrial production and equipment used in the production of suspensions and emulsions.
- To study the peculiarities of obtaining modern nano- and radiopharmaceuticals, their role and place in modern pharmacy and medicine.

11. Criteria and evaluation order of educational outcomes

The evaluation of the success of the student of higher education in the educational component 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, taking into account the evaluations of the mastery of individual content modules and evaluations of other types of student educational activities.

For those students who want to improve their performance in the discipline according to the ECTS scale, the final control of the learning of the module is additionally carried out according to the schedule approved by the educational institution.

Control methods: current (oral, written, didactic tests), content module control (test tasks, situational tasks, control of practical skills. Exam.

Current testing and independent work									
Content module 1		Content module 2		Total	Content module 3		Content module 4		Total
T1	3-5	T7	3-5		T13	5-7	T18	6-9	
T2	3-5	T8	3-5		T14	4-7	T19	5-9	
T3	3-5	T9	3-5		T15	4-7	T20	5-9	
T4	6-10	T10	6-10		T16	4-7	T21	5-8	
T5	6-10	T11	6-10		T17	4-7			
T6	3-5	T12	3-5						
CCM1	6-10	CCM2	6-10		CCM3	9-15	CCM4	9-15	
	30-50		**30-50**	**60-100**		**30-50**		**30-50**	**60-100**

Evaluation scale: national and ECTS

Total points	**Estimation of ECTS**	**Evaluation on a national scale**	
		rating	**credit**
90-100	A	Excellent	Passed
82-89	B	Good	
74-81	C		
64-73	D	Satisfactory	
60-63	E		
35-59	FX	Unsatisfactory	Not passed

12 Forms of progress and semester supervision of academic achievements

Current educational activities of higher education students are monitored in laboratory and seminar classes in accordance with specific goals and during the individual work of the teacher with students. The following means of determining the assimilation of educational material by students are used: test tasks, control works, solving situational problems, conducting educational research with interpretation and evaluation of their results, control of practical skills, drawing up a technological scheme for obtaining a given drug, etc. At each class, tasks are checked and logs of practical work are received.

The student's independent work is monitored during each laboratory session, during the control of the content module and/or the final module control. Self-mastery of the educational material is also controlled during the defense of the course work.

Control of the learning of the module is carried out after its completion and involves writing a control paper or test tasks by the student and control of practical skills by preparing a medicinal product or evaluating its quality. After successfully completing the tasks, the student receives a grade.

Semester control is carried out in the form of semester control of the module and semester exam

13. Methodological support

Lecture material (multimedia presentations, lecture texts, calendar and thematic plan of lectures).
Calendar and thematic plans of laboratory classes.
Questions for independent work of students of higher education.
Questions, problems, assignments or cases for current, substantive and final modular controls of knowledge and skills of students of higher education.
Sets of tickets for comprehensive work, CM 1÷CM 4
Video films.
Internet resources.
Training manual "Practicum on industrial technology of medicinal products".
Study guide for preparation for the final modular control and state certification in the discipline "Industrial technology of medicinal products".
Study guide for independent work of students "Industrial technology of medicines".
Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing integrated exam "Step 2. Pharmacy".
Normative documentation in the production of medicinal products: a study guide
Alcoholometry. Recovery and rectification of ethanol: Study guide for laboratory exercises
Laboratory journal

14. Reading suggestions

The main reading suggestions

1. Industrial drug technology: tutorial for control. Laboratory classes for students of specialty Production of liquid extracts. “Pharmacy”/ Yu. V. Yudina, Yu. V. Shmyreva, Stages of technological process. S.V. Stepanenko [et. al]. – Kharkiv: NUPh : Equipment. Technological Original, 2012. – 254 p.
2. Train aid for preparation for the licensed integrated test-based exam «Krok 2. Pharmacy» in specialty «226 Pharmacy, industrial pharmacy» for students of the Faculty for Foreign Citizens’ Education / A. A. Sichkar, S. V. Stepanenko, D. P. Soldatov, O. S. Kukhtenko. – Kharkiv: NUPh, 2021. – 73 p.

Supplementary reading suggestions

1. All about hard gelatine capsules.— Basel: Firma extracts. Stages of technological “Capsugel”, 1994.— 47 p.
2. Good manufacturing practices for pharmaccutical products. in; WHO Expert Committee on Specifications for Pharmaceutical Preparalions. Thirly-second report. Geneva, Wor1d Health Organization, 1992, Annex 1 (WHO Technical Report Series, No. 823).
3. Enciclopaedia of Pharmaceutical Technology / Ed. J. Swarbrick, I.C. Boylan.— 2-nd — New-York, Basel: Marcek Dekker, Inc.— 2002.— Vol. 3.— 3032 p.
4. Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York ; London : Informa Healthcare, 2007. – 4128 p.
5. European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & HealthCare. – Strasbourg, 2013. – 3638 p.
6. Handbook of Pharmaceutical Excipients, 6th edition / R. C. Rowe, P. J. Sheskey, M. E. Quinn. – Pharmaceutical Press and American Pharmacists Association, 2009. – 521 p.
7. All about hard gelatine capsules.— Basel: Firma “Capsugel”, 1994.— 47 p.
8. British Pharmacopeia.— V. 1. 2 — 2001 — 2639 p.
9. Enciclopaedia of Pharmaceutical Technology / Ed. J. Swarbrick, I.C. Boylan.— 2-nd — New-York, Basel: Marcek Dekker, Inc.— 2002.— Vol. 3.— 3032 p.

10. European Pharmacopeia.— 5 Edition.— Strasbourg: Council of Europe, 2005.— 2416 p.
11. European Pharmacopeia.— 7 Edition.— Strasbourg: Council of Europe, 2010.— 2416 p.
12. Mouth Dissolving Tablets I: An Overview of Formulation Technology / D. Shukla, S. Chakraborty, S. Singh, Br. Mishra // Sci Pharm.— 2009.— Vol. 76.—P. 309—326.
13. Sastry S.V, Nyshadham J.R, Fix J.A. Recent technological advances in oral drug delivery: a review // Pharm Sci Technol Today.— 2000.— No 3.— P. 138—145.

15. Electronic resources, including the Internet

1. Наукова бібліотека НФаУ: Режим доступу : http://dspace.ukrfa.kharkov.ua; http://lib.nuph.edu.ua
2. www.moz.gov.ua – офіційний сайт Міністерства охорони здоров'я України
3. nuph.edu.ua – офіційний сайт Національного фармацевтичного університету
4. Сайт кафедриТФП НФаУ. – Режим доступу: tfp.nuph.edu.ua.
5. *Module 1 https://pharmel.kharkiv.edu/moodle/course/view.php?id=3750*
6. *Module 2 https://pharmel.kharkiv.edu/moodle/course/view.php?id=2690*