

MINISTRY OF HEALTH OF UKRAINE

ODESA NATIONAL MEDICAL UNIVERSITY

Department of general and clinical pharmacology and pharmacognosy



APPROVED

Vice-rector for scientific and pedagogical activity  
Eduard BURIACHKIVSKYI

« 01 » 09 2023 y.

WORKING PROGRAM IN THE DISCIPLINE

«Theoretical foundations of the technology of dosage forms»

(full-time education)

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

**Field of knowledge:** 22 «Health care»

**Specialty:** 226 «Pharmacy, industrial pharmacy»

**Educational and professional program:** Pharmacy, industrial pharmacy

The program was compiled on the basis of the educational and professional program "Pharmacy, industrial pharmacy", training of specialists of the second (master's) level of higher education in the specialty 226 "Pharmacy, industrial pharmacy" field of knowledge 22 "Health care", approved by the Scientific Council of ONMedU (from 29.06 .2023, protocol No. 8).

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The work program was approved at the meeting of the department of pharmacology and pharmacognosy  
Protocol No. 1 dated August 28, 2023

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Approved by the subject-cycle methodological commission on pharmacy of ONMedU  
Protocol No. 1 dated 29.08.2023

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Revised and approved at the meeting of the department of Pharmacology and Pharmacognosy  
Protocol No. \_\_ dated \_\_/\_\_/20\_\_.

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Head of the department

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## 1. Description of the discipline:

Name of indicators	Field of knowledge, specialty, specialization, level of higher education	Characteristics of the discipline	
Total number:	Field of knowledge 22 «Health care»  Specialty 226 « Pharmacy, industrial pharmacy »  Level of higher education second (master's degree)	<i>Full-time (day) education</i>	
Credits of ECTS: 3		<i>Elective discipline</i>	
Hours: 90		<i>Course:</i>	2
Content topics 1		<i>Semester:</i>	IV
		<i>Lectures</i>	0 hours
		<i>Practical classes</i>	30 hours
		<i>Independent work</i>	60 hours
		<i>including individual tasks</i>	0 hours
	<i>Form of final control</i>	Credit	

## 2. Goals and objectives of the discipline

**Purpose:** formation of students of theoretical knowledge and acquisition of practical skills regarding the basic principles and regularities of the development and production of medicinal products of various groups, theoretical justification of the rational technology of medicinal products, the dependence of the quality of medicinal products on the technological parameters of production. The main tasks of studying discipline

1. Formation of technical and pharmaceutical thinking in students, knowledge of historical aspects of the development of pharmaceutical technology;
2. Acquaintance with the theoretical bases of the technology of various medicinal forms;
3. Familiarization with the main technological processes of grinding, dissolution, diffusion, filtration, emulsification, extraction and other general processes of production of various medicinal forms.

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

### **Integral (IR):**

The ability to solve problems of a research and/or innovative nature in the field of pharmacy; to comprehend critically and solve practical problems in professional pharmaceutical activity using the 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 one's own knowledge, conclusions and their validity to a professional and non-professional audience. The ability to continue learning with a high degree of autonomy.

### **General (GC):**

- GC01. Ability to abstract thinking; ability to analyze and synthesize, study, and be up-to-date educated.
- GC02. Knowledge and understanding of the subject area and understanding of professional activity.
- GC03. Ability to communicate in the national language both orally and in writing.
- GC05. Ability to evaluate and ensure the quality of the work performed.
- GC09. Ability to use information and communication technologies;
- GC11. Ability to apply knowledge in practical situations;
- GC15. Knowledge and understanding of the subject area and understanding of professional activity;

### **Specialists (SC):**

Special (professional) competences are formed taking into account the Standard of higher education in the specialty 226 Pharmacy, Industrial Pharmacy, specialization 226.01 Pharmacy, the field of knowledge 22 Health care for the second (master's) level of education.

- SC02. Ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.
- SC03. Ability to solve pharmacy problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility.
- SC04. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to people who are studying.
- SC10. Ability to monitor the effectiveness and safety of the population's use of medicines according to data on their clinical and pharmaceutical characteristics.
- SC24. Ability to use knowledge of regulatory and legislative acts of Ukraine and recommendations of proper pharmaceutical practices in professional activity;

**Program learning outcomes (PLO):**

- PLO01. Have and apply specialized conceptual knowledge in the branch of pharmacy and related fields, taking into account modern scientific achievements.
- PLO02. Critically comprehend scientific and applied problems in the field of pharmacy.
- PLO03. Have specialized knowledge and skills for solving professional problems and tasks, including the further development of knowledge and procedures in pharmacy.
- PLO04. Communicate in the national and English languages fluently, both orally and in writing, to discuss professional problems and results of professional activities and present scientific research and innovative projects.
- PLO07. Collect the necessary information on the development and production of medicinal products, using such sources as special literature, patents, databases, and others; systematize, analyze, and evaluate the information using statistical analysis.
- PLO09. Formulate, argue, clearly and in detail convey to specialists and non-specialists, including those seeking higher education, information based on one's own knowledge and professional experience, the main trends in the development of world pharmacy and related industries.
- PLO27. Perform professional activities using creative methods and approaches.
- PLO28. Carry out professional communication in the state language, use oral communication skills in a foreign language while analyzing specialized texts and translating foreign language information sources.
- PLO29. To carry out professional activities using information technologies, databases, navigation systems, Internet resources, software, and other information and communication technologies.
- PLO33. Determine the influence of factors that affect the processes of absorption, distribution, deposition, metabolism, and excretion of the medicinal product and that are determined by the condition and features of the human organism and the physicochemical properties of medicinal products.

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

**Know:**

- classification of medicinal forms;
- modern tasks and prospects of pharmaceutical technology;
- influence of pharmaceutical factors on drug bioavailability;
- appointment of auxiliary substances;
- influence of physico-chemical and technological properties on the technology of dosage forms;
- theoretical bases of grinding, sieving and mixing medicinal raw materials;
- theoretical foundations of creating a compact body;
- mechanisms and types of dissolution;
- patterns of dissolution of solid and liquid substances;
- characteristics of solvents;
- methods of obtaining purified water;
- theoretical foundations of the process of cleaning liquids and gases from mechanical impurities;
- peculiarities of extracting raw materials with a cellular structure;
- the main factors affecting the completeness and speed of extraction;
- principles of increasing the stability of medicinal forms;
- patterns of oxidation-reduction processes;
- methods of stabilization of unstable substances;
- mechanisms of action of stabilizers and antioxidants;
- influence of the nature of emulsifiers, structure, ratio, hydrophilic-lipophilic balance on the stability of

emulsions;

- factors affecting the physical, chemical and microbiological stability of emulsions.

**Be able:**

- to determine the bioequivalence of hard and soft dosage forms by the "in vitro" method;
- determine the technological properties of powdered materials;
- choose equipment and grinding methods depending on the properties of the materials;
- choose equipment for sieving and mixing powders depending on the properties of the materials;
- carry out pressing of powdery materials;
- to carry out processes of dissolution of medicinal substances in optimal conditions;
- determine equipment for high-quality filtration of liquid medicinal forms;
- carry out filtration of liquid medicinal forms;
- to determine the optimal modes of BAR extraction from raw materials with a cellular structure, using calculation and experimental methods;
- choose methods of stabilization of unstable substances, relying on the general regularities of stabilization processes;
- carry out an assessment of surface-active substances used in HLZ technology;
- evaluate the quality of emulsions and choose the most stable one in the built series, taking into account the physico-chemical and technological properties of the systems.

**Master the skills:**

- Evaluation of the effectiveness of the technological process of the production of medicinal preparations of various dosage forms;
- Rational selection of auxiliary substances;
- Learn the relationship between the theoretical foundations of pharmaceutical technologies and the industrial technology of pharmaceutical preparations;
- Possession of information on the stabilization and extension of the shelf life of medicinal preparations;
- Evaluation of the relationship between pharmaceutical factors and the therapeutic effectiveness of medicinal products.

### **3. The content of the work program**

#### ***Content module 1. Theoretical foundations of the technology of dosage forms***

##### **Topic 1. Historical aspects of the formation and development trends of pharmaceutical technology in the countries of the world and in Ukraine.**

The development of medicine and pharmacy in Ukraine from Ancient Rus to the beginning of the 20th century. Pharmacy in Russia in the XVI-XVII centuries. Medical professions of the 16th century. Pharmacy order. Pharmacy at the beginning of the 18th century. Development of Ukrainian medicine and pharmacy in the XIII–XIX centuries. Development of the pharmacy business in Ukraine in the 18th century. Historical aspects of the development of pharmaceutical education in Ukraine and abroad. Outstanding scientists and their contribution to the development of medicine and pharmacy.

##### **Topic 2. Pharmaceutical technology. Modern tasks and prospects of pharmaceutical technology. Basic terms and concepts of pharmaceutical technology.**

The main tasks of pharmaceutical technology as a science. General principles of pharmaceutical production organization. Basic terms and concepts in the field of drug production. Principles of classification of dosage forms. Classification of dosage forms depending on the method of administration of drugs into the body. Classification of dosage forms depending on the field of action. Classification of

dosage forms according to Y. I. Khadzhai. Regulatory and technical documentation for the industrial production of medicinal products. State Pharmacopoeia of Ukraine.

### **Topic 3. Pharmaco-technological properties of powdered materials.**

Physico-chemical properties of powdered materials. Technological volume density, degree of compaction, flowability, moisture, fractional composition, dispersity, compressibility of powdery materials. Structural and mechanical properties: plasticity, strength, elasticity, viscosity of the crystal lattice, etc. Determination of the shape, size and nature of the powder surface, determination of moisture content, fractional composition, bulk density, true density, relative density, porosity, flowability, compressibility, etc.

### **Topic 4. Theoretical foundations of crushing of solid bodies. Theories of crushing of solid bodies.**

Grinding. Grinding classes, degree of grinding. Methods of grinding (crushing, splitting, breaking, cutting). Mohs hardness scale. Strength limit and modulus of elasticity of some materials. Groups of materials depending on strength. Grinding methods depending on the type of material. Physico-mechanical basics of grinding. Energy consumption. Stages and main grinding schemes. Classification of shredders. Comparison and selection of shredders.

### **Topic 5. Methods of determining the size of particles of solid bodies. Sifting and mixing of powdered materials. Theoretical foundations of pressing.**

Methods of determining the size of particles of solid bodies. Mechanical processes. Shredding of solid materials. Classification and sorting of materials. Mixing solid materials. Drum, screw and blade mixers. Theoretical foundations of pressing. Features of pressing and basic stages.

### **Topic 6. Criteria and methods of evaluation of surfactants.**

Lyophilic and lyophobic dispersion systems. Criterion for the formation of lyophilic dispersed systems. Amphiphilic properties of molecules of surfactants. Principles of classification of surfactants. Surface tension and adsorption of surfactants at different interphase boundaries. Self-organized structures based on surfactants: surface films, micelles, liquid crystal structures. The role of surfactants in improving or worsening wetting and spreading. The influence of surfactants on the environment and people. Environmental protection as a stimulus for the search for new safe surfactants.

### **Topic 7. Classification of emulsifiers. Properties of surfactants. Surfactants, their classification and purpose.**

Classification of emulsifiers. Polymer-induced aggregation of surfactants. Models that describe the interaction of surfactants and polymers. Correlation of the behavior of surfactant-polymer mixtures with the phase behavior of mixtures of two polymers or mixtures of surfactants. Diphilic structure of proteins. The role of interactions between proteins and surfactants. Phase separation of solutions of mixtures of surfactants and proteins. Introduction to the rheology of solutions of polymers and surfactants. Foaming in surfactant solutions. The influence of polymers on the stability of foams. surfactants, their classification and purpose.

### **Topic 8. Influence of HLB emulsifiers and production technology on the quality parameters of emulsions. Types of emulsions. Types of instability of emulsions.**

Highly concentrated emulsions, mechanisms of emulsion destruction. Theory physical theory of stability of lyophobic colloids (DLFO) for emulsions. The concept of hydrophilic-lipophilic balance (HLB). Selection of emulsifier. Bancroft's rule and the dynamics of surfactant adsorption. New surfactants. Surface-active substances with an unusual structure. Surfactants capable of polymerization and their use for obtaining coatings. Polymer surfactants. Special surfactants for extreme reduction of surface tension. Surface-active polymers. Types of instability of emulsions.

### **Topic 9. Rheological properties of ointment bases. Methods of determining rheological properties.**

Rheological properties of ointment bases. Requirements for ointment bases. Classification of ointment bases. Technology of production of ointments at pharmaceutical enterprises. Standardization of ointments. Basic methods of determining rheological properties. Influence of the nature of ointment bases on the osmotic activity of soft dosage forms.

### **Topic 10. Peculiarities of extracting raw materials with a cellular structure. Stages of the extraction process.**

Factors affecting the efficiency of the extraction process. The process of extracting dried and fresh plant material. Convective diffusion. Choice of extractant. Requirements for extractants. Classification of extracted substances. Porosity and porosity of raw materials. Stages of the extraction process.

**Topic 11. The main factors affecting the completeness and speed of extraction.**

Hydrodynamic conditions. The difference in concentrations. Extraction time. Viscosity of the extractant. Temperature. Addition of surfactants (surfactants). Choice of extractant. Porosity and porosity of raw materials. The influence of vibration, pulsation, crushing and deformation of raw materials in the environment of the extractant.

**Topic 12. Requirements for extractants. Methods of extraction.**

Requirements for extractants due to specific features of pharmaceutical production. Acetone, ethyl ester, chloroform, dichloroethane, methylene chloride, methanol, methyl, liquefied gases. Extractive methods (maceration and its varieties, percolation).

**Topic 13. Characteristics of the filtering process.** Filter partitions and materials.

Filtering process. Features of the filtering process. Filtering through filter partitions. Filtering speed. Filter device. Specific volume of filtrate (volume of filtrate obtained from a unit of filtering surface). The highest productivity of filters.

**Topic 14. Theories of redox processes. Methods of chemical protection and prevention of oxidation. Physical methods of drug stabilization.**

Theories of redox processes. Methods of chemical protection and prevention of oxidation. Methods of stabilization of medicines. Classification of methods of drug stabilization (physical, chemical and complex method). Stabilizers, stabilizer requirements. The main three groups of stabilizers. Advantages and disadvantages of stabilizers.

**4. The structure of the academic discipline**

Topic	Number of hours				
	That's all	Including			
		lectures	practical	seminars	IWS
<i>Content module 1. Theoretical foundations of the technology of dosage forms</i>					
<b>Topic 1.</b> Historical aspects of the formation and development trends of pharmaceutical technology in the countries of the world and in Ukraine.	4,0	0	2,0	0	2,0
<b>Topic 2.</b> Pharmaceutical technology. Modern tasks and prospects of pharmaceutical technology. Basic terms and concepts of pharmaceutical technology.	8,0	0	2,0	0	6,0
<b>Topic 3.</b> Pharmaco-technological properties of powdered materials.	8,0	0	4,0	0	4,0
<b>Topic 4.</b> Theoretical foundations of crushing of solid bodies. Theories of crushing of solid bodies.	6,0	0	2,0	0	4,0
<b>Topic 5.</b> Methods of determining the size of particles of solid bodies. Sifting and mixing of powdered materials. Theoretical foundations of pressing.	6,0	0	2,0	0	4,0
<b>Topic 6.</b> Criteria and methods of evaluation of surfactants.	6,0	0	2,0	0	4,0
<b>Topic 7.</b> Classification of emulsifiers. Properties of surfactants. Surfactants, their classification and purpose.	6,0	0	2,0	0	4,0

<b>Topic 8.</b> Influence of HLB emulsifiers and production technology on the quality parameters of emulsions. Types of emulsions. Types of instability of emulsions.	6,0	0	2,0	0	4,0
<b>Topic 9.</b> Rheological properties of ointment bases. Methods of determining rheological properties.	8,0	0	2,0	0	6,0
<b>Topic 10.</b> Peculiarities of extracting raw materials with a cellular structure. Stages of the extraction process.	8,0	0	2,0	0	6,0
<b>Topic 11.</b> The main factors affecting the completeness and speed of extraction.	6,0	0	2,0	0	4,0
<b>Topic 12.</b> Requirements for extractants. Methods of extraction.	6,0	0	2,0	0	4,0
<b>Topic 13.</b> Characteristics of the filtering process.	6,0	0	2,0	0	4,0
<b>Topic 14.</b> Theories of redox processes. Methods of chemical protection and prevention of oxidation. Physical methods of drug stabilization.	6,0	0	2,0	0	4,0
<b>Total by content module (hours)</b>	90	0	30	0	60

## 5. Topics of lectures / seminars / practical / laboratory classes

### 5.1 Thematic plan of lectures

Lectures classes are not provided

### 5.3. Topics of seminars classes

Seminars classes are not provided.

### 5.2. Topics of practical classes

№№ п/п	Title of the topic	Number of hours
1.	Historical aspects of the formation and development trends of pharmaceutical technology in the countries of the world and in Ukraine	2
2.	Pharmaceutical technology. Modern tasks and prospects of pharmaceutical technology. Basic terms and concepts of pharmaceutical technology.	2
3.	Pharmaco-technological properties of powdered materials.	4
4.	Theoretical foundations of grinding of solid bodies. Theories of crushing of solid bodies.	2
5.	Methods of determining the size of particles of solid bodies. Sifting and mixing of powdered materials. Theoretical foundations of pressing.	2
6.	Criteria and methods of evaluation of surfactants.	2
7.	Classification of emulsifiers. Properties of surfactants (surfactants). Classification of PAs and their purpose.	2
8.	Influence of HLB emulsifiers and production technology on quality parameters of emulsions. Types of emulsions. Types of instability of emulsions	2
9.	Rheological properties of ointment bases. Methods of determining rheological properties.	2
10.	Features of extraction of raw materials with a cellular structure. Stages of the extraction process.	2



11.	The main factors affecting the completeness and speed of extraction.	2
12.	Requirements for extractants. Methods of extraction.	2
13.	Characteristics of the filtering process. Filter partitions and materials.	2
14.	Theories of redox processes. Methods of chemical protection and prevention of oxidation. Physical methods of drug stabilization.	2
<b>РАЗОМ</b>		<b>30</b>

#### 5.4. Topics of laboratory classes

Laboratory classes are not provided.

### 6. Independent work

№№ п/п	Title and contents	Number of hours
1.	Modern medicine and pharmacy in the countries of the world. Development trends of the world pharmaceutical market.	2
2.	Pharmaceutical information as a component of scientific and technical information.	4
3.	Regulatory and technical documentation for the industrial production of medicinal products.	4
4.	Stages and main grinding schemes. Classification of shredders.	4
5.	Mixing solid materials. Drum, screw and blade mixers.	4
6.	Principles of classification of surfactants (surfactants).	4
7.	The influence of surfactants on the environment and people	4
8.	Diphilic structure of proteins. The role of interactions between proteins and surfactants.	2
9.	Bancroft's rule and the dynamics of surfactant adsorption.	2
10.	Special surfactants for extreme reduction of surface tension. Surface-active polymers.	4
11.	Influence of the nature of ointment bases on the osmotic activity of soft dosage forms.	2
12.	Choice of extractant. Requirements for extractants.	4
13.	The influence of vibration, pulsation, crushing and deformation of raw materials in the environment of the extractant.	4
14.	Methods of extraction of plant raw materials.	4
15.	Features of the filtering process. Filtering through filter partitions.	4
16.	Classification of methods of drug stabilization (physical, chemical and complex method).	4
17.	Stabilizers, stabilizer requirements. Main groups of stabilizers.	4
<b>Total:</b>		<b>60</b>

### 7. Teaching methods

**Practical classes:** lectures, conversation, solving situational problems, preparation and presentations.

**Independent work:** independent work with a textbook, lecture notes, independent solution of typical situational problems, preparation and defense of a report-presentation.

#### 8. Control methods and criteria for evaluating learning outcomes

**Current control:** oral survey, testing, evaluation of the performance of practical skills, solving situational problems, evaluation of activity in the lesson.

**Final control:** credit.

**Evaluation of the current educational activity in a practical session:**

**1. Evaluation of theoretical knowledge on the subject of the lesson:**

- methods: survey, solving a situational problem
- maximum score – 5, minimum score – 3, unsatisfactory score – 2.

**2. Assessment of practical skills on the topic of the lesson:**

- methods: assessment of the correctness of the performance of practical skills
- maximum score – 5, minimum score – 3, unsatisfactory score – 2.

The grade for one practical lesson is the arithmetic average of all components and can only have a whole value (5, 4, 3, 2), which is rounded according to the statistical method.

### Current evaluation criteria in practical training

Rating	Evaluation criteria
«5»	The applicant knows the program in its entirety, illustrating the answers with various examples; gives exhaustively accurate and clear answers without any leading questions; teaches the material without errors and inaccuracies; performs practical tasks of varying degrees of complexity (knows thoroughly all the physico-chemical properties of components for the manufacture of medicinal products, the theoretical foundations of the technology of medicinal forms);
«4»	The applicant knows the entire program and understands it well, answers the questions correctly, consistently and systematically, but they are not exhaustive, although the applicant answers additional questions without errors; performs practical tasks, feeling difficulties only in the most difficult cases (orients himself within the limits of the above-mentioned issues);
«3»	It is given to the applicant on the basis of his knowledge of the entire scope of the program on the subject and a satisfactory level of understanding of it. the applicant is able to solve simplified tasks with the help of leading questions; performs practical skills, experiencing difficulties in simple cases; is not able to systematically explain the answer on his own, but he answers correctly to directly asked questions (has a superficial idea of the theoretical foundations of the technology of dosage forms).
«2»	The applicant does not know the material, does not know any of the above questions, or knows less than 50% of the questions and does not know how to write a prescription.

Credit is given to the applicant who has completed all tasks of the work program of the academic discipline, actively participated in practical classes, completed and defended an individual assignment and has an average current grade of at least 3.0 and has no academic debt.

Assessment is carried out: at the last lesson before the beginning of the examination session - with the tape-learning system, at the last lesson - with the cyclical learning system. The credit score is the arithmetic average of all components according to the traditional four-point scale and has a value that is rounded according to the statistics method with two decimal places after the decimal point.

### 9. Distribution of points received by students of higher education

The average score for the discipline is translated into a national score and converted into points on a multi-point scale (200-point scale).

The conversion of a traditional grade into a 200-point grade is performed by the information and technical department of the University using the "Contingent" program according to the formula:

Average success score (current success in the discipline) x 40

### Table of conversion of traditional assessment to multi-point assessment

National assessment for discipline	The sum of points for the discipline
Excellent ("5")	185 – 200
Good ("4")	151 – 184
Satisfactory ("3")	120 – 150
Unsatisfactory ("2")	Lower 120

A multi-point scale (200-point scale) characterizes the actual success of each applicant in learning the educational component. The conversion of the traditional grade (average score for the academic discipline) into a 200-point grade is performed by the information and technical department of the University.

According to the obtained points on a 200-point scale, the achievements of the applicants are evaluated according to the ECTS rating scale. Further ranking according to the ECTS rating scale allows you to evaluate the achievements of students from the educational component who are studying in the same course of the same specialty, according to the points they received.

The ECTS scale is a relative-comparative rating, which establishes the applicant's belonging to the group of better or worse among the reference group of fellow students (faculty, specialty). An "A" grade on the ECTS scale cannot be equal to an "excellent" grade, a "B" grade to a "good" grade, etc. When converting from a multi-point scale, the limits of grades "A", "B", "C", "D", "E" according to the ECTS scale do not coincide with the limits of grades "5", "4", "3" according to the traditional scale. Acquirers who have received grades of "FX" and "F" ("2") are not included in the list of ranked acquirers. The grade "FX" is awarded to students who have obtained the minimum number of points for the current learning activity, but who have not passed the final examination. A grade of "F" is given to students who have attended all classes in the discipline, but have not achieved a grade point average (3.00) for the current academic activity and are not admitted to the final examination.

Applicants who study in one course (one specialty), based on the number of points scored in the discipline, are ranked on the ECTS scale as follows:

#### Conversion of traditional discipline grade and ECTS scores

Оценка ECTS	Statistical indicator
«A»	Top 10% of students
«B»	The next 25% of students
«C»	The next 30% of students
«D»	The next 25% of students
«E»	The last 10% of students

#### 10. Methodological provision of discipline:

Working program of the academic discipline

- Syllabus
- Multimedia presentations
- Methodical developments for practical classes
- Methodical recommendations for independent work of higher education applicants

#### 11. List of questions to set off:

1. Development of medicine and pharmacy in Ukraine. Outstanding scientists of Ukraine and their contribution to the development of pharmacy.
2. Pharmaceutical technology. Modern tasks and prospects of pharmaceutical technology.
3. Basic classifications of medicinal products. Classification of dosage forms according to Y. I. Khadzhai.
4. Regulatory and technical documentation for the industrial production of medicinal products.

5. Physico-chemical properties of powdered materials.
6. Theoretical foundations of grinding solid bodies.
7. Mohs hardness scale. Strength limit and modulus of elasticity of some materials.
8. Classification of shredders. Comparison and selection of shredders.
9. Methods of crushing solid bodies depending on the type of material.
10. Stages and main schemes of grinding solid bodies.
11. Mixing solid materials. Drum, screw and blade mixers.
12. Theoretical foundations of pressing. Features of pressing and main stages.
13. Lyophilic and lyophobic dispersion systems. Criterion for the formation of lyophilic dispersed systems.
14. Principles of classification of surfactants (surfactants).
15. The role of surfactants in improving or worsening wetting and spreading, their necessity in the manufacture of medicinal products.
16. The impact of South Africa on the environment and people.
17. Self-organized structures based on surfactants: surface films, micelles, liquid crystal structures.
18. Correlation of the behavior of surfactant-polymer mixtures with the phase behavior of mixtures of two polymers or mixtures of surfactants.
19. Models describing the interaction of surfactants and polymers.
20. Modern classification of emulsifiers.
21. Highly concentrated emulsions, mechanisms of emulsion destruction.
22. The concept of hydrophilic-lipophilic balance (HLB).
23. Bancroft's rule and the dynamics of surfactant adsorption.
24. Special surfactants for extreme reduction of surface tension. Surface-active polymers.
25. Rheological properties of ointment bases.
26. Technology of production of ointments at pharmaceutical enterprises. Standardization of ointments.
27. Classification of ointment bases. Basic requirements for ointment bases.
28. Influence of the nature of ointment bases on the osmotic activity of soft dosage forms.
29. Factors affecting the efficiency of the extraction process of plant raw materials.
30. The process of extracting dried and fresh plant material. Convective diffusion.
31. Selection of an extractant for maximum extraction of biologically active substances. Requirements for extractants.
32. The main factors affecting the completeness and speed of extraction.
33. Extractive methods (maceration and its varieties, percolation).
34. Characteristics of the filtering process. Features and disadvantages.
35. Filter partitions and materials. Filtering speed. Filter device.
36. Theories of redox processes. Methods of chemical protection and prevention of oxidation.
37. Classification of methods of stabilization of medicines (physical, chemical and complex method).
38. Stabilizers, requirements for a stabilizer. The main three groups of stabilizers.

## **12. LITERARY SOURCES**

### **Basic**

1. Gladukh E.V. Theoretical foundations of pharmaceutical technology. Study guide for extracurricular independent work / E.V. Gladukh, I.V. Saiko, A.A. Sichkar, D.P. Soldatov. Kh.: NFaU, 2016. - 202 p.
2. Technology of drugs of industrial production (vol. 2 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2013. - 638 p.
3. Technology of drugs of industrial production (vol. 1 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2012. - 694 p.

### Additional

1. Technological equipment of the pharmaceutical and biotechnological industry: tutorial. for university students education closing III-IV accreditation level / M.V. Stasevych and others; 2nd ed., revision. and added – Lviv: Novy svit-2000, 2018. – 410 p.
2. Yarnykh, T. G. Extemporaneous formulation (technology, analysis, application): method. rec. / T. G. Yarnykh, Fr. I. Tikhonov, I. S. Hryshchenko and others. - Kh., 2015. -379 p.
3. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 1. -1128 p.
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### 13. Electronic information resources

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3. State Formulary of Medicinal Products 12th issue, 2020: – Access mode: <https://www.dec.gov.ua/materials/chinnij-vipusk-derzhavnogo-formulyara-likarskih-zasobiv/>
4. State Expert Center of the Ministry of Health of Ukraine [http:// https://www.dec.gov.ua/](http://https://www.dec.gov.ua/)
5. National Scientific Medical Library of Ukraine [https:// library.gov.ua/](https://library.gov.ua/)
6. National Library of Ukraine named after V.I. Vernadskyi <http://www.nbu.gov.ua/>
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