MINISTRY OF HEALTH OF UKRAINE

ODESSA NATIONAL MEDICAL UNIVERSITY

Department of Pharmaceutical Chemistry and Drug Technology

APPROVED

Vice-rector for scientific and pedagogical work

_____ Eduard BURYACHKIVSKY

September 1st, 2025

WORKING PROGRAM IN THE DISCIPLINE
« INDUSTRIAL PRACTICE IN DRUG TECHNOLOGY »

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

Area of Knowledge: 22 «Health care»

Specialty: 226 «Pharmacy, industrial pharmacy»

Specialization: 226.01 «Pharmacy»

Educational and professional program: Pharmacy, industrial pharmacy

2025

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

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

Head of Department _____ Volodymyr GELMBOLDT

Agreed with the EPP guarantor _____ Liana UNHURIAN

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

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

_____ Natalia FIZOR

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

Head of the department _____ Volodymyr GELMBOLDT

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

Head of the department _____ Volodymyr GELMBOLDT

1. DESCRIPTION OF THE ACADEMIC DISCIPLINE

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

Credits: 4

Hours: 120</td><td rowspan="8">Area of Knowledge
22 "Healthcare"

Specialty
226 "Pharmacy, Industrial Pharmacy"

Specialization
226.01 "Pharmacy"

Level of higher education
second (master's)</td><td>Full-time education
Mandatory discipline</td></tr>
<tr><td>Year of preparation: 5</td></tr>
<tr><td>Semesters IX</td></tr>
<tr><td>Lectures (0 h.)</td></tr>
<tr><td>Practical (80 h.)</td></tr>
<tr><td>Independent work (40 h.)</td></tr>
<tr><td>Final control form – differential credit</td></tr>
</table>

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

Goal: to consolidate and expand theoretical knowledge and practical skills in the preparation of dosage forms, implementation of stage-by-stage control, improvement of technology, determination of the influence of storage conditions and type of packaging on the stability of dosage forms in order to prepare for future activities in the pharmaceutical industry. To bring higher education applicants as close as possible to their specialty, to teach them to use all the theoretical knowledge and practical skills in the technology of medicinal products they have acquired in working with medicines and patients, to ensure the rigor and accuracy of quality control of medicines and their dispensing.

Task: deepening knowledge of the technology of various dosage forms (solid, liquid, soft) based on the theoretical provisions of the technology of medicinal products, knowledge of properties, medicinal and auxiliary substances; studying the modern assortment and physicochemical properties of medicinal products; mastering the requirements of current regulatory documents (GPP and current orders) for the organization of the production activities of pharmacies for the manufacture of medicinal products in various dosage forms; using in professional activities regulatory and legislative acts, the requirements of good pharmacy practice (GPP) for the manufacture of medicinal products in pharmacies; forming in higher education students knowledge of the theoretical foundations of technology and practical skills necessary for the manufacture of various types of medicinal forms, conducting staged control, ways to improve the technology of medicinal forms in pharmacies; studying the influence of storage conditions and type of packaging on the stability of medicinal forms.

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

General (GC):

GC 1 – The ability to think abstractly, analyze and synthesize, learn and be up-to-date.

GC 2 – Knowledge and understanding of the subject area and understanding of professional activity.

GC 5 – Ability to evaluate and ensure the quality of work performed.

GC 6. Ability to work in a team.

GC 9 – Ability to use information and communication technologies.

Specialists (SC):

SC 8 – Ability to provide advice on prescription and non-prescription medicines and other

pharmacy products; pharmaceutical care during the selection and sale of medicines of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.

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

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

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

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

Program learning outcomes (PLO):

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

PLO 11. To determine the advantages and disadvantages of medicines of natural and synthetic origin of various pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic, pharmacodynamic characteristics and the type of dosage form. To recommend medicines and other pharmacy products to consumers, providing advisory assistance and pharmaceutical care.

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

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

PLO 22 – To ensure and carry out quality control of medicinal products of natural and synthetic origin and document its results; to issue quality certificates and certificates of analysis taking into account the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QCM), technological instructions, etc.; to take measures to prevent the distribution of low-quality, falsified and unregistered medicinal products.

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

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

Know:

- structure and main content of the State Pharmacopoeia of Ukraine (SFU) with additions;
- modern requirements of regulatory documentation regulating the technology and quality control of extemporaneous medicinal products in Ukraine and abroad;
- main current orders and other regulatory documents of the Ministry of Health of Ukraine on the preparation, testing, labeling and storage of medicines;

- characteristics and classification of dosage forms as dispersed systems;
- theoretical foundations of the technology of various dosage forms;
- rules of rational technology of solid, liquid, soft, sterile and aseptic dosage forms;
- influence of physicochemical properties of medicinal substances on the technology of extemporaneous solid, liquid, soft, sterile and aseptic dosage forms;
- nomenclature of industrially produced medicinal products, their general characteristics, storage conditions;
- quality control of dosage forms.

Be able to:

- use regulatory, reference, educational and scientific literature to solve professional tasks;
- prepare the workplace, work utensils and dispensing containers, auxiliary materials;
- prepare scales for work depending on their type;
- weigh dry, liquid, viscous medicines, medicinal plant raw materials;
- measure various liquids;
- use pharmacy equipment and apparatus;
- follow safety rules when operating devices and apparatus, when working with poisonous, potent medicines, medicinal plant raw materials;
- make calculations: check single and daily doses of poisonous and potent medicines; the number of medicines in various medicines (powders, mixtures, suppositories, etc.) depending on the method of prescription; the volume of solvent in aqueous solutions; isotonic concentration of solutions for injections, infusion solutions and eye drops; amounts of isotonic component; amounts of base for preparation of medicines for local use (ointments, suppositories);
- determine the mortar number, losses of solid medicines during grinding, permissible and actual deviations in the process of preparation of medicines;
- determine the form of the finished medicine and choose the optimal sequential technological operations;
- mix ingredients;
- prepare trituration, concentrated solutions and use them during 6 manufactures of medicines;
- dissolve medicines depending on their physicochemical properties, determine the order of their dissolution;
- add ready-made medicines of industrial production to mixtures;
- strain or filter solutions depending on the application;
- prepare aqueous solutions (true, high-molecular compounds, colloidal), prepare non-aqueous solutions (alcoholic, oily, glycerin, dimexide, in combined solvents), prepare suspensions, emulsions, prepare aqueous extracts from various medicinal plant raw materials and using concentrated extracts, prepare various injectable dosage forms in aqueous, non-aqueous solvents, ensure compliance with the requirements of the State Federal University of Medicine and other regulatory legal acts during their manufacture, prepare eye medications in accordance with the requirements of the State Federal University of Medicine and other regulatory legal acts, prepare medications with antibiotics;
- identify incompatible combinations of medicinal substances in various forms of medications, resolve issues regarding the preparation and dispensing of dosage forms, taking into account the compatibility of ingredients;
- assess the quality of prepared medications;
- ensure proper labeling and storage of medications ready for dispensing.

3. CONTENT OF THE COURSE

Topic 1. **General introduction to the pharmaceutical company; internal regulations. Instruction on occupational safety and health regulations.**

- general acquaintance with the pharmaceutical enterprise, the purpose of its premises and the work schedule. Study of safety rules and sanitary regime at the enterprise;

- observance of pharmaceutical order in production premises. Study of the regulatory framework regulating the sanitary regime and pharmaceutical order at the pharmaceutical enterprise. Familiarization with the briefing on occupational safety and health rules;
- master the basic terms used in the production of medicines. Familiarization with regulatory and methodological documentation. Drawing up regulations.

Topic 2. **Production of solid dosage forms according to GMP requirements (tablets, granules, dragees).**

- get acquainted with the categories, structure of regulatory documentation and industrial production of drugs according to the rules of the GMR;
- study the physicochemical and pharmacotechnological properties of powders and granulates, be able to determine their influence on the technology of obtaining solid dosage forms. Study the methods of granulating powders, types of granulators, justify the feasibility of their use;
- study the range and properties of excipients for the production of TDF;
- study the methods of producing tablets, granules, dragees and be able to choose the manufacturing technology. Study the stages of obtaining uncoated and coated tablets, methods of applying coatings to tablets, types of machines, their structure and principle of operation, setting weight and pressure on various tablet machines during their operation.
- be able to draw up a block diagram of tablet production, indicate the equipment at each stage and indicate quality indicators;
- to study the types of packaging materials for tablets, types of automatic machines for packing tablets in polymer film, foil, glass containers. Causes of defects in the production of tablets and ways to eliminate them.

Topic 3. **Production of solid dosage forms according to GMP requirements (capsules in a gelatin shell).**

- to study the range and properties of excipients for the production of capsules in a gelatin shell. To study the methods of capsule production and be able to choose the manufacturing technology;
- methods of obtaining hard and soft gelatin capsules, types of machines, their structure and principle of operation;
- to be able to draw up a flowchart of capsule production, indicate the equipment at each stage and indicate quality indicators. To be able to draw up a flowchart of capsule production, indicate the equipment at each stage and indicate quality indicators;
- to study the types of packaging materials for capsules, types of machines for packing capsules in polymer film, foil, glass containers.

Topic 4. **Production of sterile medicinal products in accordance with GMP requirements (dosage forms for injections in ampoules, vials, infusion solutions in containers, etc.).**

- to study the structure and principle of operation of devices for obtaining demineralized water and water for injections;
- general rules for preparing solutions and ampoules;
- to study the stages of ampoule formation, methods of sterilization of ampoules, the structure of the equipment used for forming, filling and sealing ampoules. To study the preparation of solutions for injections, methods of stabilization and isotonization of solutions, methods of their sterilization, filtration, stage-by-stage quality control, rejection of injection solutions, labeling and packaging of ampoules of aseptically prepared drugs in industrial conditions;
- to acquire skills in working with sterilizers, autoclaves, drying cabinets and other sterilization equipment.

Topic 5. **Production of soft dosage forms according to GMP requirements (ointments, gels, suspensions, emulsions, suppositories, plasters, etc.).**

- the main representatives of this group of drugs;

- to master the principles of the production of dosage forms in the chemical workshop (ointment preparation section);
- preparation of bases and other basic materials. Introduction of medicinal substances into ointment bases;
- development of practical skills in the preparation of non-aqueous solutions, drops, solutions of HMWs and colloids, liniments. Acquisition of practical experience in the preparation of such heterogeneous dosage forms as suspensions and emulsions;
- technological schemes for the preparation of suppositories. Equipment for the production of soft drugs, as well as their packaging and packaging.

Topic 6. **Production of phytochemicals according to GMP requirements.**

- the ratio of raw materials and extractant;
- to study the stages of the technological process of obtaining and extracting galenic and maximally purified preparations. Preparation of aqueous extracts from plant raw materials and extract concentrates;
- types and structure of apparatus for obtaining extracts. Methods of purification of extracts, liquid, thick and dry extracts and new galenic preparations;
- structure and principle of operation of installations for evaporation and drying, methods of determining the quality of the obtained preparations and their storage conditions;
- methods of rectification and recovery of ethyl alcohol from spent raw materials and equipment used in this case;
- learn how to choose packaging and sealing material for liquid dosage forms depending on the type of dosage form and the properties of the active substances.

Topic 7. **Packaging and wrapping of finished products.**

- organization of production flow, nomenclature of containers and packaging materials, packaging of tablets, dragees, ointments;
- construction and maintenance of packaging machines of various types.

Topic 8. **Introduction to the work of the pharmaceutical quality control department and the central factory laboratory.**

- familiarization with the work of laboratories and departments: scientific and organizational unit, central factory laboratory, quality control department, shop laboratories.
- preparation of necessary documentation;
- carrying out standardization of finished products in accordance with the requirements of regulatory and technical documentation.

4. STRUCTURE OF THE ACADEMIC DISCIPLINE

Topic names	Number of hours of full-time study			
	Total	including		
		lectures	practical	IWS
Topic 1. General introduction to the pharmaceutical company; internal regulations. Instruction on occupational safety and health regulations.	10	0	6	4
Topic 2. Production of solid dosage forms according to GMP requirements (tablets, granules, dragees).	16	0	10	6
Topic 3. Production of solid dosage forms according to GMP requirements (capsules in a gelatin shell).	18	0	12	6
Topic 4. Production of sterile medicinal products in accordance with GMP requirements (dosage forms for injections in ampoules, vials, infusion solutions in containers, etc.).	18	0	14	4
Topic 5. Production of soft dosage forms according to GMP requirements (ointments, gels, suspensions, emulsions, suppositories, plasters, etc.).	16	0	12	4
Topic 6. Production of phytochemicals according to GMP requirements.	14	0	12	4
Topic 7. Packaging and wrapping of finished products.	14	0	8	4
Topic 8. Introduction to the work of the pharmaceutical quality control department and the central factory laboratory.	12	0	4	8
Differential credit	2	0	2	0
Total hours	**120**	**0**	**80**	**40**

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

5.1. Lecture topics

Lectures are not provided

5.2. Seminar topics

Seminars are not provided

5.3. Topics of practical classes

№ i/o	Topic name	Number of hours
1.	Topic 1. Practical lesson 1. Instruction on safety and occupational health and safety rules.	2
2.	Topic 1. Practical lesson 2. Introduction to the departments of a pharmaceutical company for the production of dosage forms.	2
3.	Topic 1. Practical lesson 3. Introduction to the rules of internal regulations of a pharmaceutical enterprise.	2
4.	Topic 2. Practical lesson 4. Production of solid dosage forms according to GMP requirements. Main stages of material preparation for solid dosage forms.	2
5.	Topic 2. Practical lesson 5. Production of solid dosage forms according to GMP requirements. Production of tablets.	2
6.	Topic 2. Practical lesson 6. Production of solid dosage forms according to GMP requirements. Production of granules.	2
7.	Topic 2. Practical lesson 7. Production of solid dosage forms according to GMP requirements. Production of dragees.	2
8.	Topic 2. Practical lesson 8. Solving test problems on the production of solid dosage forms according to GMP requirements.	2
9.	Topic 3. Practical lesson 9. Production of gelatin capsules according to GMP requirements. Modern classification and general characteristics.	2

10.	Topic 3. Practical lesson 10. Characteristics of basic and auxiliary substances.	2
11.	Topic 3. Practical lesson 11. Production of capsules in a gelatin shell according to GMP requirements. Soft gelatin capsules, their production.	2
12.	Topic 3. Practical lesson 12. Production of gelatin capsules according to GMP requirements. Hard gelatin capsules, their production.	2
13.	Topic 3. Practical lesson 13. Production of microcapsules according to GMP requirements	2
14.	Topic 3. Practical lesson 14. Solving test problems on the production of capsules in a gelatin shell according to GMP requirements.	2
15.	Topic 4. Practical lesson 15. Production of sterile medicinal products according to GMP requirements. Creation of conditions for the production of sterile products.	2
16.	Topic 4. Practical lesson 16. Production of sterile medicinal products according to GMP requirements. Production of primary packaging for sterile products.	2
17.	Topic 4. Practical lesson 17. Production of sterile medicinal products according to GMP requirements. Solvents for parenteral forms.	2
18.	Topic 4. Practical lesson 18. Production of sterile medicinal products according to GMP requirements. Isotonization and stabilization of solutions. Preservatives.	2
19.	Topic 4. Practical lesson 19. Production of sterile medicinal products according to GMP requirements. Sterilization methods.	2
20.	Topic 4. Practical lesson 20. Production of sterile medicinal products according to GMP requirements. Non-aqueous solutions for injections. Infusion medicinal products.	2
21.	Topic 4. Practical lesson 21. Solving test tasks on the production of sterile medicines according to GMP requirements.	2
22.	Topic 5. Practical lesson 22. Production of soft dosage forms according to GMP requirements. Ointments.	2
23.	Topic 5. Practical lesson 23. Production of soft dosage forms according to GMP requirements. Gels.	2
24.	Topic 5. Practical lesson 24. Production of soft dosage forms according to GMP requirements. Suspensions.	2
25.	Topic 5. Practical lesson 25. Production of soft dosage forms according to GMP requirements. Emulsions.	2
26.	Topic 5. Practical lesson 26. Production of soft dosage forms according to GMP requirements. Suppositories, plasters.	2
27.	Topic 5. Practical lesson 27. Solving test tasks on the production of soft dosage forms according to GMP requirements.	2
28.	Topic 6. Practical lesson 28. Production of phytochemicals according to GMP requirements. Theoretical foundations of extraction.	2
29.	Topic 6. Practical lesson 29. Production of phytochemicals according to GMP requirements. Extractants. Requirements for them. Extraction methods.	2

30.	Topic 6. Practical lesson 30. Production of phytochemicals according to GMP requirements. Tinctures.	2
31.	Topic 6. Practical lesson 31. Production of phytochemicals according to GMP requirements. Extracts.	2
32.	Topic 6. Practical lesson 32. Production of phytochemicals according to GMP requirements. Novogalen preparations.	2
33.	Topic 6. Practical lesson 33. Solving test problems on the production of phytochemicals according to GMP requirements.	2
34.	Topic 7. Practical lesson 34. Packaging and packaging of finished products.	2
35.	Topic 7. Practical lesson 35. Marking of finished products.	2
36.	Topic 7. Practical lesson 36. Transportation and storage of finished products.	2
37.	Topic 7. Practical lesson 37. Solving test tasks on packaging and packaging of finished products.	2
38.	Topic 8. Practical lesson 38. Introduction to the work of the quality control department of pharmaceuticals.	2
39.	Topic 8. Practical lesson 39. Acquaintance with the central factory laboratory.	2
40.	Differentiated credit.	2
Number of hours of practical classes in the discipline		**80**

6. INDEPENDENT WORK OF A HIGHER EDUCATION STUDENT

№ i/o	**Topic name / types of tasks**	**Number of hours**
1.	Topic 1. General introduction to the pharmaceutical enterprise; internal regulations.	5
2.	Topic 2. Production of solid dosage forms according to GMP requirements (tablets, granules, dragees).	5
3.	Topic 3. Production of solid dosage forms according to GMP requirements (capsules in a gelatin shell).	5
4.	Topic 4. Production of sterile medicinal products in accordance with GMP requirements (dosage forms for injections in ampoules, vials, infusion solutions in containers.	5
5.	Topic 5. Production of soft dosage forms according to GMP requirements (ointments, gels, suspensions, emulsions, suppositories, plasters).	5
6.	Topic 6. Production of phytochemicals according to GMP requirements.	5
7.	Topic 7. Packaging and packaging of finished products.	5
8.	Topic 8. Familiarization with the work of the pharmaceutical quality control department and the central factory laboratory.	5
Number of hours of independent work on the discipline		**40**

7. FORMS AND METHODS OF TEACHING

Forms of education:

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

Methods of learning:

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

test problems.

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

8. FORMS OF CONTROL AND CRITERIA FOR ASSESSING LEARNING OUTCOMES

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

Final control form: differential credit.

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

Assessment	Assessment criteria
Excellent «5»	The applicant is fluent in the material, actively participates in the discussion and solution of a situational clinical problem, confidently demonstrates practical skills during the examination of the patient and the interpretation of clinical, laboratory and instrumental research data, expresses his opinion on the topic of the lesson, and demonstrates clinical thinking.
Good «4»	The applicant has a good command of the material, participates in the discussion and solution of a situational clinical problem, demonstrates practical skills during the examination of the patient and the interpretation of clinical, laboratory and instrumental research data with some errors, expresses his opinion on the topic of the lesson, and demonstrates clinical thinking.
Satisfactory «3»	The applicant does not have sufficient knowledge of the material, participates uncertainly in the discussion and solution of a situational clinical problem, demonstrates practical skills during the examination of the patient and the interpretation of clinical, laboratory and instrumental research data with significant errors.
Unsatisfactory «2»	The applicant does not possess the material, does not participate in the discussion and solution of a situational clinical problem, does not demonstrate practical skills during the examination of the patient and the interpretation of clinical, laboratory and instrumental research data.

Only those applicants who have fulfilled the requirements of the curriculum in the discipline, have no academic debt, and their average score for current academic activity in the discipline is at least 3.00 are allowed to take the final examination in the form of a differentiated assessment..

Differentiated credit is carried out: in the last lesson (the lesson is separated as a separate control measure) after the end of classes before the start of the examination session - in the case of a tape learning system, in the last lesson of the educational component - in the case of a cyclical learning system.

The methodology for conducting final (semester) control of the educational component in the form of differentiated assessment is unified and involves the use of standardized forms.

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

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

9. DISTRIBUTION OF POINTS RECEIVED BY HIGHER EDUCATION STUDENTS

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

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

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

According ***to the ECTS rating scale***, the achievements of the students in the academic discipline who are studying in the same course of the same specialty are evaluated, according to

the points they received, by means of ranking, namely:

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

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

10. METHODOLOGICAL SUPPORT

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

11. QUESTIONS FOR PREPARATION FOR THE FINAL TEST

1. Mixing. Mixing of powdered materials. Classification of mixers.
2. Powders. Classification. Powder technology. Automatic powder dispensers.
3. Methods of cleaning solutions. Centrifuges for settling and filtering. Super-centrifuges. Filters: suction and printing, filter press.
4. Syrups. Characteristics. Classification. Production of syrups.
5. Aromatic waters. Aromatic waters. Equipment for obtaining distilled aromatic waters.
6. Alcoholometry. Alcohol concentration, methods and devices for its determination.
7. Determination of the content of anhydrous alcohol in water-alcohol solutions. Accounting for alcohol.
8. Extractive preparations. Theoretical foundations of extraction.
9. Factors affecting the extraction process. Viscosity. Surfactants. Hydrodynamics of the layer of plant raw materials.
10. Extraction equipment: maceration tanks, communicated and uncommunicated batteries of extractors. Continuous extractors.
11. Recovery and rectification of alcohol. Recovery of alcohol from spent raw materials by displacement with water and distillation with a water pore. Equipment.
12. Maceration, possibilities of its intensification. Percolation.

13. Extracts. Classification by consistency and extractant used. Liquid extracts - methods of production.
14. Nomenclature of liquid extracts. Thick and dry extracts - methods of production.
15. Animal raw materials preparations. Features of animal raw materials.
16. Technology of production of preparations for internal use and parenteral administration. Standardization.
17. Enzyme preparations. Characteristics. Classification. Enzymes of higher plants.
18. Enzymes of microbiological synthesis. Strains of microbiological synthesis and requirements for them.
19. Preparation and disinfection of nutrient media, air purification and sterilization.
20. Microbiological control of production stages. Conducting fermentation processes. Fermenters.
21. Culture storage and propagation of seed material. Obtaining seed material in a pure culture workshop.
22. Basic fermentation. Isolation of fermentation products. Equipment for processing fermentation products.
23. The value of granulation. Dry, wet granulation, powdering of granulate.
24. The influence of the type of granulation on the bioavailability of drugs. Granulate analysis.
25. Pressing. Tablet presses: impact and rotary.
26. Comparative characteristics of tablet presses and the principle of their operation. The influence of pressing pressure on the therapeutic effectiveness of tablets. Direct pressing.
27. Methods of coating. Purpose of coating.
28. Coating technology: rolling, grinding, glossing, polishing. Obductors. Film coatings.
29. Types and properties of film coatings. Equipment.
30. Pressed coatings. Film coating technology. Equipment.
31. Technology of coating by pressing. Double and triple pressing machines.
32. Excipients in the production of gelatin capsules. Methods of obtaining.
33. Automated lines, presses. Filling capsules with medicinal substances.
34. Screw, rotary, piston machines. Assortment of medicines in factory-made gelatin capsules, dosing accuracy.
35. Microencapsulation of medicines. Methods of obtaining microcapsules.
36. Plasters. Mustard plasters. Technology of obtaining. Equipment.
37. Rectal dosage forms. Characteristics of suppositories. Equipment for the production and packaging of suppositories.
38. Aerosols. Characteristics. Inhalation aerosols. Composition and principle of operation of an aerosol can.
39. Methods of filling aerosols. Quality assessment. Accuracy of dosage of contents. Qualitative and quantitative composition.
40. Factory-produced medicines prepared under aseptic conditions. Dosage forms for injections: solutions in ampoules, suspensions, emulsions, powders, tablets.
41. Requirements for dosage forms for injections. Sources of contamination of injection solutions.
42. Cleanliness classes of premises. Requirements for personnel, overalls, equipment.
43. Obtaining water for injections in factory conditions. Distillation devices.
44. Glass. Obtaining, technical requirements for it. Glass classes. Research on chemical and thermal stability of ampoules.
45. Preparation of glass wire: calibration, washing methods. Production of ampoules on semi-automatic machines.
46. Preparation of ampoules for filling. Apparatus for opening capillaries. Annealing of ampoules.
47. Vacuum, syringe and steam condensation washing of ampoules. Use of ultrasound for washing ampoules. Drying and sterilization.

48. Production of injection solutions in factory conditions. Dehydration. Additional purification in the process of obtaining solutions.
49. Filtering materials. Filtering devices. Metal, ceramic, glass, fluoroplastic membrane filters. Sterilization by filtration.
50. Filling ampoules. Filling devices. Sealing ampoules. Sealing in a stream of inert gases. Sealing quality control.
51. Methods of sterilization of solutions in ampoules. Sterilization mode control. Leakage check.
52. Quality assessment of finished products. Concept of sterile batch.
53. Ophthalmic dosage forms. Features of the technology of ophthalmic dosage forms of factory production.
54. Biotechnology in the manufacture of medicines. Scientific and technical prerequisites for the formation of biotechnology.
55. Fundamentals of biotechnological production. Production of medicines based on microbiological synthesis.
56. Isolation of biosynthesis products. Purification of biosynthesis products.
57. Genetic engineering. Methods of obtaining drugs based on genetic engineering.
58. Packaging of finished dosage forms. Packaging materials. Containers. Filling of dosage forms.
59. Modern range of containers and packaging materials used in the pharmaceutical industry.
60. Container washing devices. Filling in conditions of increasing enterprises.
61. Dosing devices for powders, liquids, ointments, filling of tablets, dragees, capsules and others. Prospects for packaging of GLP.
62. Solid dispersion systems. Carriers of first-generation medicinal substances. Microcapsules. Microspheres.
63. Methods of industrial production of suspensions, emulsions, ointments. Mixing of phases.
64. Grinding in a liquid medium. Grinding using ultrasound. Equipment.
65. Design features and operating principle of the reactor-mixer, MKL type machines, "Jupitron" mixers, grinding mills, three-roll ointment mixer.
66. Tube-filling dosing machines. Main factors affecting the rheological properties of ointments.

12. RECOMMENDED LITERATURE

Basic:

1. Industrial Pharmacy: A Textbook / Dr. Marina Koland, Dr. Anoop Narayanan, D.S. Sandeep, R. Harshitha, Dr. M P Gowrav. Published by I.K. International Pvt. Ltd. 2023. – 388 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.

Additional:

1. Промислова технологія лікарських засобів: базовий підручник для студ. вищ. навч. фармац. закладу (фармац. ф-тів) / Є.В.Гладух, О.А.Рубан, І.В.Сайко [та ін.].; за ред.. Є.В. Гладуха, В.І. Чуєшова. – Вид. 2-ге, випр. та допов. –Х.: НФаУ: Новий Світ-2000, 2018. – 486 с.: іл. – (Серія «Національний підручник»).
2. Технологія ліків: у питаннях та відповідях. Навчальний посібник для здобувачів освіти спеціальності 226 Фармація, промислова фармація за освітньо-професійною програмою «Фармація». Косяченко Н.М., Зубрицька Т.Р., Бур'янова В.В., Марчук О.С., Мороз О.Г. Житомир. 2023. – 209 с.
3. Допоміжні речовини в технології ліків: вплив на техно- логічні, споживчі, економічні характеристики і терапевтичну ефективність: навч. посіб. для студ. вищ. фармац. навч. закл. / авт.- уклад.: І. М. Перцев, Д. І. Дмитрієвський, В. Д. Рибачук та ін.; за ред.

І. М. Перцева. — Х.: Золоті сторінки, 2010. — 600 с.
4. Фармацевтична технологія. Збірник тестових завдань з поясненнями для підготовки провізорів-інтернів спеціальність «Загальна фармація» до ліцензійного іспиту «Крок 3. Фармація» / Г. П. Смойловська, О. О. Малюгіна. – Вид. 2-ге, допрац. і допов. – Запоріжжя: ЗДМУ, 2021. – 100 с.

13. INFORMATION RESOURCES

1. www.moz.gov.ua – official website of the Ministry of Health of Ukraine
2. fp.com.ua – website of the journal "Practitioner Pharmacist"
3. www.provisor.com.ua – official website of the magazine "Provizor"
4. State Register of Medicinal Products of Ukraine. − [Electronic resource]. – Access mode: http://www.drlz.com.ua/ − as of 10.01.2017
5. Database "Equalizer" LLC "Business-Credit" – [Electronic resource]. – Access mode: http://eq.bck.com.ua/ − as of 09/20/2016