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 PHARMACEUTICAL CHEMISTRY »

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:
Head of the Department of Pharmaceutical Chemistry and Drug Technology, Doctor of Chemical Sciences, Professor Volodymyr GELMBOLDT, Senior lecturer at the higher education institution, Department of Pharmaceutical Chemistry and Drug Technology Oleksii NIKITIN, Docent of the Department of Pharmaceutical Chemistry and Drug Technology, PhD in Chemistry Tetyana LOZHYCHEVSKA.

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 X</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 test</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 chemistry of medicines, their standardization and quality control of medicines and their technological forms, familiarization with the latest medicines that enter the pharmacy. 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 chemistry of medicines they have acquired in working with medicines and patients, to ensure the rigor and accuracy of quality control of medicines and their dispensing.

Task: acquiring skills in the field of providing high-quality pharmaceutical care to patients, taking into account knowledge of the physical, physicochemical and chemical properties of drugs, the basic laws of the "structure-activity" relationship, avoiding possible interactions of drugs during their manufacture and use, establishing the good quality of individual drugs, their multicomponent mixtures and ensuring their proper storage, acquiring knowledge of the basic methods of drug synthesis or extraction from natural raw materials; in the field of pharmaceutical analysis.

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

- public policy and public administration in the field of creation, production and quality control of medicines;
- chemical formulas, Latin and chemical names of medicines, their properties, methods of extraction and synthesis;
- analytical and functional groups that are part of drug molecules and the chemistry of identification reactions;
- identification reaction techniques, purity testing;
- methods for quantitative determination of medicinal products;
- methods of qualitative and quantitative rapid analysis of dosage forms;
- the use of drugs in medicine. The relationship between the structure and action of drugs.

Be able to:

- independently prepare titrated solutions from aliquots of reagents and fixans, establish the correction factor and titer for these solutions;
- prepare standard solutions, indicator solutions and reagents;
- determine the quality of medicines and dosage forms (presence of impurities of chlorides, sulfates, nitrates, mercury, arsenic, etc.);

- determine the solubility of drugs, determine density, determine the pH of solutions by potentiometric and colorimetric methods;
- apply physical and physicochemical methods of analysis (refractometry, polarimetry, spectrophotometry, thin layer chromatography of sorbent) and have skills in working with appropriate equipment;
- carry out drug identification reactions by cations (argentum, sodium, potassium, calcium, iron II and III, bismuth, zinc, hydrargyrum), anions (fluoride, chloride, bromide, iodide, sulfate, phosphate, nitrite, nitrate, bicarbonate, benzoate, salicylate, oxalate, etc.);
- carry out reactions to identify drugs by analytical and functional groups: primary aromatic amino group, phenolic, aldehyde, oxy-, oxo-, ester, oxyacetyl groups, steroid system in various groups of steroid hormones, reactions to cardiac glycosides (five-membered lactone cycle, steroid system, amino- and deoxysugars), to double and triple bonds, pyridine cycle, quinine, quinuclidine, phenothiazine, purine, etc.;
- carry out quantitative determination of medicines by methods of acid-base titration in aqueous and non-aqueous solvents, bromatometry, complexometry, iodometry, argentometry, etc.;
- conduct an analysis of purified water;
- conduct analysis of inorganic and organic medicines;
- analyze industrially produced dosage forms (injection solutions, tablets, ointments, etc.);
- analyze dosage forms prepared extemporaneously (powders, mixtures, ointments, eye drops, etc.);
- analyze medications that arrive from the material room to the assistant's room;
- conduct analysis of concentrates and in-pharmacy preparations;
- analyze unstable medicines and perishable substances;
- conduct analysis of tinctures, extracts;
- conduct analysis of medicinal plant raw materials (determination of ash, organic and mineral impurities, etc.);
- conduct research on pharmaco-technological indicators of medicines;
- calculate analysis results (equivalent mass, active substance content, mass deviation);
- to conclude on the compliance of medicinal products with the requirements of the pharmacopoeial article or the QCM.

3. CONTENT OF THE COURSE

Topic 1. **Modern pharmaceutical analysis methods.**

- classification and characterization;
- features of pharmaceutical analysis related to the intended purpose of medicines;
- professional responsibility of the pharmacist;
- state principles and regulations regulating the quality of medicines.

Topic 2. **General pharmacopoeial methods of analysis. General provisions on chemical methods of analysis of medicinal products.**

- state principles and regulations regulating the quality of medicines;
- organization of quality control of medicines in Ukraine;
- State Pharmacopoeia of Ukraine;
- modern strategies for creating innovative medicines;
- pharmacopoeial analysis.

Topic 3. **Tests for maximum impurity content.**

- pharmacopoeial reactions for detecting impurities in medicinal products.

Topic 4. **Analysis of physicochemical properties of medicinal products as one of the elements of assessing the quality of medicinal products. Analysis of purified water. Physicochemical properties of water.**

- state of aggregation;
- color;
- temperature characteristics;

- optical properties.

Topic 5. **General principles of drug substance identification.**

- identification of medicinal substances of inorganic nature.
- identification of medicinal substances of organic nature by functional groups (functional analysis).

Topic 6. **Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of the concentration of solutions.**

- using physical methods;
- using chemical methods;
- using physico-chemical methods.

Topic 7. **Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of unstable medicines.**

- study of the influence of the environment on the physicochemical properties of drugs;
- selection of sensitive methods;
- establishment of storage conditions.

Topic 8. **Analysis of unstable and perishable drugs. Analysis of 5% alcoholic iodine solution.**

- study of the influence of the environment on the physicochemical properties of drugs;
- selection of sensitive methods;
- establishment of storage conditions.

Topic 9. **Analysis of unstable and perishable drugs. Analysis of anise-antise drops.**

- study of the influence of the environment on the physicochemical properties of drugs;
- selection of sensitive methods;
- establishment of storage conditions.

Topic 10. **Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Preparation and analysis of dosage forms for injections.**

- study of the influence of the environment on the physicochemical properties of drugs;
- control of injection solutions for sterility;
- presence of pyrogenic substances;
- selection of sensitive methods;
- establishment of storage conditions.

Topic 11. **Processing of auxiliary material, personal hygiene of aseptic unit workers.**

- processing of auxiliary material;
- personal hygiene of workers;
- regular cleaning and compliance with sanitary rules when working with medicines.

Topic 12. **Features of preparation and analysis of dosage forms for injections. Chemical analysis of 50% analgin solution for injections.**

- control of injection solutions for sterility;
- presence of pyrogenic substances;
- selection of sensitive methods;
- establishment of storage conditions.

Topic 13. **Features of preparation and analysis of dosage forms for injections. Chemical analysis of a 5% aminocaproic acid solution.**

- control of injection solutions for sterility;
- presence of pyrogenic substances;
- selection of sensitive methods;
- establishment of storage conditions.

Topic 14. **Features of preparation, analysis and storage of children's medicines, including those for newborns.**

- oral dosage forms with improved taste;
- rectal dosage forms;
- solid dosage forms.

Topic 15. **Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of a 1% glutamic acid solution.**

- study of the influence of the environment on the physicochemical properties of drugs;
- control of injection solutions for sterility;
- presence of pyrogenic substances;
- selection of sensitive methods;
- establishment of storage conditions.

Topic 16. **Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of dibazol 0.005, glucose 0.2.**

- incoming control;
- process control;
- final control: physical and chemical methods, conformity assessment.

Topic 17. **Features of the use of pharmaceutical analysis in the quality control of medicines. Analysis of eye drops. Analysis of a 0.25% zinc sulfate solution.**

- incoming control;
- process control;
- final control: physical and chemical methods, conformity assessment.

Topic 18. **Features of the use of pharmaceutical analysis in the quality control of medicines. Analysis of alcoholic solutions. Calculations, examples.**

- incoming control;
- process control;
- final control: physical and chemical methods, conformity assessment.

Topic 19. **Features of the use of pharmaceutical analysis in the quality control of medicines. Qualitative express analysis of medicines.**

- using physical methods;
- using chemical methods;
- color or precipitate chemical reactions to the corresponding cations, anions or functional groups of organic substances;
- using physicochemical methods - fluorimetry, chromatography, etc.

Topic 20. **Quality control and chemical-pharmaceutical examination of plant raw materials.**

- macroscopic analysis;
- microscopic analysis;
- chromatographic analysis.

4. STRUCTURE OF THE ACADEMIC DISCIPLINE

Topic names	Number of hours of full-time study			
	Total	including		
		lectures	practical	IWS
Topic 1. Modern pharmaceutical analysis methods.	6	0	4	2
Topic 2. General pharmacopoeial methods of analysis. General provisions on chemical methods of analysis of medicinal products.	6	0	4	2
Topic 3. Tests for maximum impurity content.	6	0	4	2
Topic 4. Analysis of physicochemical properties of medicinal products as one of the elements of assessing the quality of medicinal products. Analysis of purified water. Physicochemical properties of water.	6	0	4	2
Topic 5. General principles of drug substance identification.	6	0	4	2
Topic 6. Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of the concentration of solutions.	6	0	4	2
Topic 7. Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of unstable medicines.	6	0	4	2
Topic 8. Analysis of unstable and perishable drugs. Analysis of 5% alcoholic iodine solution	6	0	4	2
Topic 9. Analysis of unstable and perishable drugs. Analysis of anise-antise drops.	6	0	4	2
Topic 10. Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Preparation and analysis of dosage forms for injections.	5	0	4	1
Topic 11. Processing of auxiliary material, personal hygiene of aseptic unit workers.	5	0	4	1
Topic 12. Features of preparation and analysis of dosage forms for injections. Chemical analysis of 50% analgin solution for injections.	5	0	4	1
Topic 13. Features of preparation and analysis of dosage forms for injections. Chemical analysis of a 5% aminocaproic acid solution.	5	0	4	1
Topic 14. Features of preparation, analysis and storage of children's medicines, including those for newborns.	6	0	4	2
Topic 15. Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of a 1% glutamic acid solution.	6	0	4	2
Topic 16. Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of dibazol 0.005, glucose 0.2.	6	0	4	2
Topic 17. Features of the use of pharmaceutical analysis in the quality control of medicines. Analysis of eye drops. Analysis of a 0.25% zinc sulfate solution.	6	0	4	2
Topic 18. Features of the use of pharmaceutical analysis in the quality control of medicines. Analysis of alcoholic solutions. Calculations, examples.	8	0	4	4
Topic 19. Features of the use of pharmaceutical analysis in the quality control of medicines. Qualitative express analysis of medicines.	8	0	4	4
Topic 20. Quality control and chemical-pharmaceutical examination of plant raw materials.	4	0	2	2
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. Modern methods of pharmaceutical analysis. Classification and characterization.	4
2.	Topic 2. Practical lesson 2. General pharmacopoeial methods of analysis. General provisions on chemical methods of analysis of medicinal products.	4
3.	Topic 3. Practical lesson 3.	4

	Testing for the limit content of impurities. Pharmacopoeial reactions for detecting impurities in medicinal products.	
4.	Topic 4. Practical lesson 4. Testing for the maximum content of impurities. Analysis of purified water. Physico-chemical properties of water.	2
5.	Topic 5. Practical lesson 5. General principles of identification of medicinal substances.	2
6.	Topic 6. Practical lesson 6. Features of using pharmaceutical analysis in quality control of medicines.	4
7.	Topic 6. Practical lesson 7. Analysis of the concentration of solutions.	4
8.	Topic 7. Practical lesson 8. Features of using pharmaceutical analysis in quality control of medicines manufactured in a pharmacy.	4
9.	Topic 8. Practical lesson 9. Analysis of unstable drugs, as well as drugs that deteriorate quickly.	2
10.	Topic 8. Practical lesson 10. Analysis of 5% alcoholic iodine solution.	2
11.	Topic 9. Practical lesson 11. Analysis of unstable drugs, as well as oxidizable drugs.	2
12.	Topic 9. Practical lesson 12. Analysis of ammonia-anis drops.	2
13.	Topic 10. Practical lesson 13. Features of using pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Preparation and analysis of dosage forms for injections.	4
14.	Topic 11. Practical lesson 14. Processing of auxiliary material, personal hygiene of aseptic unit workers.	2
15.	Topic 1-12. Practical lesson 15. Solving situational and test tasks: "Modern methods of pharmaceutical analysis. Classification and characterization; General pharmacopoeial methods of analysis. General provisions on chemical methods of analysis of medicinal products; Testing for the limit content of impurities; General principles of identification of medicinal substances."	2
16.	Topic 12. Practical lesson 16. Chemical analysis of a 50% analgin solution for injection.	2
17.	Topic 13. Practical lesson 17. Features of preparation and analysis of dosage forms for injections.	2
18.	Topic 13. Practical lesson 18. Chemical analysis of a 5% aminocaproic acid solution.	2
19.	Topic 14. Practical lesson 19. Features of preparation, analysis and storage of children's medicines.	2
20.	Topic 14. Practical lesson 20. Features of preparation, analysis and storage of children's medicines, including those for newborns.	4
21.	Topic 15. Practical lesson 21. Analysis of a 1% glutamic acid solution.	2
22.	Topic 16. Practical lesson 22. Features of using pharmaceutical analysis in quality control of medicines. Soft dosage forms.	2
23.	Topic 16. Practical lesson 23.	2

	Analysis of dibazole 0.005, glucose 0.2.	
24.	Topic 17. Practical lesson 24. Features of using pharmaceutical analysis in quality control of medicines. Analysis of eye drops.	2
25.	Topic 17. Practical lesson 25. Analysis of a 0.25% zinc sulfate solution.	2
26.	Topic 18. Practical lesson 26. Features of using pharmaceutical analysis in quality control of medicines. Analysis of alcoholic solutions.	4
27.	Topic 18. Practical lesson 27. Features of using pharmaceutical analysis in quality control of medicines. Calculations, examples.	4
28.	Topic 19. Practical lesson 28. Qualitative express analysis of medicines.	2
29.	Topic 20. Practical lesson 29. Quality control and chemical and pharmaceutical examination of plant raw materials.	2
30.	Differential 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.	Modern methods of pharmaceutical analysis. Classification and characterization. Features of pharmaceutical analysis related to the intended purpose of medicines and the professional responsibility of a pharmacist. State principles and regulations regulating the quality of medicines.	2
2.	General pharmacopoeial methods of analysis. General provisions on chemical methods of analysis of medicinal products. State principles and provisions regulating the quality of medicinal products. Organization of quality control of medicinal products in Ukraine. State Pharmacopoeia of Ukraine. Modern strategies for the creation of innovative medicinal products. Pharmacopoeial analysis.	2
3.	Tests for the limit content of impurities. Pharmacopoeial reactions for the detection of impurities in medicinal products.	2
4.	Analysis of physicochemical properties of drugs as one of the elements of drug quality assessment. Analysis of purified water. Physicochemical properties of water.	2
5.	General principles of identification of medicinal substances. Identification of medicinal substances of inorganic nature. Identification of medicinal substances of organic nature by functional groups (functional analysis).	3
6.	Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of the concentration of solutions.	3
7.	Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy. Analysis of unstable medicines.	3
8.	Analysis of unstable drugs, as well as drugs that deteriorate quickly.	3
9.	Processing of auxiliary material, personal hygiene of aseptic unit workers.	1
10.	Features of preparation and analysis of dosage forms for injections.	3
11.	Features of preparation, analysis and storage of children's medicines, including those for newborns.	2
12.	Features of the use of pharmaceutical analysis in quality control of medicines manufactured in a pharmacy.	3

13.	Features of the use of pharmaceutical analysis in the quality control of medicines. Analysis of eye drops.	3
14.	Features of the use of pharmaceutical analysis in the quality control of medicines. Analysis of alcoholic solutions.	3
15.	Features of the use of pharmaceutical analysis in the quality control of medicines. Qualitative express analysis of medicines.	2
16.	Quality control and chemical and pharmaceutical examination of plant raw materials.	3
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. Structure and functions of the state system of quality assurance and control of medicines.
2. Pharmaceutical analysis and its importance for ensuring the quality of pharmaceutical products.
3. Pharmacopoeial analysis.

4. Legislative acts regulating the quality control of medicines in Ukraine.
5. State Pharmacopoeia of Ukraine, its structure and content.
6. Incoming quality control of medicines during wholesale and retail trade.
7. Main criteria of pharmaceutical analysis: specificity and sensitivity.
8. Preparation of titrated solutions and titer determination.
9. Reference solutions and their use in pharmaceutical analysis.
10. Determination of transparency and degree of turbidity of liquids.
11. Determination of the degree of color of liquids.
12. Analysis of purified water and water for injection. Main quality indicators.
13. Testing for purity of purified water in containers.
14. Determination of nitrate impurities in purified water.
15. Determination of sulfate impurities in purified water.
16. Determination of chloride impurities in purified water.
17. Determination of ammonium salts impurities in purified water.
18. Determination of calcium and magnesium impurities in purified water.
19. Determination of oxidizable substances impurities in purified water.
20. Analysis of highly purified water.
21. Quality indicators of a substance according to the general article of the State Federal University of Health Sciences "Substances".
22. Testing of substances for purity.
23. Testing for the maximum content of impurities in medicines according to the State Federal University of Health Sciences.
24. QCM of the pharmaceutical manufacturer.
25. Determination of ethanol content in liquid medicines.
26. Definition of the indicator "Extracted volume".
27. Use of physical methods of analysis in quality control of starting materials, intermediate products, raw materials, materials intended for the production of finished products.
28. Use of physico-chemical methods of analysis in quality control of starting materials, intermediate products, raw materials, materials intended for the production of finished products.
29. Use of chemical methods of analysis in quality control of starting materials, intermediate products, raw materials, materials intended for the production of finished products.
30. Qualitative reactions to cations, anions, functional groups and their use for the identification of substances and active ingredients in medicinal products.
31. Physical methods of identification of substances.
32. Determination of the pH of the solution medium according to the requirements of the State Federal University of Medicine and Pharmacy.
33. Determination of the refractive index and its use for determining the purity and quantitative content of the active ingredient.
34. Polarimetry and its use for identification, purity testing and determination of the quantitative content of the active substance.
35. UV spectrophotometry and its use for identification, purity testing and determination of the quantitative content of the active substance.
36. Use of IR spectrophotometry in pharmaceutical analysis.
37. Photocolorimetry and its use in pharmaceutical analysis.
38. Classification of chromatography methods: thin-layer chromatography, liquid and gas chromatography, ion-exchange chromatography and others; their use in quality control of medicines.
39. Use of acid-base titration methods in aqueous and non-aqueous media in pharmaceutical analysis.
40. Use of titrimetric redox methods in pharmaceutical analysis.
41. Use of titrimetric precipitation methods in pharmaceutical analysis.

42. Use of complexometric titration methods in pharmaceutical analysis.
43. The essence of gravimetry and its use in pharmaceutical analysis.
44. Types of intra-pharmacy control of medicines in accordance with the requirements of the current order of the Ministry of Health of Ukraine.
45. Organoleptic control of dosage forms.
46. Physical control of dosage forms.
47. Chemical control of dosage forms.
48. Control of pharmaceutical preparations manufactured in pharmacies during dispensing.
49. Basic requirements for qualitative and quantitative express analysis of dosage forms.
50. Analysis of intra-pharmacy preparations: concentrates, semi-finished products.
51. Methods for determining the concentration of ethyl alcohol.
52. Features of intra-pharmacy control of medicines for newborns.
53. General requirements for the organization of storage of medicines and medical devices.
54. Features of storage of medicines that require protection from light.
55. Features of storage of medicines that require protection from moisture.
56. Features of storage of medicines that require protection from weathering (evaporation).
57. Features of storage of medicines that require protection from elevated or lowered temperatures.
58. Features of storage of fragrant and colored medicines.
59. Features of storage of medicinal plant raw materials.
60. Features of storage of finished dosage forms.

12. RECOMMENDED LITERATURE

Basic:

1. Pharmaceutical, Biological and Chemical Patents. RA Dr. Marco Stief, LL.M., RiOLG Prof. Dr. Maximilian Haedicke, LL.M., Dr. Annelie Wünsche. Nomos, 1. Edition 2025, 1200 p.
2. Pharmaceutical chemistry. Section 2.3. Analysis of medicines of the hormon group: study and methodical guide for 4th year students of the specialty "Pharmacy, Industrial Pharmacy" / K. Shabelnik, N. Derevianko, S. Borsuk. – Zaporizhzhia: ZSMPhU, 2024. - 104 p.
3. Pharmaceutical analysis: навч. посіб. для студ. вищ. навч. закл. / V.A. Georgiyants, P.O. Bezugly, I.V. Ukrainets [et al.]; edited by V.A. Georgiyants. – Kharkiv : NUPh: , 2018. – 400 p.
4. Pharmaceutical Chemistry. Analysis of the Medicinal Substances according to Functional Groups: study guide (III—IV a. l.) / O.O. Tsurkan, I.V. Nizhenkovska, O.O. Hlushachenko. – 2018. – 152 p.

Additional:

1. Коновалова О.Ю., Геращенко І.І., Джан Т.В., Гуртовенко І.О., Гудзенко Н.В., Рибак Л.М. Фармацевтична хімія. Навчальний посібник для студентів вищих медичних та фармацевтичних навчальних закладів ІІІ-ІV рівнів акредитації. - К.: Книга-плюс, 2023. - 384 с.
2. Фармацевтичний аналіз : Підручник / П. О. Безуглий, В. А. Георгіянц, Р. Б. Лесик та ін. ; за заг. ред. В. А. Георгіянц. – Харків : Вид-во НФаУ : Золоті сторінки, 2019. – 568 с.
3. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.
4. Державна Фармакопея України : в 3 т. / ДП Український науковий фармакопейний центр якості лікарських засобів". – 2–е вид. – Х. : Державне підприємство "Український науковий фармакопейний центр якості лікарських засобів", 2015. – Т. 1. – 1128 с.
5. Державна Фармакопея України : в 3 т. / ДП Український науковий фармакопейний центр якості лікарських засобів". – 2–е вид. – Х. : Державне підприємство "Український науковий фармакопейний центр якості лікарських засобів", 2014. – Т. 2. – 724 с.

6. Державна Фармакопея України : в 3 т. / ДП Український науковий фармакопейний центр якості лікарських засобів". – 2–е вид. – Х. : Державне підприємство "Український науковий фармакопейний центр якості лікарських засобів", 2014. – Т. 3. – 732 с.
7. Цуркан О.О. Фармацевтична хімія. Аналіз лікарських речовин за функціональними групами: навч. посіб. / О.О. Цуркан, І.В. Ніженковська, О.О. Глушаченко. – К.: ВСВ «Медицина», 2012. – 152 с.
8. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.
9. Туркевич М., Владзімірська О., Лесик Р. Фармацевтична хімія (стероїдні гормони, їх синтетичні замінники і гетероциклічні сполуки як лікарські засоби). Підручник. – Вінниця: Нова Книга, 2003. – 464 с.

13. INFORMATION RESOURCES

1. Матеріали у інфармаційній системі ОНМедУ https://info.odmu.edu.ua/chair/pharmaceutical_chemistry/files/214/ua
2. Компендіум - лікарські препарати
3. European Pharmacopoeia (Ph. Eur.)
4. DrugBank онлайн