MINISTRY OF HEALTH PROTECTION OF UKRAINE

ODESSA NATIONAL MEDICAL UNIVERSITY

Department of Pharmaceutical Chemistry and Drug Technology

APPROVED

Vice-rector for scientific and pedagogical work

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September 1st, 2024

WORKING PROGRAM IN THE DISCIPLINE «MANUFACTURING PRACTICE IN PHARMACEUTICAL CHEMISTRY»

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

2024

The working 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 specialty 226 "Pharmacy, Industrial Pharmacy" (protocol no. 10 of June 27, 2024).

Developers:
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The working program was approved at the meeting of the Department of Pharmaceutical Chemistry and Drug Technology
Protocol No. 1 from "29 " August 2024

Head of Department _____ Volodymyr GELMBOLDT

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Approved by the subject cycle methodical commission for pharmaceutical disciplines of ONMedU
Protocol No. 1 from "30 " August 2024

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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__ .

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1. Description of practice:

Name of indicators	Field of knowledge, specialty, specialization, level of higher education	Characteristics of practice
Total number: Credits: 4 Hours: 120	Field of knowledge 22 "Health care" Specialty 226 "Pharmacy, industrial pharmacy" Level of higher education second (master's)	*Full-time education* *Compulsory discipline*
		Year of preparation: 5
		Semesters: X
		Lectures (0 h.)
		Practical (60 h.)
		Independent work (60 h.)
		Form of final control – differentiated credit.
		Correspondence form of education *Compulsory discipline*
		Year of preparation: 5, 6
		Semesters: X, XI
		Lectures (0 h.)
		Practical (4 h.)
		Independent work (116 h.)
		Form of final control – differentiated credit.

2. The purpose and tasks of practice, competences, program results of training.

Goal:

- consolidate and expand theoretical knowledge and practical skills in the chemistry of drugs, their standardization and quality control of drugs and their technological forms, familiarization with the latest drugs that enter the pharmacy;
- to bring students of higher education as close as possible to their specialty, to teach them to use all the theoretical knowledge and practical skills they have acquired in the chemistry of medicinal products 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, physico-chemical and chemical properties of drugs, the main laws of structure-activity dependence, avoiding possible interaction of drugs in the process of their manufacture and use, establishing the good quality of individual drugs , their multicomponent mixtures and ensuring their proper storage, acquiring knowledge of basic methods of synthesis of medicines 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 competencies (GC):

GC 1 – Ability to think abstractly, analyze and synthesize, learn and be modernly educated.
GC 2 – Knowledge and understanding of the subject area and understanding of professional activity.
GC 5 – The ability to evaluate and ensure the quality of the work performed.
GC 11 – Ability to apply knowledge in practical situations.
GC 16 – The ability to conduct experimental research at the appropriate level.

Professional competencies (PC):

PC 12 – Ability to ensure proper storage of natural and synthetic drugs and other pharmacy products in accordance with their physico-chemical properties and Good Storage Practice (GSP) rules in healthcare facilities.
PC 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 (QC), technological instructions, etc.; to prevent the distribution of low-quality, falsified and unregistered medicinal products.
PC 20 – Ability to develop and evaluate methods of quality control of medicinal products of natural and synthetic origin, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological, pharmaco-technological methods; carry out standardization of medicinal products in accordance with current requirements.
PC 24 – Ability to use knowledge of regulatory and legal acts of Ukraine and recommendations of proper pharmaceutical practices in professional activity.

Program learning outcomes (PLO):

PLO 3 – Have specialized knowledge and skills/skills for solving professional problems and tasks, including for the purpose of further development of knowledge and procedures in the field of pharmacy.
PLO 20 – Carry out pharmaceutical development of medicinal products of natural and synthetic origin in the conditions of industrial production.
PLO 22 – Ensure and carry out quality control of medicinal products of natural and synthetic origin and document its results; draw up quality certificates and analysis certificates taking into account the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QCM), technological instructions, etc.; 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; choose and/or develop quality control methods for the purpose of their standardization using physical, chemical, physico-chemical, biological, microbiological and pharmaco-technological methods in accordance with current requirements.
PLO 25 – Adhere to the norms of the sanitary and hygienic regime and the requirements of safety equipment when carrying out professional activities.
PLO 28 – Carry out professional communication in the state language, use oral communication skills in a foreign language, analyze specialized texts and translate foreign language information sources.
PLO 29 – To carry out professional activities using information technologies, "Information databases", navigation systems, Internet resources, software and other information and communication technologies.
PLO 36 – Plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of proper pharmaceutical practices.
PLO 40 – Ensure quality control of medicinal products and document its results. To carry out quality risk management at all stages of the life cycle of medicinal products.

As a result of the study of practice, the student of higher education should:

to know:

- state policy and state management in the field of creation, production and quality control of medicines;
- chemical formulas, Latin and chemical names of medicines, their properties, extraction and synthesis methods;
- analytical and functional groups, which are part of drug molecules, and the chemistry of identification reactions;
- methods of identification reactions, research on purity;
- methods of quantitative determination of medicinal products;

- methods of qualitative and quantitative express analysis of medicinal forms;
- use of medicinal products in medicine. The connection between the structure and action of drugs.

be able:

- independently make titrated solutions from reagent and fixanal weights, set the correction factor and titer for these solutions;
- to make reference solutions, solutions of indicators and reagents;
- determine the quality of medicinal products and dosage forms (presence of impurities of chlorides, sulfates, nitrates, mercury, arsenic, etc.);
- to determine the solubility of medicinal products, to determine the density, to determine the pH of solutions by potentiometric and colorimetric methods;
- apply physical and physico-chemical methods of analysis (refractometry, polarimetry, spectrophotometry, chromatography in a thin layer of sorbent) and have skills in working with appropriate equipment;
- carry out drug identification reactions by cations (argentum, sodium, potassium, calcium, ferrum II and III, bismuth, zinc, hydrargyrum), anions (fluoride, chloride, bromide, iodide, sulfate, phosphate, nitrite -, nitrate-, hydrocarbonate-, benzoate-, salicylate-, oxalate-, etc.);
- perform drug identification reactions 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), on double and triple bonds, pyridine cycle, quinine, quinuclidine, phenthiazine, purine, etc.;
- carry out quantitative determination of medicinal products by methods of acid-base titration in aqueous and non-aqueous solvents, bromatometry, complexonometry, iodometry, argentometry, etc.;
- conduct an analysis of purified water;
- conduct analysis of inorganic and organic medicinal products;
- carry out analysis of medicinal forms of industrial production (solutions for injections, tablets, ointments and others);
- to analyze medicinal forms produced extemporaneously (powders, mixtures, ointments, eye drops and others);
- carry out an analysis of medicines that come from the material room to the assistant's room;
- conduct analysis of concentrates and intrapharmacy preparations;
- perform analysis of unstable medicines and perishable substances;
- analyze tinctures, extracts;
- analyze medicinal plant raw materials (determination of ash, organic and mineral impurities, etc.);
- conduct research on the pharmaco-technological indicators of medicinal products;
- calculate the results of the analysis (equivalent mass, active substance content, mass deviation);
- draw a conclusion about the compliance of medicinal products with the requirements of the pharmacopoeial article or QCM.

3. Content of practice

Topic 1 Modern methods of pharmaceutical analysis. Classification and characteristics. Peculiarities of pharmaceutical analysis are related to the intended use of drugs and the professional responsibility of the pharmacist. State principles and provisions regulating the quality of medicinal products.

Topic 2 General pharmacopoeial methods of analysis. General provisions on chemical methods of drug analysis. 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 creating innovative medicines. Pharmacopoeial analysis.

Topic 3 Testing for the limit content of impurities. Pharmacopoeial reactions for the detection of impurities in medicinal products.
Topic 4 Testing for the limit content of impurities. Analysis of the physicochemical properties of medicinal products as one of the elements of the quality assessment of medicinal products. Analysis of purified water. Physical and chemical properties of water.
Topic 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).
Topic 6 Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Analysis of concentration of solutions.
Topic 7 Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Analysis of unstable medicinal products.
Topic 8 Analysis of unstable medicinal products, as well as perishable medicinal products. Analysis of 5% alcohol iodine solution.
Topic 9 Analysis of unstable medicinal products, as well as perishable medicinal products. Analysis of aniseed drops.
Topic 10 Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Preparation and analysis of dosage forms for injections.
Topic 11 Processing of auxiliary material, personal hygiene of aseptic block workers.
Topic 12 Peculiarities of preparation and analysis of dosage forms for injections. Chemical analysis of a 50% analgin solution for injections.
Topic 13 Peculiarities of preparation and analysis of dosage forms for injections. Chemical analysis of 5% aminocaproic acid solution.
Topic 14 Peculiarities of preparation, analysis and storage of children's medicines, including for newborns.
Topic 15 Peculiarities of the use of pharmaceutical analysis in the quality control of medicines manufactured in a pharmacy. Analysis of 1% glutamic acid solution.
Topic 16 Peculiarities of the use of pharmaceutical analysis in the quality control of medicines manufactured in a pharmacy. Analysis of dibazole 0.005, glucose 0.2.
Peculiarities of using pharmaceutical analysis in drug quality control. Analysis of eye drops. Analysis of 0.25% zinc sulfate solution.
Topic 18 Peculiarities of using pharmaceutical analysis in drug quality control. Analysis of alcohol solutions. Calculations, examples.
Topic 19 Peculiarities of using pharmaceutical analysis in drug quality control. Qualitative express analysis of medicines.
Topic 20 Quality control and chemical-pharmaceutical examination of plant raw materials.

4. Practice structure

Names of topics	Number of hours of full-time education					Number of hours of correspondence form of education				
	In total	including				In total	including			
		lectures	seminars	practical	IWS		lectures	seminars	practical	IWS
Topic 1. Modern methods of pharmaceutical analysis. Classification and characteristics. Peculiarities of pharmaceutical analysis are related to the intended use of drugs and the professional responsibility of the pharmacist. State principles and provisions regulating the quality of medicinal products.	4	0	0	2	2	4	0	0	2	2

Topic 2. General pharmacopoeial methods of analysis. General provisions on chemical methods of drug analysis. 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 creating innovative medicines. Pharmacopoeial analysis.	6	0	0	2	4	6	0	0	2	4
Topic 3. Testing for the limit content of impurities. Pharmacopoeial reactions for the detection of impurities in medicinal products.	5	0	0	2	3	5	0	0	0	5
Topic 4. Testing for the limit content of impurities. Analysis of the physicochemical properties of medicinal products as one of the elements of the quality assessment of medicinal products. Analysis of purified water. Physical and chemical properties of water.	7	0	0	2	5	7	0	0	0	7
Topic 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).	5	0	0	2	5	5	0	0	0	5
Topic 6. Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Analysis of concentration of solutions.	7	0	0	4	3	7	0	0	0	7
Topic 7. Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Analysis of unstable medicinal products.	5	0	0	2	3	5	0	0	0	5
Topic 8. Analysis of unstable medicinal products, as well as perishable medicinal products. Analysis of 5% alcohol iodine solution.	7	0	0	4	3	7	0	0	0	7
Topic 9. Analysis of unstable medicinal products, as well as perishable medicinal	6	0	0	4	2	6	0	0	0	6

products. Analysis of aniseed drops.										
Topic 10. Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Preparation and analysis of dosage forms for injections.	3	0	0	2	1	3	0	0	0	3
Topic 11. Processing of auxiliary material, personal hygiene of aseptic block workers.	3	0	0	2	1	3	0	0	0	3
Topic 12. Features of preparation and analysis of dosage forms for injections. Chemical analysis of a 50% analgin solution for injections.	3	0	0	2	1	6	0	0	0	6
Topic 13. Peculiarities of preparation and analysis of dosage forms for injections. Chemical analysis of 5% aminocaproic acid solution.	6	0	0	4	2	6	0	0	0	6
Topic 14. Peculiarities of preparation, analysis and storage of children's medicines, including for newborns.	6	0	0	4	2	4	0	0	0	4
Topic 15. Peculiarities of the use of pharmaceutical analysis in the quality control of medicinal products manufactured in a pharmacy. Analysis of 1% glutamic acid solution.	7	0	0	4	3	7	0	0	0	7
Topic 16. Peculiarities of the use of pharmaceutical analysis in quality control of medicinal products manufactured in a pharmacy. Analysis of dibazole 0.005, glucose 0.2.	6	0	0	4	2	6	0	0	0	6
Topic 17. Peculiarities of using pharmaceutical analysis in drug quality control. Analysis of eye drops. Analysis of 0.25% zinc sulfate solution.	7	0	0	4	3	7	0	0	0	7
Topic 18. Peculiarities of using pharmaceutical analysis in drug quality control. Analysis of alcohol solutions. Calculations, examples.	9	0	0	4	5	9	0	0	0	9
Topic 19. Peculiarities of using pharmaceutical analysis in quality control of medicines. Qualitative express analysis of medicines.	8	0	0	2	6	8	0	0	0	8
Topic 20. Quality control and chemical-pharmaceutical	9	0	0	4	5	9	0	0	0	9

examination of plant raw materials.										
Individual tasks	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Total in hours	**120**	**0**	**0**	**60**	**60**	**120**	**0**	**0**	**4**	**116**

5. Topics of lectures / seminars / practical / laboratory lessons

5.1. Topics of lectures

Lectures are not provided.

5.2. Topics of seminar lessons

Seminar lessons are not provided.

5.3. Topics of practical lessons

№	Topic name	Number of hours	
		Full-time	Corre-spondence
1.	Topic 1. Practical lesson 1. Modern methods of pharmaceutical analysis. Classification and characteristics.	2	2
2.	Topic 2. Practical lesson 2. General pharmacopoeial methods of analysis. General provisions on chemical methods of drug analysis.	2	2
3.	Topic 3. Practical lesson 3. Testing for the limit content of impurities. Pharmacopoeial reactions for the detection of impurities in medicinal products.	2	0
4.	Topic 4. Practical lesson 4. Testing for the limit content of impurities. Analysis of purified water. Physical and chemical properties of water.	2	0
5.	Topic 5. Practical lesson 5. General principles of identification of medicinal substances.	2	0
6.	Topic 6. Practical lesson 6. Peculiarities of using pharmaceutical analysis in quality control of medicines.	2	0
7.	Topic 6. Practical lesson 7. Analysis of concentration of solutions.	2	0
8.	Topic 7. Practical lesson 8. Peculiarities of the use of pharmaceutical analysis in the quality control of medicines manufactured in a pharmacy.	2	0
9.	Topic 8. Practical lesson 9. Analysis of unstable medicinal products, as well as perishable medicinal products.	2	0
10.	Topic 8. Practical lesson 10. Analysis of 5% alcohol iodine solution.	2	0
11.	Topic 9. Practical lesson 11. Analysis of unstable drugs, as well as oxidizable drugs.	2	0
12.	Topic 9. Practical lesson 12. Analysis of ammonia-anise drops.	2	0
13.	Topic 10. Practical lesson 13. Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Preparation and analysis of dosage forms for injections.	2	0
14.	Topic 11. Practical lesson 14. Processing of auxiliary material, personal hygiene of aseptic block workers.	2	0

15.	Topic 1-12. Practical lesson 15. Thematic control work on the topics: "Modern methods of pharmaceutical analysis. Classification and characteristics; General pharmacopoeial methods of analysis. General provisions on chemical methods of drug analysis; Testing for the maximum content of impurities; General principles of identification of medicinal substances".	2	0
16.	Topic 12. Practical lesson 16. Chemical analysis of 50% analgin solution for injections.	2	0
17.	Topic 13. Practical lesson 17. Features of preparation and analysis of dosage forms for injections.	2	0
18.	Topic 13. Practical lesson 18. Chemical analysis of 5% aminocaproic acid solution.	2	0
19.	Topic 14. Practical lesson 19. Peculiarities of preparation, analysis and storage of children's medicines.	2	0
20.	Topic 14. Practical lesson 20. Peculiarities of preparation, analysis and storage of children's medicines, including for newborns.	2	0
21.	Topic 15. Practical lesson 21. Analysis of 1% glutamic acid solution.	2	0
22.	Topic 16. Practical lesson 22. Peculiarities of using pharmaceutical analysis in quality control of medicines. Soft dosage forms.	2	0
23.	Topic 16. Practical lesson 23. Analysis of dibazole 0.005, glucose 0.2.	2	0
24.	Topic 17. Practical lesson 24. Peculiarities of using pharmaceutical analysis in quality control of medicines. Analysis of eye drops.	2	0
25.	Topic 17. Practical lesson 25. Analysis of 0.25% zinc sulfate solution.	2	0
26.	Topic 18. Practical lesson 26. Peculiarities of using pharmaceutical analysis in quality control of medicines. Analysis of alcohol solutions.	2	0
27.	Topic 18. Practical lesson 27. Peculiarities of using pharmaceutical analysis in quality control of medicines. Calculations, examples.	2	0
28.	Topic 19. Practical lesson 28. Qualitative express analysis of medicines.	2	0
29.	Topic 20. Practical lesson 29. Quality control and chemical-pharmaceutical examination of plant raw materials.	2	0
30.	Topic 13-20. Practical lesson 30. Thematic control work on the topics: "Peculiarities of preparation and analysis of medicinal forms for injections, Peculiarities of preparation, analysis and storage of children's medicines, soft medicinal forms, analysis of eye drops, analysis of alcohol solutions, qualitative express analysis of medicines, control quality and chemical-pharmaceutical examination of plant raw materials.	2	0
The number of hours of practical lessons		**60**	**4**

6. Independent work of a student of higher education

№	Title of the topic / types of tasks	Number of hours	
		Full-time	Corre-spondence
1.	Modern methods of pharmaceutical analysis. Classification and characteristics. Peculiarities of pharmaceutical analysis are related to the intended use of drugs and the professional responsibility of the pharmacist. State principles and provisions regulating the quality of medicinal products.	2	2
2.	General pharmacopoeial methods of analysis. General provisions on chemical methods of drug analysis. 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 creating innovative medicines. Pharmacopoeial analysis.	4	4
3.	Testing for the limit content of impurities. Pharmacopoeial reactions for the detection of impurities in medicinal products.	3	5
4.	Analysis of the physicochemical properties of medicinal products as one of the elements of the quality assessment of medicinal products. Analysis of purified water. Physical and chemical properties of water.	5	7
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	5
6.	Peculiarities of the use of pharmaceutical analysis in the quality control of medicines manufactured in a pharmacy. Analysis of concentration of solutions.	3	7
7.	Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Analysis of unstable medicinal products.	3	5
8.	Analysis of unstable medicinal products, as well as perishable medicinal products.	5	13
9.	Processing of auxiliary material, personal hygiene of aseptic block workers.	1	3
10.	Features of preparation and analysis of dosage forms for injections.	5	15
11.	Peculiarities of preparation, analysis and storage of children's medicines, including for newborns.	2	4
12.	Peculiarities of the use of pharmaceutical analysis in the quality control of medicines manufactured in a pharmacy.	5	13
13.	Peculiarities of using pharmaceutical analysis in quality con-trol of medicines. Analysis of eye drops.	3	7
14.	Peculiarities of using pharmaceutical analysis in quality control of medicines. Analysis of alcohol solutions.	5	9
15.	Peculiarities of using pharmaceutical analysis in quality control of medicines. Qualitative express analysis of medicines.	6	8
16.	Quality control and chemical-pharmaceutical examination of plant raw materials.	5	9
Total		**60**	**116**

7. Teaching methods

Practical lessons: conversation, solution of situational problems, control of knowledge, abilities and skills of higher education students, presentation of a general problem by the teacher and its discussion with the participation of higher education students, performance of control tasks, their verification, evaluation. Performance of laboratory work, in which students of higher education under the guidance of a teacher conduct educational experiments in specially equipped educational laboratories using equipment adapted to the conditions of the educational process.

Independent work: independent work with the recommended main and additional literature, with electronic information resources, independent work with the bank of test tasks STEP-2, preparation of the practice report.

8. Forms of control and assessment methods (including criteria for evaluating learning outcomes)

Current control: testing, oral interview, checking the ability to apply existing theoretical knowledge in practice and conducting analysis of the medicinal substance, checking filling in the production practice diary.

Final control: differentiated credit.

Assessment of current educational activity in a practical session:

1. Assessment of theoretical knowledge on the topic of the lesson:
   - methods: survey, testing, solving a situational problem
   - maximum score – 5, minimum score – 3, unsatisfactory score – 2.
2. Assessment of practical skills on the subject 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 an integer value (5, 4, 3, 2), which is rounded according to the statistical method.

Criteria for current assessment in a practical session

Assessment	Assessment criteria
«5»	The winner takes an active part in discussing the most difficult questions on the subject of the lesson, gives at least 90% correct answers to standardized test tasks, answers written tasks without errors, performs practical work and draws up a protocol.
«4»	The applicant participates in the discussion of the most difficult questions on the topic, gives at least 75% correct answers to standardized test tasks, makes some minor mistakes in the answers to written tasks, performs practical work and draws up a protocol.
«3»	The applicant participates in the discussion of the most difficult questions on the topic, gives at least 60% correct answers to standardized test tasks, makes significant mistakes in answers to written tasks, performs practical work and draws up a protocol.
«2»	The applicant does not participate in the discussion of complex questions on the topic, gives less than 60% correct answers to standardized test tasks, makes gross mistakes in answers to written tasks or does not give answers to them at all, does not perform practical work and does not draw up a report.

Only those applicants who have fulfilled the requirements of the training program in the discipline, have correctly filled out the industrial practice diary according to the requirements and have a report on the completion of the industrial practice, feedback from the immediate supervisor about the work, do not have an academic background are admitted to the final control in the form of a differentiated credit govt., their average score for the current educational activity in the discipline is at least 3.00.

Assessment of the results of the students' training during the final control - differentiated credit.

Content of assessed activity	Scores
The answer to a theoretical question	2
Conducting the analysis of the medicinal substance in the conditions of the practice base	2
Submission of a practice diary designed on the basis of the completed work	1

Criteria for assessment the results of the students' training during final control – differentiated credit.

Assessment	Assessment criteria
Perfectly «5»	The applicant worked systematically during the semester, showed during the exam versatile and in-depth knowledge of the program material, is able to successfully perform the tasks provided for in the program, mastered the content of the main and additional literature, realized the relationship of individual sections of the discipline, their importance for the future profession, showed creative abilities in understanding and using educational program material, demonstrated the ability to independently update and replenish knowledge; the level of competence is high (creative).
Good «4»	The applicant has demonstrated complete knowledge of the educational program 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 their independent updating and renewal in the course of further education and professional activity; the level of competence is sufficient (constructive and variable).
Satisfactorily «3»	The applicant who has demonstrated knowledge of the main curriculum material in the amount necessary for further education and subsequent work in the profession, copes with the tasks provided for by the program, made some mistakes in the answers on the exam and when completing the exam tasks, but has the necessary knowledge to overcome the mistakes made mistakes under the guidance of a scientific and pedagogical worker; level of competence - average (reproductive).
Unsatisfactorily «2»	The applicant did not demonstrate sufficient knowledge of the main educational program material, made fundamental mistakes in the performance of tasks provided for by the program, cannot use the knowledge in further studies without the help of a teacher, did not manage to master the skills of independent work; the level of competence is low (receptive-productive).

9. Distribution of points received by higher education applicants

The obtained average score for the academic discipline for applicants who successfully mastered the work program of the academic discipline is converted from a traditional four-point scale to points on a 200-point scale, as shown in the table:

Conversion table of a traditional assessment into a multi-point scale

Traditional four-point scale	Multipoint 200-point scale
Perfectly («5»)	185 – 200
Good («4»)	151 – 184

Satisfactorily («3»)	120 – 150
Unsatisfactorily («2»)	Less than 120

A multi-point scale (200-point scale) characterizes the actual success of each applicant in mastering the educational component. The conversion of a traditional assessment (average score for an academic discipline) into a 200-point one 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 makes it possible to evaluate the achievements of students in the educational component who are studying in the same course of the same specialty, in accordance with 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 " perfectly " 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 attended all lessons in the discipline, but did not receive an average score (3.00) for the current academic activity and were not admitted to the final examination.

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

Conversion of the traditional grade from the discipline and the sum of points on the ECTS scale

Assessment on the ECTS scale	Statistical indicator
A	Top 10% students
B	The next 25% students
C	The next 25% students
D	The next 25% students
E	The next 25% students

10. Methodical support:

- Working program of the academic discipline
- Syllabus of the academic discipline
- Textbooks:
- Multimedia presentations
- Situational tasks
- Methodical development of practical lessons
- Electronic bank of test tasks by subdivisions of the discipline.

11. Питання для підготовки до підсумкового контролю

1. The structure and functions of the state system of ensuring and controlling the quality of medicinal products.
2. Pharmaceutical analysis and its significance for ensuring the quality of pharmaceutical products.
3. Pharmacopoeial analysis.
4. Legislative acts regulating the quality control of medicines in Ukraine.
5. The State Pharmacopoeia of Ukraine, its structure and content.
6. Incoming quality control of medicinal products during wholesale and retail trade.
7. Main criteria of pharmaceutical analysis: specificity and sensitivity.
8. Preparation of titrated solutions and determination of the titer.

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 coloring of liquids.
12. Analysis of purified water and water for injections. Main quality indicators.
13. Testing for the purity of purified water in containers.
14. Determination of nitrate impurities in purified water.
15. Determination of sulfate admixture in purified water.
16. Determination of chloride admixture in purified water.
17. Determination of impurities of ammonium salts in purified water.
18. Determination of calcium and magnesium impurities in purified water.
19. Determination of impurities of oxidizable substances in purified water.
20. Analysis of highly purified water.
21. Substance quality indicators according to the general article of the SPhU "Substances".
22. Testing of substances for purity.
23. Testing for the maximum content of impurities in medicinal products according to the Federal Drug Administration.
24. QCM of the manufacturer of pharmaceutical products.
25. Determination of ethanol content in liquid medicines.
26. Definition of the "Extractable Volume" indicator.
27. The use of physical methods of analysis during quality control of initial, intermediate products, raw materials, and materials intended for the production of finished products.
28. Use of physico-chemical methods of analysis during quality control of initial, intermediate products, raw materials, and materials intended for the production of finished products.
29. Use of chemical methods of analysis during quality control
initial, intermediate products, raw materials, materials intended for the production of finished products.
30. Qualitative reactions to cations, anions, functional groups and their use for identification of substances and active substances 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 Federal State of Ukraine.
33. Determination of the refractive index and its use to determine the purity and quantitative content of the active substance.
34. Polarimetry and its use for identification, purity tests and determination of the quantitative content of the active substance.
35. UV-spectrophotometry and its use for identification, purity tests 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 during quality control of medicinal products.
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 sedimentation 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 in-pharmacy control of medicinal products in accordance with the requirements of the current order of the Ministry of Health of Ukraine.
45. Organoleptic control of medicinal forms.
46. Physical control of medicinal forms.

47. Chemical control of dosage forms.
48. Control of medicinal products manufactured in a pharmacy upon release.
49. Basic requirements for qualitative and quantitative express analysis of dosage forms.
50. Analysis of in-pharmacy preparations: concentrates, semi-finished products.
51. Methods of determining the concentration of ethyl alcohol.
52. Features of in-pharmacy control of medicines for newborns.
53. General requirements for the organization of storage of medicines and medical products.
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 medicinal products, which require protection from the effect of elevated or reduced temperature.
58. Features of storage of fragrant and colored medicines.
59. Features of storage of medicinal plant raw materials.
60. Features of storage of finished medicinal forms.

12. Recommended literature

Base:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.
2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.
3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.
4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.
5. Pharmaceutical drug analysis / Addis Ababa. 2005. – 554 p.
6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.
7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.
8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.

13. Information resources

1. Materials in the information system of ONMedU https://info.odmu.edu.ua/chair/pharmaceutical_chemistry/files/214/ua
2. Компендіум - лікарські препарати
3. European Pharmacopoeia (Ph. Eur.)
4. DrugBank онлайн