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 1, 2025

WORKING PROGRAM IN THE DISCIPLINE «DRUG DEVELOPMENT»

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
Elective 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 (40 h.)</td></tr>
<tr><td>Independent work (80 h.)</td></tr>
<tr><td>Final control form – credit</td></tr>
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2. GOALS AND OBJECTIVES OF THE ACADEMIC DISCIPLINE, COMPETENCES, PROGRAM LEARNING OUTCOMES

Goal: disclosure of modern scientific concepts, concepts and methods for developing new medicines using all the capabilities of modern pharmacy.

Task: formation of basic concepts about the scheme of development of modern medicines and methods of their further verification; acquaintance with modern biotechnological methods used in the process of development of a medicine; forecasting promising directions based on computer methods for the development of medicines; identification of ways and methods of increasing the efficiency of using natural raw materials for the creation of new medicines.

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

General (GC):

GC1 – The ability to think abstractly, analyze and synthesize, learn and be up-to-date.
GC2 – Knowledge and understanding of the subject area and understanding of professional activity.
GC5 – Ability to evaluate and ensure the quality of work performed.
GC9 – Ability to use information and communication technologies.

Specialists (SC):

SC12 – 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.
SC19 – 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.
SC20 – 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):

PLO3 – 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.

PLO20 – To carry out pharmaceutical development of medicinal products of natural and synthetic origin in industrial production conditions.

PLO22 – 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.

PLO23 – 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:

- specific terminology of pharmaceutical technology;
- main groups of drugs;
- methods of administering drugs to animals and humans;
- stages of development of modern drugs;
- methods of analysis and testing of new drugs;
- rules for approving new drugs in the European Union, the USA and Ukraine.

Be able to:

- determine the principles of rational drug development;
- make informed decisions when assessing the object of pharmacological action of the developed drug;
- predict the necessary physicochemical characteristics of a potential drug depending on the specific molecular structure of the receptor;
- plan and conduct preclinical and clinical studies of new drugs, using a scientific approach;
- predict and evaluate the consequences of side effects of drugs after entering the market

3. CONTENT OF THE COURSE

***Topic 1*. History of drug development.**

- terminology, definitions. Pharmacology and toxicology;
- pharmacology of the Ancient World, the Middle Ages and the beginning of the 20th century;
- overview of the current state of the pharmaceutical industry.

***Topic 2*. Classification of medicines. Types of medicines.**

- classification of medicines;
- plants as sources of medicines;
- main directions of creation of new medicinal substances;
- medicines, which are available by prescription and without prescription.

***Topic 3*. Methods of drug delivery.**

- drug delivery methods. Main mechanisms of membrane transport of drugs;
- liposomes, monoclonal antibodies, modified plasma proteins, microspheres and nanoparticles, polymer micelles, collagen;
- lysosomes, mitochondria, nuclei and cytoplasm of cells as objects for delivery.

***Topic 4*. Principles of creating new medicines. Rational design – the latest technology for drug development.**

- rational drug development;

- object of pharmacological action, characteristics;
- potential objects: receptors, proteins and enzymes, ion channels.

***Topic 5*. Establishing the object of pharmacological action of a medicinal product.**

- establishing the object of pharmacological action, based on the mechanism of disease development and the relationship of certain genes with the disease;
- the role of transgenic animals, nonsense DNA and RNA;
- chemical methods of gene knockout.

***Topic 6*. Main legislative and regulatory acts on the production and circulation of medicinal products.**

- state control bodies;
- State Pharmacopoeia of Ukraine (SPhU).

***Topic 7*. Preclinical research.**

- liquid chromatography;
- mass spectroscopy, nuclear magnetic resonance;
- preclinical drug studies.

***Topic 8*. Clinical research.**

- drug efficacy as a pharmacoeconomic category;
- conditions for effective treatment;
- legislative framework;
- experimental and clinical studies of substances - "candidates" in drugs;
- clinical trials of drugs, treatment methods and healthcare reorganization.

***Topic 9*. General principles of naming medicines.**

***Topic 10*. Major human diseases and leading groups of medicinal substances on the modern pharmaceutical market.**

- list and characteristics of human diseases;
- leading groups of medicinal substances on the modern pharmaceutical market.

4. СТРУКТУРА НАВЧАЛЬНОЇ ДИСЦИПЛІНИ

Topic names	Number of hours of full-time study		
	Total	including	
		practical	IWS
Topic 1. History of drug development.	12	2	10
Topic 2. Classification of medicines. Types of medicines.	12	2	10
Topic 3. Methods of drug delivery.	12	2	10
Topic 4. Principles of creating new medicines. Rational design – the latest technology for drug development.	12	6	6
Topic 5. Establishing the object of pharmacological action of a medicinal product.	12	6	6
Topic 6. Main legislative and regulatory acts on the production and circulation of medicinal products.	12	6	6
Topic 7. Preclinical research.	12	4	8
Topic 8. Clinical research.	12	4	8
Topic 9. General principles of naming medicines.	12	4	8
Topic 10. Major human diseases and leading groups of medicinal substances on the modern pharmaceutical market.	12	4	8
Total hours	**120**	**40**	**80**

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.	Classification of medicines. Types of medicines.	2
2.	Auxiliary operations in the manufacture of drugs.	2
3.	Production of solid drugs (powders).	2
4.	Technology for manufacturing solid dosage forms (tablets).	2
5.	Solid dosage forms of prolonged action.	2
6.	Microencapsulation of medicinal substances.	2
7.	Extractive preparations. Technology of making tinctures.	2
8.	Novogalenic drugs.	2
9.	Preparation and analysis of aqueous solutions.	2
10.	Alcohol solutions.	2
11.	Syrups.	2
12.	Injection solutions in ampoules.	2
13.	Main legislative and regulatory acts regarding the production and circulation of medicinal products.	2

14.	Liquid chromatography.	2
15.	Microbiological control.	2
16.	Microbiological control methods (part 1).	2
17.	Microbiological control methods (part 2).	2
18.	Preclinical trials of drugs.	2
19.	Selection of evaluation methods.	2
20.	Main phases of clinical trials.	2
Number of hours of practical classes in the discipline		**40**

6. INDEPENDENT WORK OF A HIGHER EDUCATION STUDENT

№ i/o	**Topic name / types of tasks**	**Number of hours**
1.	Topic 1. History of drug development.	10
2.	Topic 2. Classification of medicines. Types of medicines.	10
3.	Topic 3. Routes of drug delivery.	10
4.	Topic 4. Principles of creating new medicines. Rational design – the latest technology for drug development	6
5.	Topic 5. Establishing the object of pharmacological action of a medicinal product.	6
6.	Topic 6. Main legislative and regulatory acts regarding the production and circulation of medicinal products.	6
7.	Topic 7. Preclinical research.	8
8.	Topic 8. Clinical research.	8
9.	Topic 9. General principles of naming medicines.	8
10.	Topic 10. Major human diseases and leading groups of medicinal substances on the modern pharmaceutical market.	8
Number of hours of independent work on the discipline		**80**

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 (survey), testing, assessment of practical exercises, assessment of communication skills, solving situational clinical tasks, assessment of activity in class and independent work of applicants.

Final control form: 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.

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

The test is carried out: in the last lesson before the beginning of the examination session - in the case of the tape learning system, in the last lesson - in the case of the cyclic learning system. The test score is the arithmetic mean of all components on the traditional four-point scale and has a value that is rounded using the statistical method to two decimal places.

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. What are the features of the development of the pharmaceutical industry observed at the beginning of the 20th century?
2. What are the main trends that characterize the current state of the world pharmaceutical industry?
3. What are the main features of the classification of medicines?
4. Give examples of medicines of natural origin.
5. What plants are the main sources of pharmacologically active substances?
6. What is the essence of creating new medicinal substances?
7. What are the main directions of searching for new medicinal compounds used in modern pharmacy?
8. What is the difference between prescription and non-prescription drugs?
9. What are the criteria for classifying a medicine as “over-the-counter”?
10. What are the main routes of administration of medicines into the body?
11. Describe the mechanisms of membrane transport of medicinal substances.
12. What are liposomes and what are their advantages in drug delivery?
13. What is the role of monoclonal antibodies in targeted drug delivery?

14. What are microspheres and nanoparticles used for in pharmacy?
15. What are polymeric micelles and what are their properties as drug carriers?
16. Why are lysosomes, mitochondria, nuclei and cytoplasm of cells important objects for intracellular drug delivery?
17. What is the concept of “rational drug design”?
18. What are the main stages of the rational drug development process?
19. What is an “object of pharmacological action” and how is it defined?
20. What characteristics should an object of pharmacological action have?
21. Name the main types of potential objects of pharmacological action.
22. What is the role of receptors in the mechanism of action of drugs?
23. How can enzymes and ion channels be used as targets for the creation of new drugs?
24. How is the object of pharmacological action of a drug determined?
25. What is the relationship between the mechanism of disease development and the choice of the target for the action of a drug?
26. What role do genes play in the development of diseases and the creation of drugs?
27. How are transgenic animals used in pharmacological research?
28. What is nonsense (illogical) DNA and RNA and what is their significance in biomedical research?
29. What is the essence of chemical methods of gene knockout?
30. What is the practical significance of establishing the exact object of pharmacological action?
31. What are the main state control bodies that supervise the circulation of medicines in Ukraine?
32. What is the purpose of the State Pharmacopoeia of Ukraine?
33. What is a pharmacopeial article and what information does it contain?
34. How is the quality control of medicines carried out in accordance with regulatory acts?
35. What international documents regulate the quality standards of medicines?
36. What is the significance of licensing in the field of pharmaceutical production?
37. How does Ukrainian legislation regulate the import and registration of new medicinal products?
38. What are preclinical studies of medicinal products and what is their purpose?
39. What are the main stages of conducting preclinical studies?
40. Explain the principle of operation of liquid chromatography.
41. What is the essence of the mass spectroscopy method?
42. What is the importance of nuclear magnetic resonance (NMR) in pharmaceutical analysis?
43. What are the requirements for experimental models in preclinical studies?
44. Why are the results of preclinical studies critically important for the transition to the clinical phase?
45. What does the effectiveness of a medicinal product mean as a pharmacoeconomic category?
46. What factors determine the effectiveness of treatment during clinical studies?
47. Describe the main stages of conducting clinical trials of medicinal products.
48. What are the ethical requirements for conducting clinical studies?
49. What is the role of experimental and clinical research of “candidate” substances for medicinal products?
50. What legislative documents regulate clinical trials in Ukraine?
51. How do clinical trials affect healthcare reform?
52. What are the main requirements for drug names?
53. What is the difference between an international non-proprietary name (INN) and a trade name of a drug?
54. What is the importance of unification of drug names at the international level?
55. Which organizations approve international non-proprietary names of drugs?

56. What are the most common mistakes made when developing trade names?
57. What is the purpose of pharmaceutical branding of drugs?
58. What are the features of the name of generic drugs compared to original ones?
59. Name the main groups of human diseases according to the WHO classification.
60. What are the main reasons for the spread of chronic non-communicable diseases in the world?
61. What pharmacological groups are used to treat cardiovascular diseases?
62. What drugs are used for infectious diseases?
63. Name the main groups of anti-inflammatory drugs and examples of representatives.
64. What pharmacological groups are the leaders of the modern global pharmaceutical market?
65. What development trends are observed in the market of biotechnological and genetically engineered drugs?

12. RECOMMENDED LITERATURE

Basic:

1. Pharmacy-based Technology of Drugs: the manual for students of English-speaking applicants of higher education of "Pharmacy" specialty / – Kh.: NUPh, 2019.
2. Europian Pharmacopoeia. 9th edition. Counsil of Europe, Strasbourg, 2017.
3. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: new estimates of R&D costs. J // Health Econ. - 2016. - Vol. 12;47. - P. 20-33

Additional:

1. Фармацевтична розробка як етап створення лікарських препаратів: навчальний посібник для позааудиторної роботи здобувачів вищої освіти третього рівня (доктора філософії) / Т. Г Ярних, О. І. Тихонов, І. В. Герасимова, Г. М. Мельник – Х.: НФаУ, 2018. – 38 с.
2. Технологічне обладнання біотехнологічної і фармацевтичної промисловості: підручник [для вищ. навч. закл.] Стасевич М.В., Миланич., А.О., Стрельников Л.С., Крутських Т.В, Бучкевич І.Р., Зайцев О.І Гузьова., І.О., Стрілець О.П., Гладух Є.В., Новіков В.П. – Львів: «Новий Світ-2000», 2018. – 410 с.
3. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів». — 2-е вид. — Доповнення 1. — Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2016. — 360 с.
4. Допоміжні речовини у виробництві ліків : навч. посібн. для студ. вищ. фармац. навч. закл. / О.А. Рубан, І.М. Перцев, С.А. Куценко, Ю.С. Маслій; за ред. І.М. Перцева. – Х.: Золоті сторінки, 2016. – 720 с.
5. Забезпечення, контроль якості і стандартизація лікарських засобів: Навчально-методичний посібник / За ред. професора Н. О. Ветютневої. – Вінниця, ПП «ТД» Едельвейс і К», 2016. – 505 с.

13. INFORMATION RESOURCES

1. Official website of the Ministry of Health of Ukraine: www.moz.gov.ua.
2. Compendium: medicinal products: - [Electronic resource]. - Access mode: http://compendium.com.ua/.
3. European Pharmacopoeia (Ph. Eur.)
4. Бібліотека ОНМедУ (odmu.edu.ua) - ONMedU Scientific Library
5. www.moz.gov.ua – official website of the Ministry of Health of Ukraine
6. DrugBank онлайн