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, 2024

WORK PROGRAM OF EDUCATIONAL DISCIPLINE "DEVELOPMENT OF MEDICINAL PRODUCTS"

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 work program is based on the educational and professional program "Pharmacy, industrial pharmacy" for training specialists of the second (master's) level of higher education in specialty 226 "Pharmacy, industrial pharmacy" field of knowledge 22 "Health care", approved by the Scientific Council of ONMedU (protocol no. 10 of June 27, 2024).

Developers: doc. Fizor N.S.

The work program was approved at the meeting of the Department of Pharmaceutical Chemistry and Drug Technology
Protocol No. 1 dated August 29, 2024.

Head of the department _____ Volodymyr GELMBOLDT

Agreed with the guarantor of EPP _____ Liana UNGURYAN

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

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

_____ Natali FIZOR

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

Head of Department _____ _____

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

Head of Department _____ _____

1. Description of the academic discipline:

Name of indicators	Field of knowledge, specialty, specialization, level of higher education	Characteristics of the academic discipline
The total number of: Credits: 3 Hours: 90 Content modules: 1	Branch of knowledge 22 "Health care" Specialty 226 "Pharmacy, industrial pharmacy" Level of higher education second (master's)	*Full-time education* *Elective discipline*
		Year of training: 4
		SemestersVIII
		Lectures (0 hours)
		Practical (30 hours)
		Independent work (60 hours)
		Final control form- test

2. The purpose and tasks of the educational discipline

The purpose :disclosure of the modern scientific concept, concepts and methods of developing new medicines using all the possibilities of modern pharmacy.

Task:

1. Formation of basic concepts about the scheme of development of modern medicines and methods of their further verification;
2. Acquaintance with modern biotechnological methods used in the process of drug development;
3. Forecasting promising directions, based on computer methods, for the development of medicinal products;
4. Determination of ways and methods of increasing the efficiency of the use of natural raw materials for the creation of new drugs;
5. Formation of a scientific outlook and modern thinking in the field of pharmaceutical biotechnology
6. Ensuring the quality of life and safety of people's livelihoods.

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

- GC01. Ability to think abstractly, analyze and synthesize, learn and be modernly educated.
- GC 02. Knowledge and understanding of the subject area and understanding of professional activity.
- GC 03. Ability to communicate in the national language both orally and in writing.
- GC 04. The ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity.
- GC 05. The ability to evaluate and ensure the quality of the work performed.
- GC 06. Ability to work in a team.
- GC 10. The ability to act socially responsibly and consciously.
- GC 11. Ability to apply knowledge in practical situations.
- GC 12. The desire to preserve the environment.
- GC 13.Ability to show initiative and entrepreneurship.
- GC 14. Ability to adapt and act in a new situation.
- GC 15. Knowledge and understanding of the subject area and understanding of professional activity
- GC 16. The ability to conduct experimental research at the appropriate level.
- *special (professional, subject):*
- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.

- PC 02. The ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.
- PC 08. The ability to consult on prescription and non-prescription drugs and other products of the pharmacy assortment; pharmaceutical care during the selection and sale of medicinal products 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.
- PC 12. Ability to ensure proper storage of medicinal products of natural and synthetic origin and other products of the pharmacy assortment in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in healthcare facilities.
- PC 16. The ability to organize and carry out the production activities of pharmacies for the manufacture of drugs in various dosage forms according to the prescriptions of doctors and the requirements (orders) of medical and preventive institutions, including the justification of technology and the selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).
- PC 17. The ability to carry out pharmaceutical development and participate in the production of medicinal products of natural and synthetic origin in the conditions of pharmaceutical enterprises in accordance with the requirements of Good Manufacturing Practice (GMP).
- PC 24. Ability to use knowledge of regulatory and legislative acts of Ukraine and recommendations of proper pharmaceutical practices in professional activities.
- PC 25. The ability to demonstrate and apply in practical activities communicative communication skills, fundamental principles of pharmaceutical ethics and deontology, based on moral obligations and values, ethical standards of professional behavior and responsibility in accordance with the Code of Ethics of pharmaceutical workers of Ukraine and WHO guidelines.
- PC 26. The ability to organize and participate in the production of medicinal products in the conditions of pharmaceutical enterprises, in particular the selection and justification of the technological process, equipment in accordance with the requirements of Good Manufacturing Practice (GMP) with the appropriate development and execution of the necessary documentation. Determine the stability of medicines.

Program learning outcomes for the discipline (PRN):

- PLO01. Have and apply specialized conceptual knowledge in the field of pharmacy and related fields, taking into account modern scientific achievements.
- PLO 03. 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 04. Communicate freely in the national and English languages orally and in writing to discuss professional problems and results of activities, presentation of scientific research and innovative projects.
- PLO 07. Collect the necessary information on the development and production of medicinal products, using professional literature, patents, databases and other sources; systematize, analyze and evaluate it, in particular, using statistical analysis.
- PLO 19. Develop technological documentation for the manufacture of medicinal products, choose a rational technology, manufacture medicinal products in various dosage forms according to the prescriptions of doctors and the requirements (orders) of treatment and prevention institutions, prepare them for release.
- PLO 20 -Carry out pharmaceutical development of medicinal products of natural and synthetic origin in the conditions of industrial production.
- PLO 25. Adhere to the norms of the sanitary and hygienic regime and the requirements of safety equipment when carrying out professional activities.
- PLO 27. Perform professional activities using creative methods and approaches.

- PLO 30. Adhere to the norms of communication in professional interaction with colleagues, management, consumers, work effectively in a team.
- PLO 36. Plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of proper pharmaceutical practices
- PLO 38. To substantiate the technology and organize the production of medicinal products at pharmaceutical enterprises and draw up technological documentation for the production of medicinal products at pharmaceutical enterprises.
- PLO 43. To organize the necessary level of individual safety (own and the persons he cares for) in case of typical dangerous situations in the individual field of activity.

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

know:

1. specific terminology of pharmaceutical technology;
2. main groups of medicines;
3. methods of administering medicines to animals and humans;
4. stages of development of modern medicines;
5. methods of analysis and testing of new drugs;
6. rules for approval of new medicinal products in the European Union, the USA and Ukraine.

be able:

1. work with the original English-language scientific literature, carry out a targeted search for scientific articles and critically analyze the presented data;
2. to determine the principles of rational development of a medicinal product;
3. make informed decisions when evaluating the object of the pharmacological action of the drug being developed;
4. predict the necessary physicochemical characteristics of a potential drug depending on the specific molecular structure of the receptor;
5. to develop a new drug delivery system, using a synthetic polymer capable of biodegradation as a carrier;
6. to plan and carry out pre-clinical and clinical research of new medicines using a scientific approach;
7. predict and evaluate the side effects of medicinal products after entering the market
8. prevent environmental pollution by the pharmaceutical industry.

3. Content of the academic discipline

Topic 1. History of drug development.

Terminology, definition. 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 drugs.

Classification of medicines. Plants as sources of drugs. The main directions of creation of new medicinal substances. Prescription and non-prescription drugs.

Topic 3. Medicine delivery methods.

Methods of drug delivery. The 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 is the newest technology of drug development.

Rational development of drugs. Object of pharmacological action, characteristic. Potential objects: receptors, proteins and enzymes, ion channels.

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

Establishment of the object of pharmacological action based on the mechanism of disease development and the connection of certain genes with the disease. The role of transgenic animals devoid of DNA and RNA. Chemical methods of gene knockout.

Topic 6. Basic legislative and regulatory acts regarding the production and circulation of medicinal products. State control bodies. State Pharmacopoeia of Ukraine (SPU).

Topic 7. Preclinical studies.

Liquid chromatography. Mass spectroscopy, nuclear magnetic resonance. Preclinical studies of drugs.

Topic 8. Clinical research.

Drug effectiveness as a pharmacoeconomic category. Conditions for effective treatment. Legislative framework. Experimental and clinical studies of substances - "candidates" in medicine. Clinical trials of drugs, methods of treatment and reorganization of health care.

Topic 9. General principles of naming medicinal products.

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

List and characteristics of human diseases and leading groups of medicinal substances on the modern pharmaceutical market.

4. The structure of the academic discipline

Topic	Number of hours			
	That's all	Including		
		Lectures	practical	Independent work
Topic 1. History of drug development.	8	0	2	6
Topic 2.Classification of medicines.Types of drugs.	10	0	4	6
Topic 3. Medicine delivery methods.	8	0	2	6
Topic 4.Principles of creation of new medicines.Rational design is the newest technology of drug development.	8	0	2	6
Topic 5. Establishing the object of the pharmacological action of the medicinal product.	10	0	4	6
Topic 6.Basic legislative and regulatory acts on the production and circulation of medicinal products. State control bodies. State Pharmacopoeia of Ukraine (SPU).	10	0	4	6
Topic 7. Preclinical studies.	10	0	4	6
Topic 8. Clinical research.	10	0	4	6
Topic 9.General principles of naming medicinal products.	8	0	2	6
Topic 10.The main human diseases and leading groups of medicinal substances on the modern pharmaceutical market.	8	0	2	6
In totalhours:	**90**	0	**30**	**60**

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

5.1. Topics of lectures

Not provided for in the curriculum.

5.2. Topics of practical classes

No.	Topic	Hours
1	Auxiliary operations in the manufacture of pharmaceuticals. Production of solid drugs (powders).	2
2	Technology of production of solid dosage forms.	4

3	Solid dosage forms of prolonged action. Microencapsulation of medicinal substances.	2
4	Extractive preparations. Tincture production technology. Novogalen preparations.	2
5	Preparation and analysis of aqueous solutions. Alcohol solutions.	4
6	Syrups. Solutions for injections in ampoules.	4
7	Liquid chromatography. Methods of microbiological control of medicinal products (beginning).	4
8	Methods of microbiological control of medicinal products (end).	4
9	Preclinical tests of medicines. Choice of assessment methods.	2
10	The main phases of clinical trials of new medicines.	2
In total		**30**

6. Independent work

No.	Types of Independent work	hours
1	History of drug development.	6
2	Classification of medicines.Types of drugs.	6
3	Ways of delivery of medicines.	6
4	Principles of creation of new medicines.Rational design is the newest technology of drug development	6
5	Establishing the object of the pharmacological action of the medicinal product.	6
6	Basic legislative and regulatory acts on the production and circulation of medicinal products. State control bodies. State Pharmacopoeia of Ukraine (SPU).	6
7	Preclinical studies.	6
8	Clinical studies.	6
9	General principles of naming medicinal products.	6
10	The main human diseases and leading groups of medicinal substances on the modern pharmaceutical market.	6
Hours in general:		**60**

7. Teaching methods.

Lectures: multimedia lectures with elements of discussion communication with students of higher education.

Practical training: conversation, solving situational tasks, demonstration and practice of manipulation skills (including demonstration films, visual equipment, means of small mechanization, operations and processes of manufacturing drugs in the conditions of a pharmacy and an industrial enterprise,practicing practical skills using pharmacy and industrial equipment.

Independent work: independent work with the textbook, independent work with the bank of test tasks, independent solution of situational tasks.

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

Current control:oral survey, testing, assessment of performance of practical skills, problem solving.

Final control: test

Evaluation of the current educational activity in a practical session:

1. Evaluation of theoretical knowledge on the subject of the lesson:
   - methods: survey, solving a situational problem
   - the maximum score is 5, the minimum score is 3, the unsatisfactory score is 2.

2. Assessment of practical skills on the topic of the lesson:
   - methods: assessment of the correctness of the performance of practical skills
   - the maximum score is 5, the minimum score is 3, the unsatisfactory score is 2.

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

Current evaluation criteria in practical training

Score	Evaluation criteria
"5"	The winner takes an active part in discussing the most difficult questions on the topic of the class, gives at least 90% correct answers to standardized test tasks, answers written tasks without errors, performs practical work and has drawn 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.

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

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

9. Distribution of points received by students of higher education

The obtained average score for the academic discipline for applicants who have 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
Excellent ("5")	185 - 200
Good ("4")	151 - 184
Satisfactory ("3")	120-150
Unsatisfactory ("2")	Below 120

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

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

The ECTS scale is a relative-comparative rating, which establishes the applicant's belonging to the group of better or worse among the reference group of fellow students (faculty, specialty). An "A" grade on the ECTS scale cannot be equal to an "excellent" grade, a "B" grade to a "good" grade,

etc. When converting from a multi-point scale, the limits of grades "A", "B", "C", "D", "E" according to the ECTS scale do not coincide with the limits of grades "5", "4", "3" according to the traditional scale. Acquirers who have received grades of "FX" and "F" ("2") are not included in the list of ranked acquirers. The grade "FX" is awarded to students who have obtained the minimum number of points for the current learning activity, but who have not passed the final examination. A grade of "F" is assigned to students who have attended all classes in the discipline, but have not achieved a grade point average (3.00) for the current academic activity and are not admitted to the final examination.

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

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

Score on the ECTS scale	Statistical indicator
A	The best 10% students
B	Next 25% students
C	Next 30% students
D	Next 25% students
E	Next 10% students

10. Methodological support:

- Working program of the academic discipline
- Syllabus of the academic discipline
- Multimedia presentations
- Situational tasks
- Methodical development of practical classes
- Methodical recommendations for students on independent extracurricular work
- An electronic bank of test tasks by discipline topics

11. Questions for final control

1. History of drug development.
2. Pharmacology of the Ancient World, the Middle Ages and the beginning of the 20th century.
3. Overview of the current state of the pharmaceutical industry.
4. Classification of medicines. Types of drugs.
5. Prescription and over-the-counter medications.
6. Ways of delivery of medicines.
7. The 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 targets for delivery.
8. Principles of creation of new medicines.
9. Rational design is the newest technology of drug development.
10. Establishing the object of the pharmacological action of the medicinal product.
11. Basic legislative and regulatory acts on the production and circulation of medicinal products. State control bodies. State Pharmacopoeia of Ukraine (SPU).
12. Preclinical studies. Liquid chromatography. Mass spectroscopy, nuclear magnetic resonance.
13. Clinical studies. Drug effectiveness as a pharmacoeconomic category. Conditions for effective treatment. Legislative framework. Experimental and clinical studies of substances - "candidates" in medicine.
14. Clinical trials of pharmaceuticals, methods of treatment and reorganization of health care).
15. General principles of naming medicinal products.
16. The main human diseases and leading groups of medicinal substances on the modern pharmaceutical market.
17. Auxiliary operations in the manufacture of pharmaceuticals. Production of solid drugs (powders).
18. Technology of production of solid dosage forms

19. Solid dosage forms of prolonged action.
20. Microencapsulation of medicinal substances.
21. Extractive preparations. Tincture production technology.
22. Novogalen drugs.
23. Preparation and analysis of aqueous solutions. Alcohol solutions.
24. Syrups. Solutions for injections in ampoules.
25. Liquid chromatography.
26. Methods of microbiological control of medicinal products.

12. Recommended literature.

Main:

1. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products". — 2nd edition. — Addendum 1. — Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicinal Products", 2016.—360 p.
2. Excipients in the production of drugs: training. manual for students higher pharmacy education closing / O.A. Ruban, I.M. Pertsev, S.A. Kutsenko, Yu.S. Oily; under the editorship I.M. Pepper - Kh.: Golden Pages, 2016. - 720 p.
3. Provision, quality control and standardization of medicinal products: Educational and methodological manual / Ed. Professor N. O. Vetyutneva. - Vinnytsia, PP "TD" Edelweiss and K", 2016. - 505 p.
4. Industrial technology of medicines: a basic textbook for students. higher education pharmacy institution (pharmacology) / E. V. Gladukh, O. A. Ruban, I. V. Saiko [and others] - Kh.: NFaU: Original, 2016. - 632 p.
5. Industrial technology of medicines: a basic textbook for students. higher education pharmacy institution (pharmacology) / E.V. Gladukh, O.A. Ruban, I.V. Saiko [and others].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, ex. and added - X: National Institute of Scientific Research: Novy svit-2000, 2018. - 526 p.
6. Technological equipment of the biotechnological and pharmaceutical industry: a textbook [for higher education. education closed.] M.V. Stasevich, A.O. Mylianych., L.S. Strelnikov, T.V. Krutskikh, I.R. Buchkevich, O.I. Guziova Zaitsev, I.O., O.P. Strelets ., Gladukh E.V., Novikov V.P. - Lviv: "New World-2000", 2018. - 410 p.
7. Pharmaceutical development as a stage of the creation of medicinal products: a study guide for extracurricular work of third-level higher education students (Ph.D.) / T. G. Yarnykh, O. I. Tikhonov, I. V. Gerasimova, H. M. Melnyk – Kh.: NFaU , 2018. – 38 p.
8. European Pharmacopoeia. 9th edition. Council of Europe, Strasbourg, 2017.
9. Pharmacy-based Technology of Drugs: the manual for students of English-speaking applicants of higher education of “Pharmacy” specialty / – Kh.: NUPh, 2019.

Additional:

1. Baula O. P., Derkach T. M. Quality assurance of medicinal products of herbal origin: state and prospects. Pharmaceutical journal. 2017. No. 2. P.79-78.
2. Medicines. Process validation.ST-N MOZ 42-3.5:2016.– Officer. kind. - K.: Ministry of Health of Ukraine, 2016. - 31 p. – (Instruction of the Ministry of Health of Ukraine).
3. Medicines. Guidelines for the production of finished medicinal products.ST-N MOZ 42-3.4:2020. - Officer. kind. - K.: Ministry of Health of Ukraine, 2020. - 37 p. – (Instruction of the Ministry of Health of Ukraine).
4. Medicines. Good Manufacturing Practice. ST-N MOZU 42-4.0:2020 - Officer. kind. - K.: Ministry of Health of Ukraine, 2020. - 338 p. – (Instruction of the Ministry of Health of Ukraine).
5. Medicines. Principles of good practice for the distribution of active substances for medicinal products for humans. ST-N of the Ministry of Health of Ukraine 42-5.2:2020 - K.: Ministry of Health of Ukraine, 2020. - 28 p. – (Instruction of the Ministry of Health of Ukraine).

6. Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing test exam "Step - 2. Pharmacy" / edited by I.Yu. Borysiuk, N.S. Fizor, A.V. Zamkova - Odesa.: ONMedU, 2019. – 88 p.
7. Normative and legal regulation of pharmaceutical and biotechnological enterprises: textbook/ M.V. Stasevich [and others]; Lviv Polytechnic, National University of Lviv: Novy svit— 2000, 2018. — 288 p.
8. 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

13. Information resources

1. Database "Equalizer" LLC "Business Credit" - [Electronic resource]. - Access mode:http://eq.bck.com.ua/- as of September 20, 2016
2. State Register of Medicinal Products of Ukraine. - [Electronic resource]. - Access mode:http://www.drlz.com.ua/- as of January 10, 2017
3. Compendium: drugs. - [Electronic resource]. - Access mode: http://compendium.com.ua/ - as of October 10, 2016. www.moz.gov.ua- the official website of the Ministry of Health of Ukraine.