

National Pirogov Memorial Medical University, Vinnytsia

«APPROVE»

Higher Educational Institution

Vice-Rector for Scientific,


Pedagogical and Academic Affairs

Inna ANDRUSHKO

"29" August 2025 year

«AGREED»

Head of the Department of Pharmacy

 Olena KRYVOVIAZ

"29" August 2025 year

SYLLABUS
of academic discipline

**PHARMACEUTICAL AND TECHNOLOGICAL ASPECTS OF DRUG
DEVELOPMENT**

Specialty	226 Pharmacy, Industrial Pharmacy
Specialization	226.01 Pharmacy
Educational level	the second (master`s) level
Educational programme	<i>EPP «Pharmacy», 2023</i>
Academic year	2025-2026
Department	Pharmacy
Lecturer (if lectures are given)	Prof. Olena KRYVOVIAZ, Ass. Prof. Yulia TOMASHEVSKA, PhD, Ass. Prof. Hanna KRAMAR
Contact information	<i>pharmacy@vnmnu.edu.ua</i>
Syllabus compiler	Prof. Olena KRYVOVIAZ

Status and structure of the discipline

Discipline status	optional courses
Discipline code in EPP/ discipline place in EPP	FC 23// optional courses, optional components of EP
Course / semester	2 nd course (IV semester)
The amount of discipline (the total number of hours / number of credits ECTS)	90 hours /3,0 credits ECTS
Number of content modules	1 modules
The structure of the discipline	Lectures – 10 hours Practical classes - 30 hours Independent work – 50 hours
Language of study	English
Form of education	Full - time (or remote/mixed according to the order)

1. Description of the course Brief annotation, actuality.

The elective course "Pharmaceutical and technological aspects of drug development" belongs to the cycle of disciplines for the professional-oriented training of specialists in specialty 226 "Pharmacy, Industrial Pharmacy", Specialisation 226.01 Pharmacy.

The main focus of the programme is to acquire the knowledge necessary for the successful mastery of professional training disciplines, namely: the development, research, registration and launch of new medicinal products on the pharmaceutical market.

The elective course "Pharmaceutical and technological aspects of drug development" **focuses** on the development of the pharmaceutical industry in Ukraine and worldwide, analysis of the state of current experimental and clinical research in the search for new drugs, laying the theoretical foundations and practical skills for the pharmaceutical development of drugs in various forms of release in accordance with the requirements of regulatory documentation, theoretical justification of the methodology of pharmaceutical development of drugs in various forms of release, the influence of pharmaceutical factors on the pharmaco-technological properties of raw materials, semi-finished products and quality indicators of drugs in various dosage forms, familiarisation with the implementation of experimental studies using the methods specified in the State Pharmacopoeia

As a result of studying the elective course, higher education students will acquire knowledge:

- Basic terms and concepts used in the field of drug development.
- Regulatory and legislative documents of Ukraine that define the basic rules and requirements for drug development and quality assurance of research.
- Your social and civic rights and responsibilities.
- Methods of applying knowledge to solve practical problems.
- Current trends in the development of the industry.
- The structure and characteristics of professional activity.
- General approaches to the pharmaceutical development of medicinal products.
- The structure of the registration dossier.
- The main stages of drug development in various dosage forms.
- Pharmacotechnological indicators of raw ingredients, semi-finished products and the final product.
- Quality control indicators for various dosage forms.

Prerequisites

The elective course is based on the study of such disciplines of the curriculum as general and inorganic chemistry, physical and colloid chemistry, biology with the basics of genetics, and introduction to pharmacy.

The aim of the course and its significance for professional activity: to prepare higher education students for their future professional activity in organising and conducting scientific research, in particular at the stage of preclinical and clinical studies of original and generic medicinal products, familiarising higher education students with the basic links in the process of development and registration, as well as with the main pharmaco-technological aspects of selecting the form of release for new medicinal products.

Post-requisites

The elective course 'Pharmaceutical and Technological Aspects of Drug Development' is the basis for studying Drug Technology: ATL, Drug Technology: PTL, technologies of medicinal cosmetics, therapeutic cosmetics, clinical pharmacy and pharmaceutical care, pharmacology, biopharmacy, pharmaceutical management and marketing, which involves the integration of teaching with the above disciplines and the formation of skills to apply knowledge in the process of further training and professional activity.

The elective course «Pharmaceutical and technological aspects of drug development» lays the foundations for professional training and promotes the development of technical and pharmaceutical thinking necessary for a career in pharmacy.

2. Learning outcomes.

• Integral (IC)

The ability to solve complex problems and critically analyse and solve practical problems in professional pharmaceutical and/or research and innovation activities using the provisions, theories and methods of fundamental, chemical, technological, biomedical and socio-economic sciences; integrate knowledge and solve complex issues, formulate judgements with insufficient or limited information; clearly and unambiguously convey one's knowledge, conclusions and their validity to professional and non-professional audiences.

• General competencies (GC):

GC 02. Ability to think abstractly, analyse and synthesise.

GC 03. Knowledge and understanding of the subject area and understanding of professional activity.

GC 06. Skills in using information and communication technologies.

GC 07. Ability to choose a communication strategy, ability to work in a team and with experts from other fields of knowledge/types of economic activity.

GC 08. Ability to evaluate and ensure the quality of work performed.

GC 09. Ability to conduct research at the appropriate level.

GC 11. Ability to preserve and multiply the moral, cultural, scientific values and achievements of society based on an understanding of the history and patterns of development of the subject area, its place in the general system of knowledge about nature and society and in the development of society, technology and technologies, to use various types and forms of physical activity for active recreation and a healthy lifestyle.

• Special (Professional, subject) competencies (PC):

PC 01. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.

PC 02. The ability to integrate knowledge and solve complex problems in pharmacy in broad or multidisciplinary contexts.

PC 04. Ability to use knowledge of regulatory and legislative acts of Ukraine and recommendations of good pharmaceutical practices in professional activities.

PC 05. Ability to demonstrate and apply in practical activities communication skills, fundamental principles of pharmaceutical ethics and deontology based on moral obligations and values, ethical standards of professional conduct and responsibility in accordance with the Code of Ethics for Pharmaceutical Workers of Ukraine and WHO guidelines.

PC 18. Ability to organise and carry out the production activities of pharmacies for the manufacture of medicinal products in various dosage forms according to doctors' prescriptions and

orders from medical institutions, including the justification of technology and the selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).

PC 19. Ability to organize and participate in the production of medicinal products in pharmaceutical enterprises, including the selection and justification of technological processes and equipment in accordance with Good Manufacturing Practice (GMP) requirements, with the corresponding development and preparation of the necessary documentation.

PC 22. Ability to organize and carry out quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and good practices in pharmacy, determine methods of sampling for control of medicinal products and carry out their standardization in accordance with current requirements, prevent the spread of counterfeit medicinal products.

• ***Integrative final program learning outcomes, the formation of which is facilitated by the elective course "Personalized Pharmacy and Cosmetology":***

- Identification of future professional activity as socially significant for human health.
- Implementation of professional activities based on general knowledge of the main stages of the formation and development of pharmaceutical science and practice in Ukraine and the countries of the world, practical approaches to the organization of providing medicines to the population and health care institutions, regulatory and legal acts of Ukraine and recommendations of proper pharmaceutical practices.

- Argumentation of decision-making in standard professional situations.
- Formation of basic knowledge and acquisition of practical skills for further study of professional educational disciplines.

• ***Program learning outcomes for the discipline:***

PLO 01. Apply specialised knowledge and skills/abilities in general and professional disciplines in professional activities.

PLO 02. Critically analyse scientific and applied problems in the field of pharmacy.

PLO 03. Evaluate and ensure the quality and effectiveness of activities in the field of pharmacy.

PLO 05. Plan and implement professional activities based on the regulatory and legal acts of Ukraine and recommendations of good pharmaceutical practices.

PLO 07. Demonstrate the ability to independently search for, analyse and synthesise information from various sources, including professional literature, patents and databases; evaluate it, in particular using statistical analysis, and apply these results to solve typical and complex specialised tasks in professional activities, including the development and production of medicinal products.

PLO 08. Develop and make effective decisions to solve complex/comprehensive pharmacy problems personally and based on the results of joint discussions; formulate the goals of one's own activities and those of the team, taking into account social and production interests, overall strategy and existing constraints, and determine the optimal ways to achieve these goals.

PLO 09. Develop and implement innovative projects in the field of pharmacy, as well as related interdisciplinary projects, taking into account technical, social, economic, ethical, legal and environmental aspects.

PLO 12. Promote health preservation, in particular disease prevention, rational prescription and use of medicines. Conscientiously perform professional duties, comply with legislation on the promotion and advertising of medicines. Possess psychological communication skills to achieve trust and mutual understanding with colleagues, doctors, patients and consumers.

PLO 13. Predict and determine the impact of environmental factors on the quality and consumer characteristics of natural and synthetic medicines and other pharmacy products, organise their storage in accordance with their physical and chemical properties and Good Storage Practice (GSP) rules.

PI.O 15. Formulate, argue, clearly and specifically convey to specialists and non-specialists, including higher education seekers, information based on their own knowledge and professional experience, the main trends in the development of global pharmacy and related industries.

PI O 16. Record cases of side effects when using natural and synthetic medicines; assess factors that may affect the processes of absorption and distribution, storage, metabolism and excretion of medicines and are determined by the condition and characteristics of the human body and the pharmaceutical characteristics of medicines.

PLO 22. Develop technological documentation for the manufacture of medicinal products, select rational technology, manufacture medicinal products in various dosage forms according to doctors' prescriptions and the requirements (orders) of medical and preventive institutions, and prepare them for release.

PI.O 23. Carry out pharmaceutical development, justify technology and organise the production of medicinal products at pharmaceutical enterprises, and draw up technological documentation for the production of medicinal products at pharmaceutical enterprises.

PLO 26. Ensure and carry out quality control of medicinal products of natural and synthetic origin and document its results; issue 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, counterfeit and unregistered medicinal products. В результаті вивчення дисципліни здобувач вищої освіти повинні:

Know:

- Basic terms and concepts used in the field of drug development.
- Regulatory and legislative documents of Ukraine that define the basic rules and requirements for drug development and quality assurance of research.
- Your social and civil rights and responsibilities.
- Methods of applying knowledge to solve practical problems.
- Current trends in the development of the industry.
- The structure and characteristics of professional activity.
- General approaches to the pharmaceutical development of medicinal products.
- The structure of the registration dossier.
- The main stages of drug development in various dosage forms.
- Pharmacotechnological indicators of raw ingredients, semi-finished products and the final product.
- Quality control indicators for various dosage forms.

Be able to:

- Identify the relationship between the development of drug technology and the general historical development of society.
- Use regulatory and legal acts governing pharmaceutical activities in Ukraine and abroad.
- Use professional knowledge to solve practical situations.
- Analyse professional information, make informed decisions, and acquire up-to-date knowledge.
- Carry out professional activities that require updating and integration of knowledge.
- Identify the main approaches to the pharmaceutical development of medicines.
- Select pharmaceutical factors in the development of medicinal products.
- Plan, execute and analyse the results obtained in the development of medicinal products.
- Determine the main quality indicators in the development of the composition and technology of medicinal products.
- Prepare the main sections of the pharmaceutical development of the registration dossier.

3. Content and logistics of the discipline

Module 1 «Pharmaceutical and technological aspects of drug development»	IV semester 90 hours /3 credits ECTS	Lectures №5 Practical classes №15 Extracurricular work №12
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The discipline includes 14 topics, which are divided into 1 module.

Module 1 «Pharmaceutical and technological aspects of drug development»

Topic 1. Basic terms and concepts of drug development.

Topic 2. State regulation of drug development and production.

Topic 3. Priority and promising areas of research in the development of modern drugs.

Topic 4. Original and generic drugs.

Topic 5. The life cycle of drugs.

Topic 6. The state pharmacovigilance system.

Topic 7. Stages and objects of pharmaceutical drug development.

Topic 8. The drug quality assurance system.

Topic 9. The interconnection between good pharmaceutical practices in ensuring the quality of medicines.

Topic 10. Ethical and legal aspects of conducting preclinical studies. Information on preclinical trials in Ukraine and worldwide.

Topic 11. Ethical and legal aspects of clinical trials. Information on clinical trials in Ukraine and worldwide.

Topic 12. Technological aspects of developing new dosage forms. Excipients in solid dosage forms. Quality control.

Topic 13. Development of the composition and technology of liquid dosage forms. Selection of excipients in the development of liquid dosage forms. Quality control.

Topic 14. Development of the composition and technology of soft dosage forms. Selection of excipients in soft dosage forms. Quality control.

The topics of the lecture course reveal problematic issues of the relevant sections of the discipline.

Lecture methods: not taught in class, materials are posted on the department's information resources.

Practical classes provide theoretical substantiation of the main issues of the topic and contribute to the formation of skills:

theoretically oriented, which include:

- entrance test control of knowledge of the student of higher education on the topic of the lesson;
- discussion and systematization of normative documents, material of the main and auxiliary literature;
- solving theoretical problems related to the lesson topic;
- solving situational tasks related to the specifics of the development and use of personalized medicinal and cosmetic products;
- conducting initial knowledge control using theoretical questions, situational and calculation problems, recipe prescriptions;

or practically oriented, which include

- conducting a test entry control of the readiness of higher education applicants for the manufacture of a certain type of medicinal forms;
- discussion of the step-by-step technology of prescriptions related to the topic of practical training;

- production of personalized medicinal and cosmetic products, or their components;
- solving individual situational tasks;
- a teacher's check of the quality of work performed by students of higher education using an oral survey;
- carrying out initial control of learning the material using theoretical questions, situational and calculation problems, recipe prescriptions.

Practical classes provide theoretical justification of the main issues of the topic and contribute to the formation of skills:

- Identify the relationship between the development of drug technology and the general historical development of society.
- Use regulatory and legal acts governing pharmaceutical activities in Ukraine and abroad.
- Use professional knowledge to solve practical situations.
- Analyse professional information, make informed decisions, and acquire up-to-date knowledge.
- Carry out professional activities that require updating and integration of knowledge.
- Identify the main approaches to the pharmaceutical development of medicines.
- Select pharmaceutical factors in the development of medicinal products.
- Plan, execute and analyse the results obtained in the development of medicinal products
- Determine the main quality indicators in the development of the composition and technology of medicinal products.
- Prepare the main sections of the pharmaceutical development of the registration dossier.

The student's independent work involves preparation for practical classes and intermediate tests, studying topics for independent extracurricular work, writing essays, preparing presentations, tables. The control of mastering the topics of independent extracurricular work is carried out at the intermediate control classes and the final control of the discipline.

Individual work includes the study of scientific literature, preparation of reviews of topics for presentation at meetings of the student scientific group, the implementation of scientific and practical research, participation in specialized competitions, scientific and practical conferences, competitions of student research papers.

Thematic plans of lectures, calendar plans of practical classes, thematic plan of independent extracurricular work, the volume and directions of individual work are published on the website of the department.

The route for obtaining materials: Department of Pharmacy / for students / Full-time education / Pharmacy, industrial pharmacy / 2 course / Educational materials / or through the link <https://www.vnmua.edu.ua/кафедра-фармації#..>. Access to the materials is carried out through the student's corporate account s000XXX@vnmua.edu.ua.

4. Forms and methods of monitoring academic performance

Current control in practical studies	Methods: <i>oral or written survey, testing, electronic survey, solving situational problems, conducting laboratory studies, interpreting them and evaluating their results (drawing up a protocol in a workbook)</i>
Final control of the discipline (credit) at the end of the 5th semester	Methods: <i>oral questioning</i> (according to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link https://www.vnmua.edu.ua/General information))
Learning success diagnostic tools	Theoretical questions, tests, clinically-oriented situational tasks, practical tasks, practical skills demonstration

5. Assessment criteria

Knowledge assessment is carried out in accordance with the Regulations of the Academic process in VNMU named after M.I. Pirogov (link [https://www.vnmua.edu.ua/General information](https://www.vnmua.edu.ua/General%20information))

Continuous assessment	On a four point system of traditional assessments: 5 «excellent», 4 «good», 3 «satisfactory», 2 «unsatisfactory»
Credit	On a 200-point scale (the arithmetic average grade for the semester is converted into points) Credited: 122 to 200 points Not credited: less than 122 points (See Grading Scale)

Discipline assessment scale: national and ECT

The sum of grades for all types of educational activities	Score ECTS	Score on a national scale	
		For exam, course project (work), practice	for credit test
180-200	A	excellent	credited
170-179,99	B	good	
160-169,99	C		
141-159,99	D	satisfactory	
122-140,99	E	satisfactory	
0-121,99	FX	Unsatisfactory with the possibility of reassembly	is not credited with the possibility of reassembling
	F	unsatisfactory with a mandatory reexamination of discipline	Is not credited with mandatory reexamination of discipline

6. Policy of discipline / course

The student has the right to receive high-quality educational services, access to contemporary scientific and educational information, qualified advisory assistance during the study of discipline and mastering practical skills. The policy of the department during the providing of educational services is a student-centered, based on normative documents of the Ministry of Education and the Ministry of Health of Ukraine, the Statute of the University and the Procedure for the Providing of Educational Services regulated by the main principles of the organization of the educational process in VNMU named after M.I.Pirogov and the principles of academic integrity (link [https://www.vnmua.edu.ua/General information](https://www.vnmua.edu.ua/General%20information)).

Adherence to the rules of VNMU, safety techniques in practical classes.

Safety instruction is given at the first practical lesson by the teacher. The briefing is registered in the Safety Briefing Journal. A student who has not been instructed is not allowed to practice.

In the event of the announcement of the "Air Alert" signal or other warning signals, the teacher stops the class, informs the students of the need to go to the civil defense shelter and stay there until the signal is canceled. The teacher informs higher education students of further actions after the signal is canceled: to continue the class or to recommend that they independently finalize the material with a subsequent survey at the next class (Order No 92 of 03.09.2024).

Requirements for preparation for practical classes. The student must be prepared for a practical lesson, tasks to prepare for the current topic must be completed.

A student should come to class on time, without delay. A student who is late is not allowed to study and must work it in the prescribed manner.

In practical classes, the student must be dressed in a work uniform. Students who do not have a work uniform are not allowed to study.

The student must follow the rules of safety in practical classes and during the stay in the department.

When discussing theoretical issues, students should demonstrate tolerance, courtesy and respect for their colleagues and the teacher; when performing practical tasks, the workplace should be kept in order and be cleaned after performing practical work.

Usage of mobile phones and other electronic devices. The use of mobile phones and other electronic devices in the classroom is allowed only on the instructions of the teacher.

Academic integrity. When studying the discipline, the student must be guided by the Code of Academic Integrity and Corporate Ethics of VNMU named after M.I. Pirogov (link : [https://www.vnmua.edu.ua/General information/](https://www.vnmua.edu.ua/General%20information/) Code of Academic Integrity). In case of violation of the norms of academic integrity during the current and final controls student receives a grade of "2" and must work it out to his teacher in the prescribed manner within two weeks after receiving an unsatisfactory assessment).

Missed classes. Missed classes are working out in the manner prescribed by Regulations of the Academic process in VNMU named after M.I. Pirogov (link [https://www.vnmua.edu.ua/General information/](https://www.vnmua.edu.ua/General%20information/)) at the time of work out schedule to the teacher on duty.

The procedure for admission to the discipline final control is given in the Regulations of the Academic process in VNMU named after M.I. Pirogov (link [https://www.vnmua.edu.ua/General information/](https://www.vnmua.edu.ua/General%20information/)). To the final control allowed students who do not have missed practical classes and lectures and received an average traditional grade of at least "3".

Additional points. Individual points in the discipline (from 1 to 12) that student can receive for individual work, the amount of which is published on the website of the department in the educational methodical materials of the discipline, the number of points is determined by the results of IRS according to Regulation of the Academic process in VNMU named after M.I. Pirogov.

Conflict resolution. In case of misunderstandings and complaints to the teacher because of the quality of educational services, knowledge assessment and other conflict situations, student should submit his / her claims to the teacher, in VNMU named after M.I. Pirogov.

Politics in terms of remote learning. Distance learning regulated by the Regulations of the elements of remote learning in VNMU named after Pirogov M.I. The procedure for conducting practical classes and lectures, practicing and consultations during distance learning is published on the department's website.

Feedback from teachers carried out through a distance learning platform (Microsoft Teams) is via messengers or e-mail (at the teacher's choice) during working hours.

Higher education applicants have the right to receive quality educational services, access to up-to-date scientific and educational information, qualified advisory assistance in the study of the discipline and mastery of practical skills. The policy of the department in the provision of educational services is student-centered, based on the regulations of the Ministry of Education and the Ministry of Health of Ukraine, the university charter and the procedure for the provision of educational services, regulated by the basic provisions of the organization of the educational process at the Pirogov National Medical University and the principles of academic integrity.

7. Educational resources.

Educational and methodological support of the discipline is published on the website of the department (<https://www.vnmua.edu.ua/кафедра-фармації#> / for students). Consultations are held twice a week according to the schedule.

8. The timetable and distribution of groups with assigned teachers are published on the web page of the department (<https://www.vnmua.edu.ua/кафедра-фармації#> / for students).

9. Questions to the intermediate and final semester control (credit) of the discipline are published on the web page of the department (<https://www.vnmua.edu.ua/кафедра-фармації#> / for students).

Recommended literature


1. European Pharmacopoeia. 10th Edition 2020, English
2. The International Pharmacopoeia / [8-th ed.]. - Geneva : World Health Organization, 2019. 2532 p. - ISBN: 9241545364.
3. British pharmacopoeia. London: Medicines and Healthcare products Regulatory Agency: 2018.
4. The United States pharmacopoeia. National formulary. Rockville (MD): United States Pharmacopeial Convention: 2017.
5. The USP Pharmacists' Pharmacopoeia. – Second edition.– 2008. - P. 1114.
6. EudraLex: The Rules Governing Medicinal Products in the European Union. Volume 4: Good Manufacturing Practice / European commission: 22 November 2017. Access: https://ec.europa.eu/health/system/files/2017-11/2017_11_22_guidelines_gmp_for_atmps_0.pdf
7. An imprint of Elsevier, 2020. - 1000 p. <https://doi.org/10.1016/C2018-0-04991-9>
8. Encyclopedia of Pharmaceutical Science and Technology. Fourth Edition. Six Volume Set (Print)/ James Swarbrick Taylor & Francis. 2013 4296 p.
9. Voigt's Pharmaceutical Technology Alfred Fahr, Gerrit L. Scherphof (Translator). Wiley, 2018. 888p.
10. Pharmaceutical Technology: A Practical Manual / Sushma Talegaonkar. - PharmaMed Press, 2019, 232 p.
11. Essentials of Pharmaceutical Technology/ Ajay Semalty, Mona Semalty, M. S. M Rawat. - PharmaMed Press, 2019, 364 p. ISBN 9385433172
12. Handbook of Pharmaceutical Technology L. K. Ghosh CBS Publishers & Distributors, 2018 283 crop. ISBN 8123908504
13. Rees J. A. Introduction to pharmaceutical calculations / Judith A Rees; Ian Smith; Jennie Watson [4-th edition]. London and Chicago : Pharmaceutical Press, 2016., 290 p. ISBN: 9780857112439.

Information resources

1. E-mail address of the university website: <http://vnmuedu.ua>
2. E-mail address of the university library website: <http://library.vnmuedu.ua>
3. E-mail address: Department of Pharmacy, Pirogov National Medical University: <http://www.vnmuedu.ua>
4. World Health Organization <http://www.who.int/en/>
5. Testing center <https://www.testcentr.org.ua/uk/>
6. Ministry of Health of Ukraine <https://moz.gov.ua/>
7. Center for Public Health of the Ministry of Health of Ukraine <https://phc.org.ua/kontrol-zakhvoryuvan>

The syllabus of the discipline "Pharmaceutical and technological aspects of drug development" was discussed and approved at the meeting of the department Department of Pharmacy (record № 1, dated August "26" 2025)

Responsible for the academic discipline  Olena KRYVOVIAZ
(signature)

The Head of the Pharmacy Department  Olena KRYVOVIAZ
(signature)