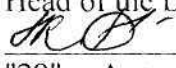


National Pirogov Memorial Medical University, Vinnytsia

«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

**FUNDAMENTALS OF LEGISLATIVE REGULATION OF THE
PHARMACEUTICAL INDUSTRY**

Specialty	226 Pharmacy, Industrial Pharmacy
Specialization	226.01 Pharmacy
Educational level	the second (master`s) level
Educational programme	<i>FPP «Pharmacy», 2023</i>
Academic year	2025-2026
Department	Pharmacy
Lecturer (if lectures are given)	Prof. of HEI Olena KRYVOVIAZ, Ass. Prof. of HEI Yulia TOMASHIVSKA, PhD, Ass. Prof. Hanna KRAMAR
Contact information	<i>pharmacy@vnmu.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	EC 27// optional courses, optional components of EP
Course / semester	2 nd course
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 «Fundamentals of legislative regulation of the pharmaceutical industry» belongs to the cycle of disciplines for the professional-oriented training of specialists in specialty 226 "Pharmacy, Industrial Pharmacy". Specialisation 226.01 Pharmacy. The discipline lays the foundations for higher education students' knowledge of contemporary trends in pharmaceutical technology and professional activity in Ukraine and abroad, and is a connecting link between the theoretical disciplines that form the profile of a Master of Pharmacy.

The course promotes in-depth study of the legislative framework and the requirements of scientific and technical documentation for the manufacture, storage and dispensing of medicines, helping higher education students to clearly understand their rights and obligations.

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

Know:

- provisions of the Law of Ukraine 'On Medicinal Products';
- main provisions of the Ministry of Health orders regarding the preparation, testing and quality control of medicinal products;
- requirements of the sanitary and anti-epidemic regime.

Be able to:

- apply technical and technological documentation regulating the quality of raw materials, medicinal products and auxiliary materials;
- check the preparation of prescriptions, the manufacture of medicinal products and the quality of finished products;
- prepare medicinal products for dispensing.

Prerequisites

The discipline is based on the study of all regulatory documents and also uses as prerequisites such disciplines of the curriculum as introduction to pharmacy (basic interdisciplinary interactions in pharmacy, concepts of drug technology and biopharmacy).

The purpose of the course and its significance for professional activities.

The aim of teaching this academic discipline is to lay the normative foundation that will subsequently enable higher education students to facilitate the study and understanding of state regulation of the pharmaceutical industry.

Postrequisites

The discipline is the basis for the study of the disciplines: "Drug technology: Industrial drug technology", "Medicinal cosmetic technology". Regulatory documentation considered during the educational process is a prerequisite for studying the discipline "Organization and Economy in Pharmacy". The educational process involves the integration of teaching with the above-mentioned disciplines and the formation of skills to apply knowledge in the process of further education and professional activity.

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. 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 communication strategies, ability to work in a team and with experts from other fields of knowledge/types of economic activity.

GC 10. Ability to exercise one's rights and responsibilities as a member of society, to understand the values of a civil (free democratic) society and the need for its sustainable development, the rule of law, and the rights and freedoms of individuals and citizens.

• 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 03 Ability to solve pharmacy problems in new or unfamiliar environments with limited information, taking into account aspects of social and aesthetic responsibility.

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 06. Ability to clearly and unambiguously convey one's knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.

PC 11. Ability to ensure proper storage of medicines and other pharmacy products in accordance with their physical and chemical properties and Good Storage Practice (GSP) rules in healthcare facilities.

PC 16. Ability to develop and implement a quality management system for pharmaceutical companies in accordance with the requirements of current Standards, to conduct quality audits and manage risks to the quality of pharmaceutical products. 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).

• ***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:***

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

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

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

PL.O 04. Comply with sanitary and hygienic regulations and safety requirements in the performance of professional activities.

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

PL.O 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 of professional activities, including the development and production of medicinal products.

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

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

PL.O 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.

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

PL.O 17. Implement appropriate organisational and managerial measures to provide the population and healthcare institutions with medicines and other pharmacy products; carry out all types of reporting and accounting in pharmacy institutions, administrative record keeping and commodity analysis.

PL.O 20. Manage pharmaceutical organisations and determine their effectiveness using management functions. Make management decisions based on the leadership and communication skills of pharmaceutical personnel regarding strategic planning of enterprise activities.

PL.O 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 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 poor-quality, counterfeit and unregistered medicinal products.

3. Content and logistics of the discipline

Module	1	IV semester	Lectures №5
«Fundamentals of legislative regulation of the pharmaceutical industry»	of	90 hours /3 credits ECTS	Practical classes №15 Extracurricular work №8

The discipline includes 14 topics, which are divided into 1 module.

Module 1 «Fundamentals of legislative regulation of the pharmaceutical industry»

- Topic 1. State regulation of pharmaceutical activities in Ukraine. State Pharmacopoeia.
- Topic 2. State Inspectorate for Quality Control of Medicines: functions
- Topic 3. Sanitary and anti-epidemic regime in production
- Topic 4. Production formulation, technological instructions, prescription, registration and storage.
- Topic 5. Manufacture of medicinal products, requirements, regulatory documents.
- Topic 6. Requirements for excipients. Selection principles.
- Topic 7. Methods of obtaining water. Standardisation of storage and use.
- Topic 8. Standardisation of the circulation of toxic and narcotic substances.
- Topic 9. State regulation of the circulation of counterfeit, substandard and unregistered medicinal products
- Topic 10. Procedure for importing medicinal products into Ukraine
- Topic 11. Regulatory documents governing the extemporaneous manufacture of medicinal products.
- Topic 12. Regulatory documents governing the industrial manufacture of medicinal products.
- Topic 13. Regulatory documents governing the storage and transportation of dosage forms.
- Topic 14. Quality control of medicinal products: technical documentation governing quality requirements. Labelling and packaging requirements.

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.

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.vnmdu.edu.ua/кафедра-фармації#..> Access to the materials is carried out through the student's corporate account s000XXX@vnmdu.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)	Methods: <i>oral questioning</i> (according to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link https://www.vnmdu.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.vnmu.edu.ua/General information/](https://www.vnmu.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.vnmu.edu.ua/General information/](https://www.vnmu.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.vnmu.edu.ua/General information/](https://www.vnmu.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.vnmu.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.vnmu.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.vnmu.edu.ua/кафедра-фармації#> / for students).

Recommended literature

Basic

1. Pharmacy - based technology of drugs: the manual for applicants of higher education / O.I. Tykhonov, O.A. Yarnykh, O.A. Rukhmakova, G.B. Yuryeva: Edited by O.I. Tykhonov and I.G. Yarnykh. Kharkiv: NUPh: Golden Pages, 2019. 488 p.
2. Remington: The Science and Practice of Pharmacy, Twenty Third Edition/ Remington J. P. Academic press: An imprint of Elsevier, 2020. 1000 p. <https://doi.org/10.1016/C2018-0-04991-9>

Additional 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 pharmacopeia. National formulary. Rockville (MD): United States Pharmacopoeial 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 стр. 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/>

The syllabus of the discipline «Fundamentals of legislative regulation of the pharmaceutical industry» was discussed and approved at the meeting of the department Department of Pharmacy (record № 1, dated August "26" 2025)

Responsible for the academic discipline
(signature)



Olena KRYVOVIAZ

The Head of the Pharmacy Department



Olena KRYVOVIAZ