

National Pirogov Memorial Medical University, Vinnytsia

"APPROVE"

Higher Educational Institution
Vice-Rector for Scientific and
Academic Work and International Links
Inna ANDRUSHKO
"30" August 2024 year

«AGREED»

Head of the Department of Pharmacy
[Signature] Olena KRYVOVIAZ
"30" August 2024 year

SYLLABUS
of academic discipline

PROCEEDING PRACTICE ON PHARMACY COMPOUNDING

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	2024-2025
Department	Pharmacy
Lecturer (if lectures are given)	-
Contact information	<i>pharmacy@vnmu.edu.ua</i>
Syllabus compiler	Ass. Prof. Hanna KRAMAR

Status and structure of the discipline

Discipline status	Obligatory
Discipline code in EPP/ discipline place in EPP	OK 52 // discipline of general training or professional training
Course / semester	4 rd (VIII semester)
The amount of discipline (the total number of hours / number of credits ECTS)	75 hours /2,5 credits ECTS
Number of content modules	-
The structure of the discipline	Practical classes - Independent work - 75 hours
Language of study	English
Form of education	Full – time (or remote/mixed according to the order)

1. Description of the discipline

Brief annotation, actuality.

The discipline "Proceeding practice on pharmacy compounding" helps to consolidate theoretical knowledge and acquire practical skills in the manufacture of medicines in a pharmacy, packaging of finished medicines and manufacturing of intra-pharmacy preparations.

The subject of practice is to improve the knowledge and skills of manufacturing drugs in pharmacies.

Together with other pharmaceutical disciplines and social sciences, educational practice in drug technology plays an important role in shaping the worldview of specialists in the field of pharmacy and in providing them with special technological training for professional activities to supply the population and medical institutions with drugs. The practice also develops practical skills on the main stages of formation and development of the pharmaceutical industry and professional activities in Ukraine and abroad, the general requirements for the manufacture of medicines.

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

- The main current orders and other regulatory documents of the Ministry of Health of Ukraine regarding the acceptance of prescriptions, production, quality control and dispensing of drugs and preparations.
- Physico-chemical, chemical, pharmacological incompatibilities and methods of their elimination.
- Rules for accepting, storing, and issuing poisonous, narcotic, intoxicating drugs and ethanol.
- Higher one-time and daily doses of poisonous, narcotic, intoxicating, potent substances, the principles of their pharmacological action and conditions that ensure the effectiveness and safety of use, current norms of one-time release.
- Modern assortment of medicines and the possibility of their adequate replacement.
- Classification of medicinal products and dosage forms.
- Composition of medicinal forms; assortment and characteristics of auxiliary substances used in the production of medicines.
- Biopharmaceutical evaluation of medicines, the main directions of scientific research in this field.
- Physico-chemical properties of medicines.
- Theoretical foundations of the technology of various dosage forms.
- Basic rules for the administration of medicinal products in medicinal forms.
- Nomenclature and principles of use of means of small mechanization.
- Quality control of dosage forms.
- Scientific and technical achievements in drug technology.

Prerequisites.

The practice is based on the study of natural science and professional disciplines: Latin, general and inorganic chemistry, organic chemistry, analytical chemistry, physical and colloidal chemistry, biology with the basics of genetics. It is integrated with such disciplines of the curriculum as pharmacology, pharmaceutical botany, pharmacognosy, pharmacotherapy, clinical pharmacy.

The purpose of the course and its significance for professional activity is to consolidate, deepen and expand the theoretical knowledge and practical skills acquired in the university, mastering basic professional competencies directly in the workplace, gaining practical experience.

Post-requisites. The discipline is the basis for the study of pharmaceutical and medical commodity science, good practices in pharmacy, pharmaceutical chemistry, management and marketing in pharmacy, biopharmacy, standardization of medicines, technology of medicinal cosmetics. The internship lays the foundation for professional training, contributes to the formation of pharmaceutical and technical thinking necessary for professional activity.

2. Learning outcomes. (*A concrete result with a focus on practical application, which will be achieved and which can be verified*).

- *Integrative final program learning outcomes, the formation of which is facilitated by the Proceeding practice on pharmacy compounding*
- Identification of future professional activity as socially significant for human health.
- Implementation of professional activity based on general knowledge of the main stages of formation and development of pharmaceutical science and practice in Ukraine and the world, practical approaches to the organization of medicines and public health facilities, regulations of Ukraine and recommendations of good pharmaceutical practices.
- Rationale for decision making in standard professional situations.
- Formation of basic knowledge and acquisition of practical skills for further study of professional disciplines.

- *Program learning outcomes for the discipline:*

PLO 2. Apply knowledge of general and special disciplines in professional activities.

PLO 3. To comply with the norms of sanitary and hygienic regime and safety requirements in the implementation of professional activities.

PLO 4. Demonstrate the ability to independently search, analyze and synthesize information from various sources to solve typical problems of professional activity.

PLO 7. Perform professional activities using creative methods and approaches.

PLO 9. To carry out professional activities using reference scientific literature, information technology, "Information databases", navigation systems, Internet resources, software and other information and communication technologies.

PLO 12. Analyze information obtained as a result of scientific research, summarize, systematize and use it in professional activities.

PLO 19. Predict and determine the impact of environmental factors on the quality of medicines and consumer characteristics of other pharmacy products during their storage.

PLO 24. Plan and implement professional activities on the basis of regulatory legal acts of Ukraine and recommendations of good pharmaceutical practices.

PLO 26: Choose a rational technology, manufacture medicines in various dosage forms according to prescriptions and orders of medical institutions, prepare them for release. Perform technological operations: weigh, measure, dose various medicines by weight, volume, etc. Develop and draw up technological regulatory documentation for the production (manufacture) of medicines in pharmacies.

PLO 30. Ensure quality control of medicinal products and document its results. To manage quality risks at all stages of the life cycle of medicines.

As a result of studying the discipline, higher education students should:

Know:

- The main current orders and other regulatory documents of the Ministry of Health of Ukraine on prescriptions, manufacturing, quality control and dispensing of medicines and drugs.
- Physicochemical, chemical, pharmacological incompatibilities and ways to eliminate them.
- Rules for the acceptance, storage, and dispensing of poisonous, narcotic, intoxicating drugs and ethanol.
- Highest single and daily doses of poisonous, narcotic, intoxicating, potent substances, principles of their pharmacological action and conditions that ensure the effectiveness and safety of use, current single-dose standards.
- The current range of medicines and the possibility of their adequate replacement.
- Classification of medicines and dosage forms.
- Composition of dosage forms; range and characteristics of excipients used in the manufacture of medicines.
- Biopharmaceutical evaluation of medicines, the main areas of research in this area.
- Physical and chemical properties of medicines.
- Theoretical foundations of the technology of various dosage forms.
- Basic rules for the introduction of drugs into dosage forms.
- Nomenclature and principles of use of small-scale mechanization.
- Quality control of dosage forms.
- Scientific and technical achievements in the technology of medicines.

Be able to:

- Use regulatory, reference, scientific literature to solve professional problems.
- Identify physical, chemical and pharmacological incompatibilities, decide on the possibility of preparing and dispensing medicines, taking into account the compatibility of the components of the prescription.
- Check and, if necessary, correct single and daily doses of medicinal substances A and B, the norms of release of narcotic and equivalent substances.
- Prepare solid, liquid, and soft dosage forms (powders, solutions, mixtures, suspensions, emulsions, infusions, decoctions, injectable solutions, eye drops and lotions, liniments, ointments, suppositories) according to individual prescriptions, taking into account the theoretical foundations of pharmacy drug technology and the requirements of regulatory documents.
- Calculate the number of components of the prescription, the total volume or weight of the medicinal product, and write a written control passport.
- Select the optimal technology option and prepare a medicinal product in accordance with it with a stage-by-stage quality assessment.
- Evaluate the quality of the prepared drug in accordance with the specifications.
- To take into account the impact of pharmaceutical factors (type of dosage form, particle size of medicinal substances, qualitative and quantitative composition of medicinal and excipients, technological processes and devices, etc.) on the quality and bioavailability of medicinal products.
- Identify frequently repeated drug prescriptions and carry out in-pharmacy procurement of medicinal products and semi-finished products according to them.
- To carry out a set of measures to ensure compliance with the sanitary regime in pharmacies and to monitor the aseptic preparation of dosage forms.
- Adhere to the deontological principles of relations with the staff of pharmacies, patients and their relatives, and doctors of health care facilities.
- To comply with the rules of labor protection and safety.
- Conduct sanitary and educational work.
- Conduct research to improve dosage forms and their technology.

3. Content and logistics of the discipline

Module 1 "Technology of dosage forms of pharmaceutical and industrial production"	8 semester 75 hours /2,5 credits ECTS	Lectures №- Practical classes №- Extracurricular work №10
--	--	---

The course includes 7 topics

Topic 1: Get acquainted with the production premises of the pharmacy.

Topic 2. Dosing in pharmacy technology of drugs by mass, volume and drops.

Topic 3. Preparation of solid dosage forms.

Topic 4. Preparation of liquid dosage forms.

Topic 5. Preparation of soft dosage forms.

Topic 6. Preparation of aseptic dosage forms.

Topic 7. Preparation for a differentiated Credit in practice.

Preparation of reporting documentation, preparation for test control.

Independent work involves the theoretical substantiation of the main issues of the topic and contributes to the acquisition of practical skills:

- To determine the relationship between the development of drug technology and the historical development of society.
- Use normative, reference, scientific literature to solve professional problems.
- Identify physical, chemical and pharmacological incompatibilities, address the possibility of preparation and release of drugs, taking into account the compatibility of the components of the prescription.
- Check and, if necessary, correct single and daily doses of drugs A and B, the norms of release of narcotic and similar substances.
- Prepare according to individual recipes solid, liquid, soft dosage forms (powders, solutions, mixtures, suspensions, emulsions, infusions, decoctions, injectable solutions, eye drops and lotions, liniments, ointments, suppositories), taking into account the theoretical foundations of pharmacy drug technology and regulatory requirements.
- Calculate the number of components of the prescription, the total volume, or weight of the drug; write a passport of written control.
- Choose the best technology and prepare a drug with a gradual assessment of quality.
- Assess the quality of the prepared drug according to the NTD.
- Adhere to storage conditions and type of packaging to ensure the stability of dosage forms.
- Take into account the influence of pharmaceutical factors (type of dosage form, particle size of medicinal substances, qualitative and quantitative composition of medicinal and excipients, technological processes and devices, etc.) on the quality and bioavailability of medicinal products.
- Identify prescriptions of frequently repeated drugs and carry out in-pharmacy procurement of drugs and semi-finished products for them.
- Carry out a set of measures to ensure compliance with the sanitary regime in pharmacies, and monitor the aseptic preparation of dosage forms.
- Adhere to the deontological principles of relations with the staff of pharmacies, with patients and their relatives, with doctors of treatment and prevention facilities.
- Follow the rules of labor protection and safety.
- Carry out sanitary and educational work.

- Conduct research to improve dosage forms and their technology.
- Use regulations governing pharmaceutical activities in Ukraine and abroad.
- Use professional knowledge to solve practical situations.
- Conduct analysis of professional information, make informed decisions, acquire modern knowledge.
- Carry out professional activities with continuous updating and integration of knowledge.

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 / 3 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>completion of individual tasks, preparation of a practice journal</i>
Control of mastering the thematic section of the discipline at intermediate control lessons	Methods: <i>oral or written survey, electronic testing, situational problem solving, control of practical skills</i>
Final semester control (differential credit) at the end of the 8 semester	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, 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»
Final control of the discipline	<i>Grade for differential credit:</i> 71-80 points - "excellent" 61-70 points - "good" 50-60 points - "satisfactory" Less than 50 points - "unsatisfactory" / did not pass
Discipline assessments:	Current academic assessment - from 72 to 120 points (conversion of the average traditional assessment of practical class on a 120-point scale): 60% of the grade for the discipline Final control - from 50 to 80 points: 40% of the grade for the discipline Individual work - from 1 to 12 points From 122 to 200 points in total.

Discipline Score Scale: National and ECTS

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.

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. 505 of 30.08.2023).

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 must come to class on time. 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.vnmue.edu.ua/General> information)/ 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.vnmue.edu.ua/General> information) 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.vnmue.edu.ua/General> information). 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 6 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.

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/ Department of Pharmacy #](https://www.vnmu.edu.ua/Department%20of%20Pharmacy%20#) / 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/ Department of Pharmacy #](https://www.vnmu.edu.ua/Department%20of%20Pharmacy%20#) / for students).

9. Questions to the intermediate and final semester control (credit) of the discipline are published on the web page of the department ([Department of Pharmacy #](https://www.vnmu.edu.ua/Department%20of%20Pharmacy%20#) / 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 T.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 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 стр.ISBN 8123908504

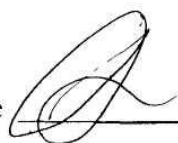
13. Rees J. A. Introduction to pharmaceutical calculations / Judith A Rees; Ian Smith; Jennie Watson – [4-th edition]. – London and Chicago : Pharmaceutical Press, 2016., 290 p. – ISBN: 9780857112439.

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/>
7. Center for Public Health of the Ministry of Health of Ukraine <https://phc.org.ua/kontrol-zakhvoryuvan>

The syllabus of the discipline «Proceeding practice on pharmacy compounding» discussed and approved at the meeting of the Department of Pharmacy (record № 1, dated August "30" 2024)

Responsible for the academic discipline
(signature)



Hanna KRAMAR

The Head of the Pharmacy Department
(signature)



Olena KRYVOVIAZ