

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

Olena KRYVOVIAZ
"30" August 2024 year

SYLLABUS
of academic discipline

EXCIPIENTS IN PHARMACEUTICAL AND COSMETIC TECHNOLOGY

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	2024-2025
Department	Pharmacy
Lecturer (if lectures are given)	Prof. of HEI Olena KRYVOVIAZ, Ass. Prof. of HEI Yulia TOMASII VSKA, PhD, Ass. Prof. Hanna KRAMAR
Contact information	<i>pharmacy@ynmu.edu.ua</i>
Syllabus compiler	Ass. Prof. of HEI Hanna KRAMAR

Status and structure of the discipline

Discipline status	optional courses
Discipline code in EPP/ discipline place in EPP	EC 25// optional courses, optional components of EP
Course / semester	2 rd course (III 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 discipline

Brief annotation, actuality.

The elective course "Excipients in pharmaceutical and cosmetic technology" belongs to the cycle of disciplines of professionally-oriented training of specialists in the specialty 226 "Pharmacy, industrial pharmacy", 2023. The discipline lays the foundations for higher education knowledge of pharmacy and industrial drug technology, modern trends to provide more complete information about excipients used in modern drug technology and their informed choice in the creation and manufacture of drugs and cosmetics.

The subject of the course is excipients used in the manufacture of medicines and cosmetics, their nomenclature and physical and chemical properties.

As a result of studying the discipline, the student must:

Know:

- current orders and other regulatory documents of the Ministry of Health of Ukraine regarding the use of excipients in the manufacture of medicines;
- the nomenclature of excipients used in the manufacture of medicines;
- the impact of the excipients on the processes of release, absorption, distribution and elimination of drugs;
- the impact of excipients on pharmaceutical and biopharmaceutical parameters of medicinal products;
- the nomenclature of the excipients included in cosmetic products;
- rules of mixing of excipients with medicinal substances in powders and preparations;
- rules of dissolution of medicinal substances in various solvents;
- rules for the selection of excipients in the manufacture of heterogeneous liquid dosage forms in a pharmacy;
- rules for the introduction of drugs into various bases in the manufacture of ointments and suppositories in a pharmacy;
- excipients used for the manufacture of injectable and infusion solutions;
- Drug substances used for the manufacture of sterile dosage forms;
- principles of selection of excipients to ensure the required quality of solid medicinal products in industrial conditions;
- principles of selection of excipients for ensuring the required quality of liquid medicinal products in industrial conditions;
- principles of selection of the excipients to ensure the required quality of soft drugs in industrial conditions;
- the impact of excipients on the quality and safety of cosmetics;

- excipients in homeopathic technology.
be able to:
- analyze and use regulatory and reference literature related to the manufacture of medicines and the use of excipients;
- to systematize and classify excipients by nature, chemical structure, diversity of their influence on the properties of active pharmaceutical ingredients, and method of their manufacture;
- to operate with knowledge of the physical and chemical properties of excipients and their influence on the processes of release, absorption, distribution and elimination of drugs and cosmetics;
- to introduce excipients into the composition of extemporaneous powders and preparations;
- correctly dissolve medicinal substances in various solvents;
- select excipients in the manufacture of heterogeneous liquid dosage forms in a pharmacy;
- mix various bases with medicinal substances in the manufacture of ointments in a pharmacy;
- prepare suppository bases and administer medicinal substances with different physical and chemical properties;
- select excipients for the preparation of injectable and infusion solutions;
- to introduce excipients into sterile dosage forms;
- to select excipients to ensure the required quality of solid medicinal products in industrial conditions;
- to select excipients to ensure the required quality of liquid medicines in industrial conditions;
- to select excipients to ensure the required quality of soft drugs in industrial conditions;

Prerequisites - disciplines that contain the knowledge, skills and abilities required to master the elective course "Excipients in pharmaceutical and cosmetic technology".

The discipline is based on the study of physics and chemistry during secondary education, and also uses as prerequisites such disciplines as general and inorganic chemistry (knowledge of physical and chemical properties of compounds, structure of matter, the concept of physical state, solutions, concentration, etc.), biological physics with physical methods of analysis (knowledge of the basics of thermodynamics, mechanics, basic knowledge of solid state physics and materials science), physical and colloid chemistry, introduction to pharmacy (basic interdisciplinary interactions in pharmacy, the concept of drug technology and biopharmacy), biology with basics genetics.

The purpose of the course and its significance for professional activities. Preparation of higher education students for future professional activities by studying the nomenclature, physical and chemical properties of excipients and their impact on the quality and safety of medicines, the rules for the use of excipients in the manufacture of medicines in pharmacies and industrial production.

Postrequisites - The discipline is the basis for studying the disciplines "Drug Technology: Pharmacy Drug Technology", "Drug Technology: Industrial Drug Technology", which involves the integration of teaching with the above disciplines and the formation of skills to apply knowledge in further education and professional activities.

2. **Learning outcomes.**

- *Integral (IC):* the ability to solve typical and complex specialised tasks and practical problems in professional pharmaceutical activity with the use of provisions, theories and methods of fundamental, chemical, technological, biomedical and socio-economic sciences; to integrate knowledge and solve complex problems, formulate judgements with insufficient or limited information: clearly and unambiguously communicate their conclusions and knowledge, reasonably justifying them, to professional and non-specialist audiences.

- *General competences (GC):*

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

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

GC 06. Skills in the use of 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 enhance 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 technology, to use various types and forms of physical activity for active recreation and healthy lifestyle.

- *special (professional, subject) competences (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: Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.

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

PC 11. Ability to ensure the proper storage of medicines and other pharmacy products in accordance with the rules of Good Storage Practice (GSP) in health care facilities.

PC 18. Ability to organise and carry out the production activities of pharmacies for the manufacture of medicines in various dosage forms according to prescriptions and orders of medical institutions, including the justification of technology and the choice of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).

PC 19. Ability to organise and carry out the procurement of medicinal plant materials in accordance with the rules of Good Practice for the cultivation and collection of raw materials and medicines based on it. Ability to predict and calculate ways to solve the problem of preservation and protection of wild medicinal plants in accordance with current legislation.

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

- *Programme learning outcomes for the discipline:*

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

PLO 02. Critically comprehend 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 04. To comply with the standards of sanitary and hygienic regime and safety requirements in the performance of professional activities.

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

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

PLO 08. Develop and make effective decisions on solving complex/complex problems of pharmacy personally and based on the results of joint discussion; formulate goals of own and team

activities, taking into account social and industrial interests, overall strategy and existing constraints, determine the best ways to achieve goals.

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

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

PLO 15. To formulate, argue, clearly and concretely communicate 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 world pharmacy and related industries. Demonstrate the ability to independently search, analyze and use normative and reference literature on excipients;

PLO 22. Develop technological documentation for the manufacture of medicines, choose a rational technology, manufacture medicines in various dosage forms according to prescriptions and requirements (orders) of healthcare facilities, and prepare them for release.

PLO 23. Carry out pharmaceutical development, substantiate the technology and organise the production of medicines at pharmaceutical enterprises and draw up technological documentation for the production of medicines 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 certificates of analysis in accordance with 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.

3. Content and logistic of the discipline

Module 1 "Excipients in pharmaceutical and cosmetic technology".	V semester 90 hours / 3 credits	Lectures № 5 Practical classes № 15 Topics for self- study №30
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The course includes 14 topics, which are divided into one thematic module.

Thematic module 1: "Excipients in pharmaceutical and cosmetic technology".

- Topic 1: The role of excipients in the development of pharmaceutical systems
- Topic 2. Excipients in extemporaneous powders, preparations
- Topic 3. Excipients in industrially manufactured solid dosage forms
- Topic 4. Solvents and extractants in liquid dosage forms manufactured in a pharmacy
- Topic 5. Substances that ensure the stability of heterogeneous liquid dosage forms
- Topic 6. Excipients in industrially manufactured liquid dosage forms
- Topic 7. Excipients in soft dosage forms of extemporaneous manufacture.
- Topic 8: Excipients in suppositories.
- Topic 9: Excipients in soft medicinal products and suppositories of industrial manufacture.
- Topic 10. Substances that ensure the stability and quality of injectable and infusion solutions
- Topic 11. Excipients in sterile dosage forms
- Topic 12: Dyes, flavour and odour correlates in the manufacture of medicinal products
- Topic 13. Excipients in the technology of therapeutic and decorative cosmetics
- Topic 14: Excipients in homeopathic technology

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

Methods of lectures: not taught in class, materials are posted on the department's information resources.

Practical classes provide a theoretical justification of the main issues of the topic and the acquisition of the following practical skills:

1. to analyse and use regulatory and reference literature on the manufacture of medicinal products and the use of excipients;
2. to systematise and classify excipients by nature, chemical structure, diversity of their influence on the properties of active pharmaceutical ingredients, and method of their manufacture;
3. to operate with knowledge of the physical and chemical properties of excipients and their influence on the processes of release, absorption, distribution and elimination of drugs and cosmetics;
4. to introduce excipients into the composition of extemporaneous powders and preparations;
5. to correctly dissolve excipients in various solvents;
6. to select excipients in the manufacture of heterogeneous liquid dosage forms in a pharmacy;
7. Mix different bases with medicinal substances in the manufacture of ointments in a pharmacy;
8. Prepare suppository bases and administer medicinal substances with different physical and chemical properties;
9. Select stabilisers, isotonicising agents in the manufacture of injectable and infusion solutions;
10. Introduce preservatives, prolongers, stabilisers, buffer solutions into sterile dosage forms;

11. to select excipients to ensure the required quality of solid medicines in industrial conditions;
12. to select excipients to ensure the required quality of liquid medicines in industrial conditions;
13. to select excipients to ensure the required quality of soft medicines in industrial conditions;
14. to evaluate and understand the possible interaction and safety of excipients in cosmetics;
15. use and rationally mix DRs in homeopathic remedies.

The student's independent work provides preparation for practical classes and intermediate tests,

study of topics for independent extracurricular work, writing essays, preparation of 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 on the topics provided for presentation at the meetings of the student scientific circle, the implementation of scientific and practical researches, participation in specialized competitions, scientific and practical conferences and organization of students' research works.

Thematic plans of lectures, calendar plans of practical classes, thematic plan of independent extracurricular work, 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.vnmu.edu.ua/кафедра-фармації#>.. Access to the materials is carried out through the student's corporate account s000XXX@vnmu.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 4th semester	Methods: <i>oral questioning</i> (according to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link https://www.vnmue.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.vnmue.edu.ua/General> information)

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 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 (link <https://www.vnmu.edu.ua/General> information).

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 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)/ 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) 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). 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. 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).

Training and methodological literature

1. Handbook of pharmaceutical excipients / Raymond C Rowe, Paul J Sheskey, Walter G Cook et al. – London: APhA/Pharmaceutical Press, 2020. – 917 c. – (7).

2. 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.

3. 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>

4. Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition, Six Volume Set (Print)/ James Swarbrick Taylor & Francis, 2013 4296 p.

5. Voigt's Pharmaceutical Technology Alfred Fahr, Gerrit L. Scherphof (Translator), Wiley, 2018. 888p.

6. Pharmaceutical Technology: A Practical Manual / Sushma Talegaonkar. - PharmaMed Press, 2019, 232 p.

7. Essentials of Pharmaceutical Technology/ Ajay Semalty, Mona Semalty, M. S. M Rawat. - PharmaMed Press, 2019.364 p. ISBN 9385433172

8. Handbook of Pharmaceutical Technology L. K. Ghosh CBS Publishers & Distributors, 2018 283 стор.ISBN 8123908504

9. Rees J. A. Introduction to pharmaceutical calculations / Judith A Rees; Ian Smith; Jennie Watson – [4-th edition]. – London and Chicago : Pharmaceutical Press, 2015., 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 "Excipients in pharmaceutical and cosmetic technology" was discussed and approved at the meeting of the department 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