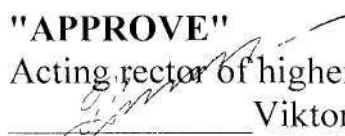


**National Pirogov Memorial Medical University, Vinnytsia**

**"APPROVE"**

Acting rector of higher education institution

 Viktoriia PETRUSHENKO

" 31 " 08 2023 year

**«AGREED»**

Head of the Department of Pharmacy

 Olena KRYVOVIAZ

" 31 " 08 2023 year

**SYLLABUS**  
of academic discipline

**OK 30 TECHNOLOGY OF DRUG: PHARMACY COMPOUNDING**

Specialty	226 Pharmacy, Industrial Pharmacy
Educational level	the second (master`s) level
Educational programme	<i>EPP «Pharmacy», 2022</i>
Academic year	2023-2024
Department	Pharmacy
Lecturer (if lectures are given)	Prof. of HEI Olena KRYVOVIAZ, Ass. Prof. of HEI Yulia TOMASHEVSKA, PhD, Ass. Prof. Hanna KRAMAR
Contact information	<i>pharmacy@vnmu.edu.ua</i>
Syllabus compiler	Ass. Prof. of HEI Yulia TOMASHEVSKA

### Status and structure of the discipline

Discipline status	Obligatory
Discipline code in EPP/ discipline place in EPP	OC 30 // professional training discipline
Course / semester	3 rd course (V–VI semester)
The amount of discipline ( the total number of hours / number of credits ECTS)	2 modules 210 hours /7,0 credits ECTS
Number of content modules	5 modules
The structure of the discipline	Lectures – 28 hours Practical classes - 108 hours Independent work – 74 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.** (What is the subject of study? What knowledge will the student acquire?)

The subject of the study of the academic discipline is the study of the academic discipline is the main provisions and trends in the development of pharmaceutical technology in the countries of the world and in Ukraine; assimilation of modern principles of regulatory documentation and production technologies of pharmaceuticals in various dosage forms with the use of new groups of excipients and modern types of equipment in pharmacy conditions.

Together with other pharmaceutical disciplines and social sciences, 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 carrying out professional activities with the aim of supplying the population and medical and preventive institutions with medicinal products. Also, the discipline forms practical skills regarding the main stages of the formation and development of the pharmaceutical industry and professional activity in Ukraine and abroad, general requirements for the manufacture of medicinal products.

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

- Your social and public rights and responsibilities.
- Methods of implementing knowledge in solving practical tasks.
- Modern trends in the development of the industry.
- Structure and features of professional activity.
- 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.** (*Knowledge of which disciplines is required for a higher education student to successfully master this discipline?*)

- The discipline is based on the study of physics and chemistry during secondary education, and also uses such curriculum disciplines as prerequisites:
- general and inorganic chemistry (knowledge of the physical and chemical properties of compounds, the structure of matter, concepts of aggregate state, solutions, concentration, etc.);
- physical and colloidal chemistry (basic knowledge of chemical thermodynamics, surface chemistry, structure and organization of the structure of molecules of high-molecular compounds, structure and properties of colloidal particles);
- biological physics with physical methods of analysis (knowledge of the basics of thermodynamics, mechanics, basic knowledge of solid state physics and materials science);
- introduction to pharmacy (main interdisciplinary interactions in pharmacy, concepts of drug technology and biopharmacy);
- biology with the basics of genetics (the concept of the cellular structure of living matter, basic knowledge of its chemical composition, knowledge of the differences in the structure of plant and animal cells);
- botany (notions of systematics, classification, histological structure and chemical composition of medicinal plants);
- theoretical foundations of the technology of dosage forms (knowledge of the classification of technological processes, biopharmaceutical factors affecting the effectiveness of drugs, the ability to determine the type of homo- and heterogeneous system, knowledge of the theoretical foundations of grinding and dissolving substances, stabilization and distribution of heterogeneous systems, extraction).

**The purpose of the course and its significance for professional activities:** assimilation by students of higher education of the theoretical foundations and practical abilities and skills of manufacturing medicines in the conditions of pharmacies, taking into account the requirements of proper pharmacy and production practices; rules for drawing up technological documentation for the manufacture of medicinal products, rules for storage and packaging; acquisition of knowledge on the characteristics, classification and assortment of extemporaneous medicinal forms; the formation of theoretical knowledge and professional skills among students of higher education by studying the influence of excipients on the quality of medicinal products, which makes it possible to more fully realize the scientific and creative potential of future specialists. Mastering the theory and practice of manufacturing dosage forms is necessary for a specialist to perform the duties of a specialist.

**Postrequisites.** (*How will it be needed in the process of further study and professional activity?*)

The discipline is the basis for the study of the disciplines: "Drug technology: Industrial drug technology", "Medicinal cosmetic technology", optional courses "Perfume and cosmetic products", passing propaedeutic practice in pharmacy drug technology, educational practice in drug technology, industrial practice in ATL, pharmaceutical biotechnology, quality systems in pharmacy. Topics related to the technology of extractive preparations are integrated with the pharmacognosy course, and topics studying the state regulation of the production (manufacturing) of medicinal products are integrated with the course "Standardization of medicinal products" and the specialization "Quality control of medicinal products". 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.** (*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 Initial: Technology of drug: Pharmacy compounding:*

- 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 2. Apply knowledge of general and professional disciplines in professional activities.

PLO 3. Adhere to the norms of sanitary and hygienic regime and safety requirements in carrying out 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. Carry out professional activities using reference literature, information technology, "Information Databases", navigation systems, Internet resources, software and other information and communication technologies.

PLO 12. Analyze the 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 products of the pharmacy range during their storage.

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

PLO 26. To choose rational technology, to make medicines in various medicinal forms according to prescriptions of doctors and orders of medical establishments, to issue them before

release. Perform technological operations: weigh, measure, dose a variety of drugs by weight, volume, etc. Develop and draw up technological regulations for the production (manufacture) of drugs in pharmacies.

PLO 30. Ensure quality control of medicinal products and document its results. To carry out quality risk management at all stages of the life cycle of medicinal products.

### 3. Content and logistics of the discipline

Module 1 "Technology of solid and liquid non-sterile dosage forms" Thematic modules 2.	5 semester 120 hours / 4,0 credits	Lectures № 8 Practical classes № 36 Extracurricular work № 9
Module 2 "Technology of soft dosage forms. Technology of sterile and aseptically made dosage forms" Thematic modules 3.	6 semester 90 hours / 3,0 credits	Lectures № 6 Practical classes № 18 Extracurricular work № 12

The course includes 34 topics, which are divided into 2 modules (5 thematic modules).

#### **Module 1. Technology of solid and liquid non-sterile dosage forms**

##### **Thematic module 1. Basic concepts of pharmacy compounding. Powders**

Topic 1. Basic concepts of pharmacy compounding. Containers and other materials which are used in pharmacy practice.

Topic 2. State setting of norms of pharmacy compounding.

Topic 3. Dosage in pharmacy compounding.

Topic 4. Compounding of simple and complex powders with the medicinal matters that differ by the prescribed amount and physical and chemical properties. Compounding of complex powders with volatile matters.

Topic 5. Compounding of complex powders with the poisonous and drastic matters. Triturations.

Topic 6. Compounding of complex powders with dyeing, hard-grinded matters, extracts, liquids and ready-to-cook mixtures. Embarrassing and incompatible prescription of powders.

Topic 7. Species.

##### **Thematic module 2. Liquid homogeneous non-sterile medicinal forms**

Topic 8. Compounding of the concentrated solutions for the buret system

Topic 9. Compounding of liquid medical forms by mass-volume method by dissolution of dry medicinal matters and using concentrated solutions.

Topic 10. Special cases of water solutions compounding. Compounding of liquid medical forms by breeding of standard pharmacopoeian liquids.

Topic 11. Compounding of non-aqueous solutions. Drops.

Topic 12. Solutions of high molecular medicines. Colloid solutions.

Topic 13. Suspensions.

Topic 14. Emulsions.

Topic 15. Infusions and decoctions from MPM, which contains strong and not strong effective.

Topic 16. Mucouses. Technology of water extractions with the use of extracts-concentrates. Embarrassing and incompatible prescription of liquid medical forms.

Topic 17. Liniments.

**Module 2. Soft dosage forms. Suppositories, pills. Aseptically made dosage forms. Difficult recipes. Pharmaceutical incompatibilities**

**Thematic module 3. Liniments. Ointments. Suppositories**

- Topic 1. Homogeneous ointments.
- Topic 2. Suspensive, emulsive and combined ointments. Author, pharmacopoeian, difficult compositions and incompatibilities in semi-solid medicinal forms.
- Topic 3. Features of ointment technology.
- Topic 4. Compounding of suppositories by rolling method
- Topic 5. Compounding of suppositories by casting method.
- Topic 6. Особливості технології супозиторіїв
- Topic 7. Pills

**Thematic module 4. Aseptic and sterile dosage forms**

- Topic 8. Organization of aseptic conditions in pharmacy. Solvents. Sterilization. Features of technology of termolabile and self-sterilizing matters. Suspensions for injections.
- Topic 9. Compounding of solutions for injections without stabilizers.
- Topic 10. Compounding of solutions for the injections with stabilizers.
- Topic 11. Compounding of isotonic solutions and infusion solutions.
- Topic 12. Eye medicinal forms.
- Topic 13. Medicinal forms with antibiotics.
- Topic 14. Medicinal forms for newborns and children under 1 year.

**Thematic module 5. Difficult prescriptions. Pharmaceutic incompatibilities**

- Topic 14. Difficult cases of medicinal forms compounding. Pharmaceutical incompatibilities.
- Topic 15. Medicinal preparations of special purpose

The topics of the lecture course reveal the problematic issues of the relevant sections of the discipline, in particular: regulatory requirements for pharmacy staff, composition of drugs, conditions and process of manufacturing drugs, as well as theoretical principles and practical features of technology and quality control of relevant drugs compounding in pharmacies. Methods of lectures: not taught in class, materials are posted on the department's information resources.

Practical classes according to the method of their organization can be:

*theoretically oriented*, involving:

- incoming test control of the applicant's knowledge on the topic of the lesson;
- discussion and systematization of lecture material, normative documents, material of basic and auxiliary literature;
- solving theoretical problems related to the topic of the lesson;
- solving situational tasks related to the peculiarities of manufacturing and quality control of medicines in the pharmacy: conducting pharmaceutical examination of prescriptions, calculations, selection of necessary equipment, active and auxiliary substances, packaging material and labels with theoretical justification;
- analysis of cases of compliance of descriptions of drug technology with the requirements of regulatory and technical documentation;
- initial control of knowledge using theoretical questions, situational and calculation problems, prescriptions;

*or practice-oriented*, involving:

- conducting a test entrance control of the readiness of higher education applicants to manufacture a certain type of dosage forms;
- discussion of step-by-step technology of prescription recipes related to the topic of practical training;

- production of medicines by applicants for higher education under the control of a teacher, their packaging and quality control or reproduction of certain technological stages of preparation of a medicine;
- teacher's examination of the quality of work performed by higher education students using an oral interview;
- carrying out initial control of assimilation of material with use of theoretical questions, situational and settlement problems, prescriptions.

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

- To determine the relationship between the development of drug technology and the general 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 release rates of narcotic drugs and similar substances.
- Prepare according to individual prescriptions solid, liquid, soft dosage forms (powders, solutions, potions, 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 written control passport.
- Choose the best technology and prepare a drug with a step-by-step quality assessment.
- Assess the quality of the prepared drug according to the NTD.
- Adhere to storage conditions and type of packaging in order 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.
- Detect prescriptions of frequently repeated drugs and carry out intra-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.
- Analyze professional information, make informed decisions, acquire modern knowledge.
- Carry out professional activities with continuous updating and integration of knowledge.

The independent work of higher education students involves preparation for practical classes and intermediate controls, studying topics for independent out-of-class work, writing essays, preparing presentations, tables. The control of mastering the topics of independent out-of-class work is carried out at intermediate control classes and final control in 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 / technology of drug: Pharmacy compounding / 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](mailto: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>
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 (credit) at the end of the V semester	According to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link <a href="https://www.vnmua.edu.ua/General">https://www.vnmua.edu.ua/General</a> information)
Final control of the discipline (exam) at the end of the VI semester	Methods: pre-examination testing, oral questioning (according to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link <a href="https://www.vnmua.edu.ua/General">https://www.vnmua.edu.ua/General</a> 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)

Continuous assessment	On a four point system of traditional assessments: 5 «excellent», 4 «good», 3 «satisfactory», 2 «unsatisfactory»
Midpoint separation assessment	On a five-point system of traditional assessments
Pass-fail exam	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)
Final control of the discipline	Exam grade: 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		
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 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.vnmdu.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).

The syllabus of the discipline "TECHNOLOGY OF DRUGS: PHARMACY COMPOUNDING" was discussed and approved at the meeting of the department Department of Pharmacy (record № 1, dated August "29" 2023)

Responsible for the academic discipline  Ass. Prof. of HEI Yulia TOMASHEVSKA  
(signature)

The Head of the Pharmacy Department  prof. of HEI Olena KRYVOVIAZ  
(signature)