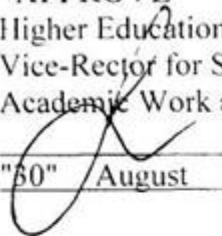


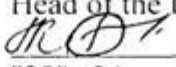
National Pirogov Memorial Medical University, Vinnytsia

"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

PRACTICE "INDUSTRIAL TECHNOLOGY OF PHARMACEUTICALS"

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)	Ass. Prof. of HEI Tetiana VOITENKO
Contact information	<i>pharmacy@vnmu.edu.ua</i>
Syllabus compiler	Ass. Prof. of HEI Tetiana VOITENKO

1. Status and structure of the discipline

Discipline status	Compulsory
Discipline code in EPP/ discipline place in EPP	SC 56 / discipline of professional training
Course / semester	5rd year (X semester)
The amount of discipline (the total number of hours / number of credits ECTS)	135 hours / 4,5 credits ECTS
Number of content modules	2 modules
The structure of the discipline	Lectures - _0_ hours Practical classes _0_ hours Independent work _135_ hours
Language of study	English
Form of study	Full-time, part-time (or distance according to the order)

2. Description of the discipline

Module volume: total number of hours – 135; lectures - 0, practical lessons - 0, independent work - 139, ECTS credits – 4,5.

"Practice Industrial technology of pharmaceuticals" refers to the cycle of the main disciplines of professionally-oriented training of specialists in the specialty "Pharmacy". The discipline "Practice Industrial technology of pharmaceuticals" is intended for applicants for higher education and provides theoretical knowledge and forms practical skills on the main stages of the formation and development of pharmaceutical technology in Ukraine, modern directions of development of the pharmaceutical industry and professional activity in Ukraine and abroad, general requirements for manufacturing of medicines of various pharmaceutical groups at industrial pharmaceutical enterprises.

Prerequisite - the discipline is based on the study of physics, general and inorganic chemistry, physical and colloidal chemistry, physiology, pharmacognosy, pharmacology; - the discipline is the basis for the study of medical and pharmaceutical commodity science, belonging to practices in pharmacy, pharmaceutical chemistry, management and marketing in pharmacy, biopharmacy, standardization of medicines, technology of medicinal cosmetics, provides for the integration of teaching with the above disciplines to form the skills to apply knowledge in the process of further training and professional activities;

Postrequisite (Postrequisite) - the discipline lays the foundations for professional training, contributes to the formation of pharmaceutical and technical thinking necessary for the implementation of professional activities;

Purpose of the course. The aim of studying the discipline "Practice in the industrial technology of pharmaceuticals" is the assimilation by applicants of higher education of the theoretical foundations and practical skills and abilities of manufacturing medicines at pharmaceutical enterprises, taking into account the requirements of good manufacturing practice; rules for drawing up technological documentation for the manufacture of medicines, rules for their storage and packaging; master the knowledge of characteristics, classification and range of finished dosage forms; the formation of applicants for higher education of theoretical knowledge and professional skills by studying the influence of excipients on the quality of drugs, 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 strapping of a specialist, it is provided for by legal procedural legislation and the corresponding order of the Ministry of Health of Ukraine.

3. Learning outcomes.

Integrative final program learning outcomes, the formation of which is facilitated by the initial theoretic bases of 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.

General competencies (GC):

GC01: Commitment to environmental protection.

GC02. Ability to abstract thinking, analysis and synthesis.

GC04. Ability to adapt and act in a new situation. Ability to take the initiative.

GC05: Ability to communicate in the state language both orally and in writing, ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity.

GC 06. Skills in the use of information and communication technologies.

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

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

GC10: Ability to exercise their rights and responsibilities as a member of society, to understand the values of civil (free democratic) society, and the need for its sustainable development, the rule of law, human and civil rights and freedoms in Ukraine.

GC11. The ability to preserve and enhance 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 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):

PC01: Ability to store, 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 03: Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and aesthetic responsibility.

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

PC 05. Ability to demonstrate and apply in practice communication skills, fundamental principles of pharmaceutical ethics and deontology. These are based on moral obligations and values, ethical standards of professional behaviour and responsibility in accordance with the Code of Ethics for Pharmacists of Ukraine and WHO guidelines.

PC 06: Ability to clearly and unambiguously communicate own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, including students.

PC 07. Ability to conduct health education among the population in order to prevent the spread of dangerous diseases, prevent dangerous infectious, viral and parasitic diseases, as well as to promote timely detection and support of adherence to treatment of these

diseases in accordance with their biomedical characteristics and microbiological characteristics.

PC11. Ability to ensure proper storage of medicines and other pharmacy products in accordance with their physical and chemical properties and the rules of Good Storage Practice (GSP) in healthcare facilities.

PC 19. Ability to organise and participate in the production of medicines in pharmaceutical enterprises, including the selection and justification of the technological process, equipment in accordance with the requirements of Good Manufacturing Practice (GMP), and the development and execution of the necessary documentation.

Program 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 04. Comply with the norms 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 06: To carry out professional communication in the state language, use oral communication skills in a foreign language, analysing professional texts and translating foreign language information sources.

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, and apply these results to solve typical and complex specialised tasks of professional activity, including the development and production of medicines.

PLO 10. To conduct sanitary and educational work in professional activities in the event of outbreaks of infectious, viral and parasitic diseases.

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 the rules of Good Storage Practice (GSP).

Translated with DeepL.com (free version)

4. Content and logistic of the discipline

Module 1 “General introduction to the pharmaceutical enterprise. Technology of manufacturing sterile, aseptically manufactured, extraction, solid, soft medicinal products and pharmaceutical solutions”	10 semester 135 hours / 4,5 credits	Lectures № Practical classes № Topics for self- study №18
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The course includes 18 topics, which are divided into 2 thematic modules.

Module 1 “ General introduction to the pharmaceutical enterprise. Technology of manufacturing sterile, aseptically manufactured, extraction, solid, soft medicinal products and pharmaceutical solutions”.

Thematic module №1: “General Introduction to the Pharmaceutical Enterprise. Manufacture of sterile and aseptically prepared products. Extraction preparations”.

Topic 1 General introduction to the pharmaceutical company. Guidance on safety and health regulations. Acquaintance with work of laboratory and departments CFL, QCD, guild laboratory. Quality control at pharmaceutical plants. Analytical equipment. Types of quality control in pharmaceutical companies. Scientific organisation of labour, work of central plant laboratories, technical control department, auxiliary workshops and services

Topic 2 Technology and equipment for the production of injectable drugs. Production of injection solutions in ampoules, syringes, vials. BFS technology (BLOW-FILL-STAL) - blowing - filling - sealing. Water for injection, requirements of the State Pharmacopoeia of Ukraine. Conditions of distillation, collection and storage of water for injection. Regulatory documents. Water distillers, design features. Demineralisation of water.

Topic 3 Industrial production of infusion medicines. The device and the principle of operation of devices, preparation, filtration of solutions, filling, sterilization. Organisation of production of solutions for injection. Regulatory documents. Methods of sterilisation. Equipment, principles of operation. Carpools - a modern dosage form. Innovative technologies for the production of sterile solutions in industrial conditions

Topic 4 Ophthalmic dosage forms. Tube - dropper production. Quality control of ophthalmic dosage forms. Prospects for the development of drugs for use in ophthalmology

Topic 5 Production of tinctures and extracts in pharmaceutical enterprises. (Methods of obtaining, equipment, quality control). Stages of the technological process and equipment for obtaining extraction preparations.

Topic 6 Getting ethyl alcohol. Raw materials for ethanol production. Varieties (brands) of ethyl alcohol, indicators of their quality. Ethanol recovery and rectification. Rectification installations.

Topic 7 Maximum purified preparations and preparations of individual substances. Methods for purification of biologically active substances. Technological stages for their production and standardization

Topic 8 Preparations of biogenic stimulants and preparations from fresh plant materials. Standardization of preparations of biogenic stimulants. Methods for obtaining juices from fresh plant materials. Production of medicinal confectionery based on finely ground plant materials.

Topic 9 Technology and use of essential oils. Methods of obtaining them. Determination of the quality of essential oils and their storage.

Content module 2 “Production of solid, soft drugs, pharmaceutical solutions. Packing and packaging of finished products. ”

Topic 10 Medicines in gelatin capsules. Manufacture of gelatin capsules. Capsule filling machines. Encapsulation methods. Effervescent tablets. Pellets. Caplets. Production technology. Equipment. Nomenclature.

Topic 11 Manufacturing of solid medicines (production methods, equipment, quality control). Types of packaging materials and types of machines for filling tablets in different containers. Industrial production of chewable tablets

Topic 12 Industrial preparation of suspensions and emulsions. Evaluation of mixing efficiency. Standardization of suspensions and emulsions

Topic 13 Production of pharmaceutical solutions. (Methods of obtaining, equipment, quality control). Stages of preparation of liquid medicines, nomenclature of aqueous and alcoholic solutions, aromatic waters. Filling and sealing equipment for liquid medicines. Active pharmaceutical ingredients and excipients in drug technology.

Topic 14 Industrial production of syrups. Raw materials and technological stages of production of medicinal and flavoring syrups. Equipment for packaging syrups.

Topic 15 Manufacture of soft drugs (production methods, equipment, quality control). Stages of the technological process and equipment for the preparation of homogeneous and heterogeneous soft drugs. Production of plasters, TTS. Characteristics, classification. Stages of the technological process. Equipment. Quality control. Technology of gels. Production of a jelly dosage form for internal use

Topic 16 Industrial production of rectal and vaginal dosage forms, preparation of bases and other basic materials, introduction of medicinal substances into suppository bases; technological schemes for the preparation of suppositories; equipment, packaging.

Topic 17 Gaseous dosage forms. Production of medical gases, requirements. Aerosol production technology, quality requirements. Sprays technology of their production. Inhalation methods of administration of medicinal substances.

Topic 18 Packing and packaging of finished products, organisation of the production flow, the range of containers and packaging materials. Filling and packaging of solid, soft, liquid dosage forms, construction and maintenance of filling machines of various types.

Mastering the discipline involves theoretical substantiation of the main issues of the topic and the acquisition of the following practical skills:

- 1) Conduct stage-by-stage control of medicinal products;
- 2) Justify the technology and organise the production of medicines at pharmaceutical enterprises using the necessary equipment;
- 3) Estimate losses and yield of the finished product, draw up a material balance and technological scheme for the production of medicines in industrial conditions;
- 4) Determine the impact of environmental factors on the stability of medicinal products and medical devices;
- 5) To be able to reasonably select the necessary excipients for the composition of medicinal products under development;
- 6) Evaluate the quality control of finished products in accordance with the current regulatory documents and the State Pharmacopoeia of Ukraine.

The independent work of a higher education student involves the preparation of diary, solving individual, situational and test tasks. The control of mastering the topics is carried out at the final control of the discipline.

Individual work includes the study of scientific literature, preparation of reviews on the topics provided for presentation at meetings of the student research club, performing scientific and practical research, participating in specialised olympiads, scientific and practical conferences, competitions of student scientific works.

The route for obtaining materials: Department of Pharmacy / for students / Full-time education / Pharmacy, industrial pharmacy / 4 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.

5. 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)	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

6. 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»
Final control of the discipline	<i>Sum of points for pre-examination testing (12-20 points) and oral questioning (38-60 points) (for disciplines included in Step 1,2)</i> 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	satisfactory	
122-140,99	E	satisfactory	
119-61	FX	unsatisfactory with the possibility of reassembly	is not credited with the possibility of reassembling
1-60	F	unsatisfactory with a mandatory reexamination of discipline	is not credited with mandatory reexamination of discipline

7. 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. Applicant for higher education who has not been instructed is not allowed to practical class. In case of announcement of the "Air Alert" signal or other warning signals, the teacher stops classes, informs higher education students about the need to go to a civil defence shelter and stay there until the signal is cancelled. The teacher informs the students about further actions after the signal is cancelled: to continue the class or to recommend to revise the material on their own with a subsequent survey at the next lesson (Order No. 505 of 30.08.2023).

Requirements for preparation for practical classes. Applicant for higher education should be present at the practical lesson on time, theoretically prepared according to the topic. Applicant for higher education should come to class on time, without lateness. Applicant for higher education who is late is not allowed to study and must rework it in the prescribed manner.

In practical classes, the applicant for higher education must be dressed in a work uniform. Applicants for higher education who do not have a work uniform are not allowed to study.

The applicant for higher education 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 cleaned after the 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).

Academic integrity. During the study of the discipline the Applicants for higher education must be guided by the Code of Academic Integrity of VNMU named after MI Pirogov. In case of violation of the norms of academic integrity during the current and final controls, the Applicants for higher education receives a grade of "2" and must work it in the prescribed manner for two weeks.

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 (published on the website of the department <https://www.vnmu.edu.ua/> department of pharmacy #) 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 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 (link <https://www.vnmu.edu.ua/General> information).

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. If the issue is not resolved, the student has the right to apply to the head of the department according to Complaints Consideration Procedure in VNMU named after M.I. Pirogov (link <https://www.vnmu.edu.ua/General> information)

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. (<https://www.vnmu.edu.ua/General> information). The main training platforms for studying are Microsoft Team and Google Meets. Practical classes and lectures, exercises and consultations during distance learning is published on the website of the department (<https://www.vnmu.edu.ua/> Department of of pharmacy / to Students or <https://www.vnmu.edu.ua/Department of Microbiology / News>).

Feedback from the teacher is provided through the distance learning platform (Microsoft Teams), messengers or e-mail (at the teacher's discretion) during working hours.

Higher education students 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 mastering practical skills. The department's policy in providing educational services is student-centred, based on the regulations of the Ministry of Education and the Ministry of Health of Ukraine, the university's charter and the procedure for providing educational services, regulated by the main provisions of the educational process at the Pirogov National Medical University and the principles of academic integrity.

8. Educational resources

The educational and methodological support of the discipline is published on the website of the department ([https:// www.vnmua.edu.ua/](https://www.vnmua.edu.ua/) department ____pharmacy____/ Student). Consultations are held twice a week according to the consultation schedule.

9. **The schedule and distribution of groups by teachers** is published on the website of the department ([https:// www.vnmua.edu.ua/](https://www.vnmua.edu.ua/) department ____pharmacy____/ Student).

10. **Questions for intermediate and final controls of the discipline** are published on the website of the department (<https://www.vnmua.edu.ua/> department ____pharmacy____/ Student).

Recommended literature

1. The practical course on Industrial Technology of Medicines for students of specialty "Pharmacy"/ Ed. By Doctor of Pharmacy, professor Ruban H.A. - Kharkov: NUPh, 2013.- 298p.
2. Industrial Drug Technology: Tutorial for laboratory classes for students of specialty "Pharmacy"/ Yu.V. Yudina, Yu V. Shmyrova, S.V. Stepanenko, Ie.V. Gladukh, V.I. Chyieshov, A.A. Sichkar, Ye.A. Bezrukaviiy, O.S. Kukhtenko. - Kharkov: NUPh: Original, 2012.- 254p.
3. The Theory and Practical Book of Industrial Pharmacy - I / Ketan B. Patil, Paresh A. Patil, Sandip S. Kshirsagar, Narendra B. Patil. 2020. – 207p.
4. Textbook of industrial pharmacy II / Mrs. Shweta S. Gedam, Shivraj P. Jadhav, Eknath D. Ahire. - Pritam Publications, 2022.- 202p.
5. A Textbook of Industrial Pharmacy I / Dr. Prashant Pingale.- Everest Publishing House, 2022.-485p.
6. Industrial pharmacy - II Dr. Ashok A. Hajare.- Nirali Prakashan, 2022.-281p.

The syllabus of the discipline "Practice Industrial technology of pharmaceuticals" was discussed and approved at the meeting of the department pharmacy (record № 1_, dated "_30_"_08_2024)

Responsible for the academic discipline


(signature)

Ass. prof. of HEI Tetiana VOITENKO

Head of the department


(signature)

Prof. of HEI Olena KRYVOVIAZ