

National Pirogov Memorial Medical University, Vinnytsia

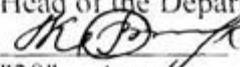
"APPROVE"

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


"30" August 2024 year

SYLLABUS
of academic discipline

DRUG TECHNOLOGY: ITD

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 32 / discipline of general training or professional training
Course / semester	4 th year (VII - VIII semester)
The amount of discipline (the total number of hours / number of credits ECTS)	180 hours / 6 credits ECTS
Number of content modules	5 modules
The structure of the discipline	Lectures - _20_ hours Practical classes __76_ hours Independent work _84__ hours
Language of study	English
Form of study	Full - time, part-time, (or distance according to the order)

2. Description of the discipline

Short annotation of the course, relevance.

Drug technology as an academic discipline plays an important role in the professional training of pharmacists and lays the foundations for the theoretical and practical manufacture of drugs in the conditions of pharmaceutical enterprises.

"Drug Technology: ITD " refers to the cycle of the main disciplines of professionally oriented training of specialists in the specialty "Pharmacy, industrial pharmacy".

The discipline program "Drug Technology:ITD" is intended for applicants for higher education, 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 activities in Ukraine and abroad, general requirements for manufacturing medicines of various pharmaceutical groups at industrial pharmaceutical enterprises.

Prerequisite - the discipline "Drug Technology:ITD" is based on the study of such subjects as physics, general and inorganic chemistry, physical and colloidal chemistry, physiology, pharmacognosy, pharmacology;

The purpose of the course and its significance for professional activities

The purpose of studying the discipline "Technology of drugs: ITD" 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; the rules for the preparation of technological documentation for the manufacture of medicines, the 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, provided for by legal procedural legislation and the relevant order of the Ministry of Health of Ukraine.

Postrequisites (Postrequisite) -discipline "Drug Technology: ITD" 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 drugs, technology of medicinal cosmetics, provides for the integration of teaching with the above-mentioned disciplines on the formation of skills to apply knowledge in the process of further education and in professional activity.

3. Learning outcomes.

Competences and learning outcomes that the discipline contributes to:

Integral

Ability to solve problems and comprehend and solve practical problems of research and / or innovation in the field of pharmacy.

General

GC01. Commitment to environmental protection.

GC02. Ability to abstract thinking, analysis and synthesis.

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

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.

Special (professional)

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 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 health care facilities.

PC 16. Ability to develop and implement a quality management system of pharmaceutical enterprises in accordance with the requirements of current Standards, to conduct quality audit and risk management for the quality of pharmaceutical products.

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

Learning outcome

Integrative final programme learning outcomes, the formation of which is facilitated by 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 06. 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 problems

professional activities, 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).

PLO 23. Carry out pharmaceutical development, substantiate the technology and organise the production of medicinal products at pharmaceutical enterprises and draw up technological documentation for the production of medicinal products at pharmaceutical enterprises.

4. Content and logistic of the discipline

Module 1 “Material balance. Manufacturing technology of extraction, aseptically prepared preparations and aerosol systems”.	7 semester 90 hours / 3,0 credits	Lectures № 20 Practical classes № 40 Topics for self- study №30
Module 2 “Technology of solid, soft drugs. Pharmaceutical solutions”	8 semester 90 hours / 3,0 credits	Practical classes № 36 Topics for self- study №54

The course includes 38 topics, which are divided into 2 thematic modules.

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

Module 1. Material balance. Manufacturing technology of extraction, aseptically prepared preparations and aerosol systems.

Thematic module 1. Normative technical documentation in the manufacture and packaging of pharmaceuticals according to GMP. Material balance.	
1.	Regulatory documentation for the production of finished products in pharmaceutical enterprises.
2.	Drawing up a material balance at the stages of the technological process».
3.	Determination of the main indicators of ampoule glass quality.
4.	Solvents for injectable drugs and methods for their obtaining. Equipment.
5.	Production of solutions for injections from thermoplastic substances.
6.	Production of injectable solutions that require stabilization.
7.	Production of infusion solutions. Freeze-dried preparations for parenteral use.
8.	Solutions for injections on non-aqueous solvents. Emulsions for parenteral use.
9.	Production of eye nasal and ear medical forms.
10.	Final lesson of the thematic module №1 «Drawing up a material balance at the stages of the technological process. Medicines for parenteral use. Eye products ».
Thematic module 2. Production of extractive drugs.	
11.	Production of tinctures at pharmaceutical companies. Trial. Recovery and rectification of ethanol at pharmaceutical companies. Equipment.
12.	Production of liquid extracts at pharmaceutical enterprises. Equipment. Testing.
13.	Production of dense and dry extracts at pharmaceutical enterprises. Testing.
14.	Production of oil extracts. Extract concentrates. Standardization.
15.	Production of maximally purified (novogalenovyh) preparations. Preparations of individual substances.
16.	Production of biogenic stimulants. Medicinal products from animal raw materials.
17.	Manufacture of drugs under pressure. Equipment. Trial.
18.	Production of nano- and radiopharmaceuticals.

19.	Final lesson of the thematic module №3 "Production of extractive drugs".
20.	Final lesson of module №2. Credit.
Module 2. Technology of solid, soft drugs. Pharmaceutical solutions	
Thematic module №3: "Solid Medicines"	
21.	Physico-chemical and technological properties of powders and granules.
22.	Grinding. Screening. Mix. The principles of machines and apparatus.
23.	Production of tablets by direct compression. Quality control.
24.	Production of tablets with the previous granulation.
25.	Effervescent tablets. Caplets. Pellets. Quality control.
26.	Industrial production of coated tablets. Quality control.
27.	Production of medical capsules. Equipment. Testing. Microcapsules.
28.	Final lesson of the thematic module №3: "Solid Medicines"
Thematic module №4: "Liquid Medicines "	
29.	Production of aqueous solutions in industrial conditions.
30.	Production of syrups, fragrant waters and essential oils.
31.	Production of non-aqueous solutions in industrial conditions.
32.	Industrial production of emulsions and suspensions.
33.	Final lesson of the thematic module №4 "Liquid Medicines".
Thematic module №5: Manufacture of soft medicines. Production of medicinal products for rectal and vaginal use. Pressure drugs.	
34.	Production of soft dosage forms. Structural - mechanical (rheological) properties of ointments. Equipment. Quality indicators of soft dosage forms. Industrial production of suppositories. Quality control.
35.	Production of patches and transdermal therapeutic systems (TTS). Quality indicators.
36.	Industrial production of suppositories. Equipment. Quality control.
37.	Final lesson of the thematic module №5 " Manufacture of soft medicines. Production of medicinal products for rectal and vaginal use. Pressure drugs "
38.	Final lesson of module №2

The *independent work* of a higher education student involves preparation for practical classes and intermediate controls, studying topics for independent out-of-class work, writing abstracts, preparation of presentations, tables. The control of mastering the topics of independent out-of-class work is carried out at intermediate control classes and the final control in the discipline.

**Independent work
VII semester**

No	Theme	Duration
Module 1 "Production of parenteral drugs and extractive drugs in industrial conditions"		
1	Preparation for practical training. Theoretical preparation and practical skills development	10
Development of topics that are not included in the classroom plan.		
2	Thermal processes in pharmaceutical production. Heating. Evaporation. Drying. Equipment	2
3	GMP requirements based on the provision for parenteral drug production at pharmaceutical companies	2
4	Requirements of isotonium, isohydry, isoionium, redox potential of solutions.	2
5	New types of packaging and sealing materials for sterile, solid, liquid medicines, irrigation solution packages, pre-filled syringes.	2
6	Raw materials and methods for ethanol production. Equipment. Requirements for medical alcohol.	2
7	Quality control of medicines. State quality control and certification of medicines.	2
8	Production of enzyme preparations based on microbiological synthesis methods.	2
9	Problems and tasks of production of phytochemicals and prospects for their development.	2
10	Ways to improve the technology of dosage forms for ophthalmology and otolaryngology.	2
11	Preparation for the final lesson of module 1.	2
Total		30

**Independent work
VIII semester**

No	Theme	Duration
Module 2 "Technology for the manufacture of solid, liquid, soft drugs in the pharmaceutical industry."		
1	Preparation for practical training. Theoretical preparation and practical skills development	10
Development of topics that are not included in the classroom plan.		
2	Pharmaceutical and medical and biological aspects of drugs of different types of disperse system.	2
3	Use of nanotechnology in the manufacture of drugs.	2
4	Medicines for children. Features of the technology. Methods for evaluating corrective substances.	2
5	Structural-mechanical properties of ointments.	2
6	Age medicines. Topical Issues and Prospects for the Development of Age-based Drugs in Ukraine	2
7	New solid dosage forms. Pellets Caps Eyebrow pills	2
8	Problems of drug development and new pharmaceutical technologies.	2
9	Achievement of pharmaceutical technology in the field of creating new drugs.	2
10	Improved production of prolonged action capsules.	2
11	The main directions of improving the technology of rectal agents.	2
12	Innovative aerosol production technologies.	2
13	Auxiliary substances in the manufacture of soft dosage forms.	4
14	Innovative technologies of suspensions and emulsions in industrial conditions.	4
15	Technology and equipment for the production of liquid medicinal products.	4
16	Preparation for the final lesson of module 1.	10
Total		54

The main objectives of the study "Technology of drugs:ITD" is the formation of students' professional thinking and assimilation of the main aspects of the production of various dosage forms in industrial production at pharmaceutical enterprises. According to the curriculum, the study of the discipline "Drug Technology:ITD" is carried out in the 4th year of study and includes lectures and practical exercises related to the technology of manufacturing the main types of dosage forms in industrial production.

The lectures on the discipline "Drug Technology: ITD" cover the issues of technological aspects of the classification of dosage forms, production features and rational choice of technology for non-sterile, sterile and aseptically manufactured drugs with different dispersion media, their dosage, choice of packaging and stepwise quality control.

The types of training sessions according to the curriculum are lectures, practical exercises, independent work of students.

Practical lessons on the methodology of their organization can be: theoretically oriented, which include:

- entrance test control of the student's knowledge on the topic of the lesson;
- discussion and systematization of lecture material, normative documents, material of the main and auxiliary literature;
- solving theoretical problems related to the topic of the lesson;
- solving situational problems concerning the peculiarities of manufacturing and quality control of medicinal products: selection of the optimal dosage form, counting the amount of active and auxiliary substances, selection of the necessary equipment, packaging;
- conducting final control of knowledge using theoretical questions, situational and calculation tasks;
 - or practically-oriented, providing:
 - conducting a test entrance control of students' readiness to manufacture a certain type of dosage forms;
 - discussion of the Step-by-step technology of a certain dosage form, concerning the topic of the practical lesson;
 - production of medicines by students under the supervision of a teacher, their packaging and quality control or reproduction of certain technological stages of manufacturing a certain dosage form;
 - check by the teacher of the quality of work performed by students using oral questioning;
 - carrying out the final control of the assimilation of the material using theoretical questions, situational and design tasks.

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 / 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) at the end of the VII semester	According to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link https://www.vnmu.edu.ua/General information)
Final control of the discipline (exam)	Methods: pre-examination testing, oral questioning (according to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link https://www.vnmu.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.vnmu.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 four-point system of traditional assessments
Control of practical skills	According to the four-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: 120 to 200 points Not credited: less than 120 points (See Grading Scale)
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.vnmue.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.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).

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 M.I. 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://](https://www.vnmu.edu.ua/) <https://www.vnmu.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://](https://www.vnmu.edu.ua/) <https://www.vnmu.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.vnmu.edu.ua/> department ___pharmacy_____/ Student).

Recommended literature

1. The practical course on Industrial Technology of Medicines for students of speciality "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 speciality "Pharmacy"/ Yu.V. Yudina, Yu V. Shmyrova, S.V. Stepanenko, Ie.V. Gladukh, V.I. Chyieshov, A.A. Sichkar, Ye.A. Bezrukaviy, 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, Shiyraj 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 "Drug Technology: IID " was discussed and approved at the meeting of the department pharmacy (record № 1 , dated " 30 " 08 2024)

Responsible for the academic
discipline

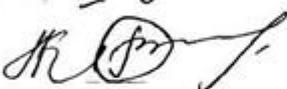
(signature)



Ass. prof. of HEI Tetiana VOITENKO

Head of the department

(signature)



Prof. of HEI Olena KRYVOVIAZ