

National Pirogov Memorial Medical University, Vinnytsia

"APPROVE"

Higher Educational Institution
Vice-Rector for Scientific and
Academic Work and International Links

Inna ANDRU'SHIKO

"30" August 2024 year

«AGREED»

Head of the Department of Pharmacy

[Signature] Olena KRYVOVIAZ

"30" August 2024 year

SYLLABUS
of academic discipline

PHARMACEUTICAL BIOTECHNOLOGY

Specialty	226 Pharmacy, Industrial Pharmacy
Specialization	226.01 Pharmacy
Educational level	the second (master's) level
Educational programme	<i>FPP «Pharmacy», 2023</i>
Academic year	2024-2025
Department	Pharmacy
Lecturer (if lectures are given)	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 41 / discipline of general training or professional training
Course / semester	5th year (X semester)
The amount of discipline (the total number of hours / number of credits ECTS)	45 hours / 1,5 credits ECTS
Number of content modules	1 module
The structure of the discipline	Lectures - _10_ hours Practical classes __20_ hours Independent work _15__ 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.

Pharmaceutical biotechnology 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 using biotechnological methods in the conditions of pharmaceutical enterprises.

Prerequisite- the discipline is based on the study of biology, microbiology, physics, general and inorganic chemistry, physical and colloidal chemistry, biochemistry, physiology, pharmacognosy, pharmacology, drug technology;

The purpose of the course and its significance for professional activities

Teaching the discipline "Pharmaceutical biotechnology" is the assimilation by applicants of higher education of the theoretical foundations, practical skills and abilities of the basics of manufacturing medicines of various dosage forms at pharmaceutical enterprises using biotechnological methods and 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; familiarization of applicants for education with new achievements in the field of genetic engineering, cell engineering, culture of isolated cells and tissues, production of antibiotics and probiotics, enzyme preparations, vaccines and sera. 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 corresponding order of the Ministry of Health of Ukraine.

Postrequisites – is - the discipline lays the foundations for professional training, contributes to the formation of pharmaceutical and technical thinking necessary for the implementation of professional activities;

3. Learning outcomes.

GC 2. Ability to apply knowledge in practical situations.

GC 4. Ability to abstract thinking, analysis and synthesis, to learn and be modernly trained.

GC 6. Knowledge and understanding of the subject area and understanding of professional activity.

GC 7. Ability to adapt and act in a new situation.

GC 11. Ability to assess and ensure the quality of work performed.

- *special (professional, subject):*

PC 2. Ability to integrate knowledge and solve complex problems of pharmacy in broad or multidisciplinary contexts.

PC 4. Ability to use in professional activities knowledge of regulatory and legal acts of Ukraine and recommendations of good pharmaceutical practices.

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.

Integrative final program learning outcomes, the formation of which is facilitated by the academic discipline:

PLO 1. - Apply specialised knowledge and skills in general and specialised disciplines in professional activities.

PLO 2. - Critically comprehend scientific and applied problems in the field of pharmacy.

PLO 3. - Evaluate and ensure the quality and effectiveness of activities in the field of pharmacy.

PLO 5. - Plan and implement professional activities on the basis of regulatory legal acts of Ukraine and recommendations of good pharmaceutical practices.

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

4. Content and logistic of the discipline

Module 1 "Biotechnology in the pharmaceutical industry"	10 semester 45 hours / 1.5 credits	Lectures № 10 Practical classes № 20 Topics for self- study №15
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The course includes 9 topics, which are divided into 1 thematic modules.

Module 1 "Biotechnology in the pharmaceutical industry"

1.	Requirements for the production and quality control of biotechnological products
2.	Biotechnological bases of antibiotic production.
3.	Basics of biotechnological production of probiotic preparations.
4.	Biotechnological bases for the production of enzyme preparations. Immobilized enzymes.
5.	The basics of biotechnological production of vitamins and coenzymes.
6.	Biotechnological methods of obtaining preparations of amino acids
7.	Technology of immunobiological preparations. Technology of antiviral vaccines and immune sera.
8.	The use of biotechnological methods in the production of hormone preparations.
9.	Technology of nanopreparations. Liposomal forms of drugs.

The subject of the study is the main provisions and trends in the development of pharmaceutical biotechnology in Ukraine and other countries of the world; assimilation of modern principles of regulatory documentation and technologies for the production of medicines in various dosage forms using biotechnological methods and modern types of equipment in an industrial environment..

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
- 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.vnmdu.edu.ua/кафедра-фармації#..> Access to the materials is carried out through the student's corporate account s000XXX@vnmdu.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.vnmdu.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.vnmdu.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.vnmdu.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	
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

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.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).

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.vnmdu.edu.ua/General> information) at the time of work out schedule (published on the website of the department <https://www.vnmdu.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.vnmdu.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.vnmdu.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.vnmdu.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.vnmdu.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.vnmdu.edu.ua/> Department of of pharmacy / to Students or <https://www.vnmdu.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.vnmdu.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.vnmdu.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.vnmdu.edu.ua/_____/department_pharmacy_____/Student).

Recommended literature

Basic

1. | Pharmaceutical Biotechnology by Rahul Dev, Rehan Uddin, Mukesh Kumar Pathak – IP Innovative Publication Pvt Ltd., 2021 – 136 p.
2. Pharmaceutical Biotechnology Fundamentals and Applications Daan J. A. Crommelin, Robert D. Sindelar, Bernd Meibohm – Springer Nature Switzerland AG, 2019 – 661p.
3. Pharmaceutical Biotechnology by Chandrakant Kokare – Nirali Prakashan, 2019 – 274p.

Supplementary

1. Pharmaceutical Biotechnology, Drug Discovery and Clinical Applications. Edited by O. Kayser and R.H. Muller. " Copyright 2004 Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim. ISBN: 3-527-30554-8
2. Textbook of Pharmaceutical Biotechnology /by Chandrakant Kokate and Ss Jalalpure – Publisher Elsevier India: 1/1: edition, 2016.
3. Pharmaceutical Biotechnology by Michael J. Groves – Taylor & Francis 2 edition, 2005 – 428p.
4. Pharmaceutical Biotechnology in Drug Development by Kanwal Irshad, Kanwal Rehman, Muhammad Sajid Hamid Akash, Shuqing Chen – Elsevier, 2023 – 236p.

The syllabus of the discipline "Pharmaceutical biotechnology" 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