**NATIONAL PIROGOV MEMORIAL MEDICAL UNIVERSITY, VINNYTSIA**

**COURSE SYLLABUS**

**For the training of master's students**

**PHARMACEUTICAL BIOTECHNOLOGY**

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|---|---|
| **Specialty** | 226 Pharmacy, Industrial Pharmacy |
| **Specialization** | 226.01 Pharmacy |
| **Educational Programme** | *EPP «Pharmacy», 2023* |
| **Higher Education Level** | the second (master`s) level |
| **Academic year** | 2026-2027 |
| **Status of the Discipline** | Mandatory |
| **Language of Instruction** | Ukrainian / English |
| **Total Workload** | 1,5 of ECTS credits |
| **Year of Study / Semester** | V/10 (full-time)<br>IV/8 (part-time) |
| **Developer** | Assoc. Prof., PhD Tetiana VOITENKO |
| **Instructor** | Assoc. Prof., PhD Tetiana VOITENKO<br>Assoc. Prof., PhD Alona VORONKINA |
| **Venue and Contact Details** | Department of Pharmacy, Vinnytsia, 56 Pirogov Street, tel. 55 39 52 *pharmacy@vnmu.edu.ua* |

## 1. DESCRIPTION OF THE ACADEMIC DISCIPLINE

### ABSTRACT

**Brief course overview and 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;

### PURPOSE AND OBJECTIVES

**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.

Competencies and learning outcomes fostered by the course/

**Integral competence (IC):** The ability to solve problems and to analyse and resolve practical issues of a research and/or innovative nature in the field of pharmacy.

**General competencies (GC):**

- GC 2. Ability to think abstractly, analyse and synthesise.
- GC 3. Knowledge and understanding of the subject area and professional activities.
- GC 5. Ability to communicate in the state language, both orally and in writing, and to communicate in a foreign language (primarily English) at a level that enables effective professional practice.
- GC 7. Ability to choose a communication strategy, work in a team and collaborate with experts from other fields of knowledge and sectors of economic activity.

**Special (professional/subject-specific) competencies (PC):**

- PC 02. Ability to integrate knowledge and solve complex problems in pharmacy in broad or multidisciplinary contexts.
- PC 04. Ability to apply knowledge of the regulatory and legislative acts of Ukraine and recommendations on good pharmaceutical practices in professional activities.
- PC 19. Ability to organise and participate in the manufacture of medicinal products at pharmaceutical enterprises, including selecting and justifying the manufacturing process and equipment in accordance with Good Manufacturing Practice (GMP) requirements, and preparing and completing the required documentation.

**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;

## 2. LEARNING OUTCOMES

**Integrative final programme learning outcomes fostered by the course:**

- 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.

## 3. FORMS OF ORGANISATION OF THE EDUCATIONAL PROCESS AND THEIR SCOPE

| Type of Learning Activity | Hours | |
|---|---|---|
| | Full-time | Part-time |
| Lectures: | 10 | 4 |
| Practical Classes: | 20 | 8 |
| Independent Study: | 15 | 33 |
| **Total** | 45 | 45 |

## 4. THEMATIC PLAN

| № | Module and Topic Titles |
|---|---|
| | **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. |

## 5. FORMS AND METHODS OF ASSESSMENT OF LEARNING OUTCOMES

| | |
|---|---|
| **Ongoing Assessment during Practical Classes** | Methods: oral and/or written assessment and testing, computer-based assessment and testing, completion of situational tasks. |
| *Final Assessment of the Academic Discipline – **Graded Pass Assessment Tools for Learning Achievement** | It is conducted during the final practical class and is assessed in accordance with the Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsia: General Information / Key Documents https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf) |
| | Theoretical questions, tests, clinically oriented situational tasks, practical assignments, demonstration of practical skills. |

## 6. ASSESSMENT CRITERIA

Assessment of students' knowledge is carried out in accordance with the current Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsia**.**

(https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf)

| Type of Assessment | Assessment Criteria / Scale |
|---|---|
| Ongoing Assessment | According to the traditional grading scale: 5 – "Excellent", 4 – "Good", 3 – "Satisfactory", 2 – "Unsatisfactory" |
| Interim Assessments | According to the traditional grading scale |
| Assessment of Practical Skills | According to the traditional grading scale |
| Final Grade of the Academic Discipline | Grade for differential credit:<br>71–80 points – "Excellent";<br>61–70 points – "Good";<br>50–60 points – "Satisfactory";<br>fewer than 50 points – "Unsatisfactory" / Failed. |
| Overall Assessment for the Academic Discipline | Ongoing academic performance – 72–120 points (conversion of the average traditional grade for practical classes to the 120-point scale): 60% of the final grade for the academic discipline. Final Assessment – 50–80 points: 40% of the final grade for the academic discipline. Individual Assignments– 1–12 points. Total: 122–200 points. |

## GRADING SCALE: NATIONAL AND ECTS

| **Total Score for All Learning Activities** | **ECTS Grade** | **National Grade: Examination, Course Project (Paper), Practical Training** | **National Grade: Pass** |
|---|---|---|---|
| **180–200** | **A** | Excellent | Passed |
| **170–179.99** | **B** | Good | Passed |
| **160–169.99** | **C** | Good | Passed |
| **141–159.99** | **D** | Satisfactory | Passed |
| **122–140.99** | **E** | Satisfactory | Passed |
| **60–121.99** | **FX** | Unsatisfactory, with the possibility of retaking | Failed, with the possibility of retaking |
| **0–59.99** | **F** | Unsatisfactory, with mandatory repetition of the discipline | Failed, with mandatory repetition of the discipline |

**Criteria for Assessing Students' Knowledge**

***Assessment of Oral/Written Responses during Ongoing Assessment***

**The grade "Excellent"** is awarded when a student demonstrates comprehensive knowledge of the topic, illustrating responses with a variety of relevant examples; provides complete, accurate, and clear answers without prompting or leading questions; presents the material without errors or inaccuracies; confidently solves problems and completes practical tasks of varying levels of complexity; and independently generates innovative ideas.

**The grade "Good"** is awarded when a student demonstrates good knowledge and understanding of the topic and provides correct, coherent, and well-structured answers, although they may not be fully comprehensive. The student answers additional questions correctly and without significant errors; successfully solves problems and completes practical tasks, experiencing difficulties only with the most complex assignments.

**The grade "Satisfactory"** is awarded when a student demonstrates knowledge of the overall content of the topic and a satisfactory level of understanding. With the help of guiding questions, the student is able to solve modified (simplified) problems; solves problems and completes practical tasks, although experiencing difficulties even with relatively simple assignments; is unable to formulate a coherent and systematic response independently but provides correct answers to direct questions.

**The grade "Unsatisfactory"** is awarded when a student's knowledge and skills do not meet the requirements for the grade "Satisfactory".

The assessment criteria for all other types of students' academic work are based on the requirements of the Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya,

(https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf) and are specified in the programme of the academic discipline.

**Assessment of Students' Independent Study**

Students' independent study undertaken as part of a topic alongside contact hours is assessed as part of the ongoing assessment of that topic during the relevant practical class.

The maximum number of points a student may receive upon completion of the discipline is 200 points. The minimum passing score is 122 points.

## 7. METHODOLOGICAL SUPPORT

Teaching and learning materials (lecture notes or extended lecture outlines), thematic plans for lectures, practical classes and independent study, assignments for ongoing assessment, methodological guidelines, and teaching manuals.

## 8. ACADEMIC DISCIPLINE POLICIES

The completion of learning activities and all academic work within the discipline must comply with the requirements of the Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya**;** (https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf), the Regulations on the Organisation of the Educational Process for Higher Education Students Pursuing the Degree of Doctor of Philosophy at National Pirogov Memorial Medical University, Vinnytsya (https://www.vnmu.edu.ua/downloads/other/pologPhD_org.pdf),; the Law of Ukraine "On Education" (Article 42**)**; the Law of Ukraine "On Academic Integrity**"**; and the Code of Academic Integrity of National Pirogov Memorial Medical University, Vinnytsya (https://www.vnmu.edu.ua/downloads/other/kodex_akad_dobr_edit%202026.pdf)

Students are entitled to high-quality educational services and a safe learning environment under martial law, emergency situations and states of emergency; access to up-to-date scientific and educational information; and qualified academic guidance and support in studying the discipline and acquiring practical skills.

The Department's policy on the provision of educational services is student-centred and is based on the regulatory documents of the Ministry of Education and Science of Ukraine and the Ministry of Health of Ukraine, the University Statute, the procedures governing the provision of educational services, including in emergency situations, as stipulated by the principal regulations and administrative directives governing the organisation of the educational process at National Pirogov Memorial Medical University, Vinnytsya, as well as on the principles of academic integrity.

**Academic Integrity.** When studying the discipline and completing all types of learning assignments and/or research activities, students must comply with the Law of Ukraine "On Education" (Article 42)**,** th**e** Law of Ukraine "On Academic Integrity"**,** and the Code of Academic Integrity of National Pirogov Memorial Medical University, Vinnytsya (University website → General Information → Key Documents → Code of Academic Integrity). In the event of a violation of academic integrity principles, appropriate measures shall be taken in accordance with the applicable regulatory documents.

**Compliance with VNMU Internal Regulations and Safety Requirements during Practical Classes.** At the first practical class, the instructor provides a safety briefing on appropriate conduct on the Department premises, informs students of the location of the shelter and the evacuation route to the shelter in accordance with the approved evacuation plan, explains the rules of conduct while proceeding to and remaining in the shelter, and provides instructions on all actions stipulated by the Emergency Response Plan (pursuant to Order No. 505 dated 30 August 2023). In the event of an air raid alert or any other emergency warning signal, the instructor suspends the class. The instructor and students proceed together to the shelter and remain there until the warning signal is cancelled. Once the alert has been lifted, the instructor and students either resume the class in the Department's classrooms or students independently complete the remaining learning material, which is subsequently assessed at the next class.

**Requirements for Preparation for Practical Classes**

Students are required to participate actively in the educational process: attend classes and come adequately prepared; complete the test tasks related to the current topic in their workbooks and fill in the required diagrams and tables; actively participate in discussions of the class topic; complete all assignments specified in the programme; search for additional information relevant to the topic and present it to their peers.

Students are expected to arrive at classes on time. Late arrival is not permitted in accordance with the Internal Regulations for Students of VNMU**.** A student who arrives more than 10 minutes late is not admitted to the class and is required to make up the missed class in accordance with the established procedure.

*For specialties within Field of Study I "Healthcare and Social Security", students are required to wear a medical coat during practical classes. Students who fail to comply with this requirement are not admitted to the class.*

Students are expected to be polite, courteous, and respectful in their interactions with teaching staff, other University employees, fellow students, and other persons studying at VNMU. Students must maintain a quiet and orderly environment and demonstrate appropriate conduct on the Department premises.

In its activities, the Department adheres to the principles of mutual respect and tolerance. Students are expected to uphold the same principles.

Students must comply with safety regulations while on the Department premises.

When working in teaching and research laboratories, students must comply with the applicable safety regulations (published on the website of the Department of Pharmacy). When completing practical assignments, students must keep their workstations clean and orderly and leave them tidy upon completion of the practical work.

While at clinical training sites, students are required to comply with the established therapeutic and protective regime and sanitary and hygiene requirements**.** Where quarantine restrictions are introduced at a healthcare institution, strict compliance with all applicable requirements is mandatory.

When entering inpatient departments, students must wear a medical coat, cap, and change of footwear**.** Students must also have a medical mask, gloves, and hand sanitiser with them. Bringing outdoor clothing, outdoor footwear, or bulky personal belongings into inpatient departments is not permitted. Students are strictly prohibited from handling any medical devices, equipment, or instruments without the instructor's permission.

When communicating with patients and their relatives, as well as outside the healthcare institution, students are required to observe ethical and deontological principles and comply with applicable legislation concerning the confidentiality and protection of information. The disclosure or dissemination of patients' medical or personal information by any means, including through social media, verbal communication, or otherwise, is strictly prohibited.

In interactions with healthcare personnel and during discussions as part of the educational process, students are expected to adhere to the principles of tolerance, courtesy, and mutual respect. Inappropriate, disrespectful, or provocative behaviour is not permitted.

**Use of Mobile Phones and Other Electronic Devices.** The use of mobile phones and other electronic devices during classes is not permitted, except for emergency calls or when such devices are used to present supplementary materials relevant to the topic of the class.

**Absence from Classes.** Missed classes must be made up in accordance with the procedure established by the current Regulations on the Organization of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf), at the times specified in the make-up schedule published on the website of the Department of Pharmacy (VNMU website), either with the instructor on duty or with the student's regular instructor. Making up a missed class involves completing the assignments related to the topic of the missed class in accordance with the specific requirements of the discipline.

Mastery of lecture topics is assessed during practical classes, seminars (including the assessment of practical skills), and final assessment, in accordance with the Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya (https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf)

**Admission to Final Assessment.** The procedure for admission to final assessment in the discipline is set out in the current Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya (https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf).

Students are admitted to final assessment provided that they have no outstanding academic requirements**:** the average grade for ongoing assessment must be at least 3.0 (72 points on the 120-point scale); all final sessions for the content modules must have been completed with a passing grade **(**"3" or higher); and all missed practical classes must have been made up with a passing grade **(**"3" or higher**).** Otherwise, the student must improve their average grade by making up unsatisfactory grades and must make up all missed classes.

**Additional Points for Individual Assignments.** Students may receive additional points in the discipline for the successful completion of individual assignments, the content of which is published on the Department's website as part of the teaching and learning materials for the discipline. The number of points awarded is determined based on the results of the individual assignment in accordance with the current Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya**.** (https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf).

**Resolution of Conflict Situations**

In the event of misunderstandings or concerns regarding the quality of educational services, assessment of academic performance, or other conflict situations involving an instructor, students should first raise their concerns directly with the instructor. If the issue remains unresolved, the student has the right to submit an appeal to the Head of the Department in accordance with the Regulations on the Consideration of Appeals from Higher Education Students at National Pirogov

Memorial Medical University, Vinnytsya (VNMU website → General Information → Key Documents).

Students also have the right to contact the student self-government bodies, the administration of the Faculty (Institute), or the University administration, either directly or through the designated feedback channels ("trust boxes"), links and addresses for which are available on the official VNMU website.

The Department recognises that a student-centred approach entails students' responsibility for the conscious and active acquisition of knowledge and for proper compliance with the rules and requirements established by applicable legislation and VNMU regulatory documents. The Department reserves the right to inform the relevant University bodies of any violations committed by students.

**Policy on Blended Learning**

The organisation of blended learning is governed by the Regulations on the Introduction of Elements of Distance Learning at National Pirogov Memorial Medical University, Vinnytsya (VNMU website → General Information → Key Documents). The main online learning platforms used for classes are Microsoft Teams and Google Meet.

The procedures for conducting practical classes, lectures, make-up classes, and consultations in the distance learning format are published on the Department's webpage (VNMU website → Department of Pharmacy → For Students/Postgraduate Students → Mode of Study → Year of Study → Teaching and Learning Materials**).**

**Communication with the Instructor.** Students may contact the instructor via Microsoft Teams chat, messaging applications (Viber, Telegram, WhatsApp), or email**,** as determined by the instructor, during working hours.

## 9. LEARNING RESOURCES

Teaching and learning materials for the discipline are available on the Department's website. The materials can be accessed via: VNMU website → Department of Pharmacy → For Students/Postgraduate Students.

## LITERATURE

**Core Literature for Pharmaceutical biotechnology**


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.
4. European Parliament and Council of the European Union. (2001). Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Official Journal of the European Communities, L 311, 67–128.
5. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004. Official Journal of the European Union. 2007. L 324. P. 121–137.
6. EudraLex. Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Annex 2: Manufacture of Biological Medicinal Substances and Products for Human Use / European Commission. Brussels : EC, 2018. 19 p.

7. Guideline on similar biological medicinal products [Electronic resource] : CHMP/437/04 Rev. 1 / Committee for Medicinal Products for Human Use (CHMP). Amsterdam : European Medicines Agency, 2014. 7 p.
8. European Commission. (2025). Proposal for a Regulation of the European Parliament and of the Council establishing a framework to strengthen the EU biotechnology and biomanufacturing sectors (European Biotech Act) (COM(2025) 1022 final).

**Supplementary Literature for Pharmaceutical biotechnology**

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/E 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.

**ELECTRONIC RESOURCES**

1. University website: National Pirogov Memorial Medical University, Vinnytsya
2. Department website: VNMU Departments — Department of Pharmacy
3. University Library website: VNMU Library
4. National Scientific Medical Library of Ukraine: National Scientific Medical Library of Ukraine
5. World Health Organization: World Health Organization (WHO)
6. Ministry of Health of Ukraine: Ministry of Health of Ukraine
7. Public Health Center of the Ministry of Health of Ukraine: Public Health Center of Ukraine
8. English-language database of medical and biomedical literature: PubMed
9. English-language online resource for physicians and other healthcare professionals: Medscape
10. European Medicines Agency. https://www.ema.europa.eu
11. European Commission: https://health.ec.europa.eu

The course syllabus for the academic discipline "Pharmaceutical biotechnology" was discussed and approved at the meeting of the Department of Pharmacy (Minutes dated № 1. "26" 08 2026)

**Course Coordinator:**

Assoc. Prof., PhD — Tetiana VOITENKO
*(Academic Degree, Academic Title)* *(Signature)*

Acting Head of the Department of Pharmacy

Assoc. Prof., PhD — Yliia TOMASHEVSKA
*(Academic Degree, Academic Title)* *(Signature)*