



SYLLABUS OF THE EDUCATIONAL COMPONENT

PHARMACEUTICAL BIOTECHNOLOGY

**for applicants for higher education of 4th years of full-time education
of educational program "Pharmacy"
in specialty "226 Pharmacy, industrial pharmacy"
field of knowledge "22 Health care"
training for second master's level of higher education**

TEACHERS

	KHOKHLENKOVA Natalia Vikrorivna	hohnatal@gmail.com
	SOLOVIOVA Alina Volodymyrivna	soloviova.alina@gmail.com

1. The name of higher education establishment and department: National Pharmaceutical University, Department of Biotechnology.

2. Address of the department: Kharkiv, Valentynivska str., 4.

3. Web site of the department: <http://biotech.nuph.edu.ua/>

4. Information about teachers:

Natalya Viktorivna Khokhlenkova

Doctor of Pharmaceutical Sciences, Head of the Biotechnology Department of the National Pharmaceutical University. Experience of scientific activity - 27 years, experience of scientific and pedagogical activity - 17 years. Reads courses: "Pharmaceutical biotechnology", "Hygiene and industrial sanitation of biotechnological productions", "GMP: quality assurance system", "Modern problems of biotechnology", "Ecodesign", "Fundamentals of pharmaceutical biotechnology", "Design of medicines". Scientific interests: pharmaceutical and industrial biotechnology, drug technology.

Alina Volodymyrivna Soloviova

PhD, assistant professor of the Department of Biotechnology of the National Pharmaceutical University. Experience of scientific and pedagogical activity - 5 years. Reads courses: "Pharmaceutical biotechnology", "Microbiology and virology". Scientific interests: pharmaceutical and industrial biotechnology, medical technology.

5. Consultations: every Mondays from 12.00 to 13.00 online.

6. Brief summary of the educational component: the educational component lays the foundations of professional training, contributes to the formation of pharmaceutical thinking, necessary for the pharmaceutical specialty. Together with other pharmaceutical educational components and social sciences, pharmaceutical biotechnology plays an important role in providing special technological training for professional activities.

7. The purpose statement of studying the educational component: the teaching of the educational component "Pharmaceutical Biotechnology" is the acquisition by students of higher education of the theoretical foundations and practical abilities and skills of conducting biotechnological processes, cultivation of individual strains of industrial microorganisms, management of cultivation processes of microorganisms and quality control of the obtained target

products, environmental safety products of biotechnology created on the basis of microorganisms, assimilation of features and familiarization with the achievements of biotechnologies in the production of pharmaceutical products of the latest generation: vaccines, hormones, immunomodulators, vitamins, enzymes, probiotics, antibiotics and other drugs for medical purposes and dietary supplements using producer organisms and other biological facilities, which will enable effective realization of the scientific and creative potential of future specialists.

Mastering the theory and practice of manufacturing medicinal products by biotechnological methods is necessary for a specialist to perform the duties of a specialist, which is provided for by the legal and procedural legislation and the relevant order of the Ministry of Health of Ukraine.

8. Competences in accordance with the educational program:

Hard-skills / Professional (special) competencies (PC):

PC 1. Ability to conduct sanitary and educational work among the population to prevent common diseases, prevent dangerous infectious, viral and parasitic diseases, as well as to facilitate the timely detection and maintenance of adherence to treatment of these diseases in accordance with their medical and biological characteristics and microbiological characteristics.

PC 15. Ability to organize and participate in the production of medications in the context of pharmaceutical companies, including the selection and justification of the technological process, equipment in accordance with the requirements of Good Manufacturing Practice (GMP) with the appropriate development and design of the necessary documentation. Determine the stability of medications.

9. The program learning outcomes (PLO):

PLO 27. To substantiate the technology and organize the production of medicines at pharmaceutical enterprises and draw up technological documentation for the production of medicines at pharmaceutical enterprises.

10. Status of the educational component: selective.

11. Prerequisites of the educational component: the educational component is based on the study of biology with the basics of genetics, inorganic chemistry, organic chemistry, physical and colloidal chemistry, biological chemistry, microbiology with the basics of immunology, pharmaceutical botany.

12. The volume of the educational component: 3 ECTS credits of 90 hours:

full-time education: lectures - 8 hours, practical classes - 24 hours, independent work - 58 hours;

correspondence form of education: lectures - 4 hours, practical classes - 8 hours, independent work - 78 hours.

13. Organization of training

Teaching format of the educational component: conducting lectures and practical classes.

Content of the educational component:

Content module 1. Fundamentals of biotechnological processes. Production technology of drugs obtained on the basis of biological objects.

Topic 1. Bioobjects and methods of pharmaceutical biotechnology.

Topic 2. Bioobjects and methods of pharmaceutical biotechnology. The main stages of the biotechnological process.

Topic 3. Cellular technologies: objects and methods; ways of use.

Topic 4. Probiotics. Bacteriophages. General characteristics, preparations, production.

Topic 5. Biotechnological production of metabolites of microorganisms.

Topic 6. Production technology of immunopreparations.

Topic 7. Hormonal drugs obtained by biotechnological methods. Principles and stages of production, dosage forms. *Control of content module 1.*

14. Forms and types of academic achievements supervision:

Current control is carried out during each practical session in accordance with specific goals and during individual work of the teacher with students of higher education. The independent work of students of higher education is also monitored during each practical or seminar session.

When mastering each topic of the module for the current educational activity, the students of higher education are given points for all types of activities, which are added up at the end of studying the module.

The control of the content module is carried out at the last lesson of the content module. The control is carried out in order to check the level of assimilation of theoretical material, acquisition of practical skills and skills from the educational component.

Semester control is conducted at the last lesson of the module in the form of a semester credit.

The evaluation of the success of a higher education student in the educational component is a rating, presented on a one-point scale and defined according to the ECTS system and the traditional scale adopted in Ukraine. Applicants of higher education who want to improve their performance in the educational component on the ECTS scale have the opportunity to do so in the last lesson of the module during the semester assessment.

Conditions for admission to the control of content module: for admission to control of content module 1, a minimum number of points for classes of content module 1 is required.

Conditions for admission to the semester control: current rating of more than 60 points, absence of unworked passes of practical and seminar classes, fulfillment of all requirements stipulated by the work program of the educational component.

15. Evaluation system from the educational component:

The results of the semester control in the form of a semester credit are evaluated on a 100-point, undifferentiated scale ("passed", "failed") and on the ECTS scale.

Points from the educational component are calculated according to the following ratio:

Types of assessment	Maximum number of points (% of the number of points for the module)
Module 1	
Content module 1: "Fundamentals of biotechnological processes. Production technology of drugs obtained on the basis of biological objects» - evaluation of topics (1-7): work in classes (oral survey, preparation of test tasks, performance of practical tasks); - control of content module 1 (written answer to a theoretical question, solution of test tasks)	60 (60%) 40 (40%)
Semester control from module 1	100

The independent work of students of higher education is evaluated during the current control and during the control of the content module.

16. Academic policies of the educational component:

Academic Integrity Policy. It is based on the principles of academic integrity stated in the POL "On measures to prevent cases of academic plagiarism at the National University of Ukraine". Writing off during the assessment of the student's success during the control measures in practical and seminar classes, control of the content module and semester control is prohibited (including with the use of mobile devices). Abstracts must have correct text references to the used literature. The detection of signs of academic dishonesty in the student's written work is a reason for the teacher not to enroll it.

Class attendance policy. A student of higher education is obliged to attend classes (POL "On the organization of the educational process of the National Academy of Sciences of Ukraine") according to the schedule (<https://nuph.edu.ua/rozklad-zanyat/>), to observe ethical norms of behavior.

Policy regarding deadlines, working out, rating increase, liquidation of academic debt. The completion of missed classes by a student of higher education is carried out in accordance with the POL "Regulations on the completion of missed classes by students and the procedure for eliminating academic differences in the curricula of the National Academy of Sciences" in accordance with the schedule for making up missed classes established by the department. Increasing the rating and liquidating academic debt from the educational component is carried out by the students in accordance with the procedure specified in the POL "On the procedure for evaluating the results of training of students of higher education at the National Academy of Sciences". Applicants of higher education are obliged to comply with all deadlines set by the department for the completion of written works from the educational component. Works that are submitted late without valid reasons are assessed at a lower grade - up to 20% of the maximum number of points for this type of work.

Policy on appeals of assessment from the educational component (appeals). Applicants of higher education have the right to contest (appeal) the evaluation of the educational component obtained during control measures. The appeal is carried out in accordance with the POL "Regulations on appealing the results of the semester control of the knowledge of students of higher education at the National Academy of Sciences".

17. Informational and educational and methodological support of the educational component:

The main reading suggestions	1. Pharmaceutical Biotechnology in Drug Development / Muhammad Sajid Hamid Akash. – Academic press, 2023.
Supplementary reading suggestions for in-depth study of the educational component	1. S. Spada. G. Walsh Directory of Approved Biopharmaceutical Products 1st Edition . – CRC Press, 2019. – 336 p. 2. Roque-Borda C.A., Pavan F.R., Meneguín A.B. Pharmaceutical Biotechnology. Life (Basel). 2022 Aug 16;12(8):1240. doi: 10.3390/life12081240. 3. Roque-Borda CA, Pavan FR, Meneguín AB. Pharmaceutical Biotechnology. Life (Basel). 2022 Aug 16;12(8):1240. doi: 10.3390/life12081240.

	<p>4. Harcum S.W., Kiss R.D. Editorial overview: Pharmaceutical biotechnology: the pandemic years - new modality development and biomanufacturing innovations in a maturing field. <i>Curr Opin Biotechnol.</i> 2022 Dec;78:102846. doi: 10.1016/j.copbio.2022.102846.</p> <p>5. Zuba-Surma EK, Józkwicz A, Dulak J. Stem cells in pharmaceutical biotechnology. <i>Curr Pharm Biotechnol.</i> 2011 Nov;12(11):1760-73. doi: 10.2174/138920111798377120.</p> <p>6. Khavari F, Saidijam M, Taheri M, Nouri F. Microalgae: therapeutic potentials and applications. <i>Mol Biol Rep.</i> 2021 May;48(5):4757-4765. doi: 10.1007/s11033-021-06422-w.</p> <p>7. Boulay JL, Miot S. Chemical biotechnology pharmaceutical biotechnology. Web alert. <i>Curr Opin Biotechnol.</i> 2000 Dec;11(6):515. doi: 10.1016/s0958-1669(00)00138-5.</p> <p>8. Bhatia, Saurabh, Tanveer Naved, and Satish Sardana. <i>Introduction to Pharmaceutical Biotechnology, Volume 3; Animal tissue culture and biopharmaceuticals.</i> 2019.</p>
<p>Current electronic information resources (magazines, websites) for in-depth study of the educational component</p>	<p>1. Europien pharmacopeia [Electronic resource]: official website. - Access mode https://pheur.edqm.eu/home.</p> <p>2. National Pharmaceutical University [Electronic resource]: Scientific library of the National Pharmaceutical University. - Access mode :http://lib.nuph.edu.ua(date of application 09/26/20).</p> <p>3. National Pharmaceutical University. Department of Biotechnology [Electronic resource]: website of the Department of Biotechnology. – Access mode: http://biotech.nuph.edu.ua</p> <p>4. Educational portal http://pharmel.kharkiv.edu - center of distance technologies of NUPh</p>
<p>Moodle distance learning system</p>	<p>https://pharmel.kharkiv.edu/moodle/course/view.php?id=4751</p>

18. Technical support and software of the educational component: A set of services for organizing online and distance learning - Google Workspace for Education Standard, license type - free license for education, unlimited. ZOOM video conferencing software, license type - free license for education for 1 year with the possibility of extension. Modular object-oriented dynamic learning environment MOODLE 3.9.8, license type - Open Source, software: Microsoft Office 2010; Microsoft Office 365, MS Teams, MS Forms, MS PowerPoint, personal computers: PC System unit VT Computers CPU INTEL Pentium G4400, PC R-Line with Intel Core i3-8100 processor, multimedia projector EPSON EV-E350, camera-video eyepiece DCM-320, pH meter pH-305, water distiller DE-10 - 1 pc, water bath (MICROmed BV-4, BV-10), electronic laboratory scales (AXIS BTU210D, SPU 402), laminar flow box AC2-4E1, microscopes (MS-10, Ulab XSP-12B, GRANUM W10, MBS-10), steam sterilizer GK-20, air sterilizer GP-80-01, ULAB 101 spectrophotometer, TS 1/80 SPU thermostat, OPN-8 laboratory centrifuge, laboratory glassware, dispensers, cultures of microorganisms, culture media for microorganisms.