

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

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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. Consultations: every Mondays from 12.00 to 13.00 online.

5. 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.

6. 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.

7. 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.

8. 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.

9. Status of the educational component: selective.

10. 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.

11. 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.

12. Organization of training

Teaching methods:

- **explanatory (informational and reproductive) method:** Lecture-based learning lectures, video materials;
- **reproductive method:** traditional practical classes;
- **problem-based teaching:** Brainstorming "brainstorming" method; Case-based learning □ case method;
- **partial search method:** Game-based learning game methods of learning (business games); Team-based learning - a method of working in small groups;
- **research method:** Research-based learning participation in research work, preparation of theses of conference reports, scientific articles

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.

13. 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.

14. Evaluation system from the educational component:

The criteria for evaluating the knowledge and skills of students of higher education from the educational component "Regulatory support of biotechnological industries" were developed in accordance with the "Regulations on the procedure for evaluating the results of studies of students of higher education at the National Pharmaceutical University POL A2.2-32-031".

The assessment of the success of higher education applicants 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.

Assessments (in points) are reflected in the calendar-thematic plans of practical and seminar classes.

Evaluation of mastering the topics of the educational component during classes:

<i>Subject number of the educational component</i>	<i>Maximum number of points for the topic</i>	<i>Distribution of the maximum number of points per topic by type of work</i>	<i>Types of work for which the applicant receives points</i>
<i>Content module 1</i>			
<i>Topic 1.</i> Bioobjects and methods pharmaceutical biotechnology	8	4	Testing
		4	Oral answer
<i>Topic 2 .</i> The main ones stages biotechnological process	8	4	Testing
		4	Solving situational (calculation) tasks
<i>Topic 3.</i> Cellular technologies: objects and methods; ways using	8	8	Testing
<i>Topic 4.</i> Probiotics . Bacteriophages. General characteristic, drugs, production	8	4	Testing
		4	Writing an essay
<i>Topic 5.</i> Biotechnological production drugs metabolites microorganisms	12	6	Testing
		6	Writing an essay
<i>Topic 6.</i> Technology production immunopreparations	8	8	Testing
<i>Topic 7.</i> Hormonal drugs, which receive biotechnological methods. Principles and stages production,dosage forms	8	8	Testing
<i>Total points for the module:</i>		<i>60</i>	

The study of the educational component by students of higher education is possible with the help of non-formal education. Instead of performing types of work on any topic of the educational component, the following types of work of a student of higher education may be counted:

–participation in workshops, forums, conferences, seminars, webinars on the topic of the educational component (with the preparation of essays, abstracts of reports, information messages, etc., which is confirmed by the program of the event, or abstracts of reports, or a corresponding certificate);

–participation in research and applied research on the topic of the educational component (in the development of questionnaire forms, conducting experimental studies, processing research results, preparing a report, presenting the results, etc., which is confirmed by the demonstration of relevant materials).

Evaluation of winners by types of work during classes:

<i>Types of work, for which the acquirer receives points</i>	<i>Maximum number of points</i>
testing	42
answers to theoretical questions	4
solving situational tasks	4
writing an essay	10
<i>Total points:</i>	<i>60</i>

Evaluation during control of the content module :

<i>Types of work, for which the acquirer receives points</i>	<i>Distribution of the maximum number of points for control of the content module by types of work</i>	<i>The maximum number of points for control of the content module</i>
Content module 1		
testing	30	40
answers to theoretical questions	10	
Total points for control of content modules:		40

Evaluation of independent work of the student of education:

during the current control: test tasks and theoretical questions on topics include tasks and questions on those questions on the topics of the educational component that were not included in classroom classes.

during the control of content module 1: tickets for content module 1 include theoretical questions and test tasks on those questions from the topics of the educational component that were not included in classroom classes.

Evaluation scale of the semester credit:

When studying the educational component, several assessment scales are used: a 100-point scale, an undifferentiated ("passed", "not passed") two-point scale and the ECTS rating scale. The results are converted from one scale to another according to the table.

Total points on a 100-point scale	ECTS scale	Evaluation on a non-differentiated scale
90-100	A	counted
82-89	B	
74-81	C	
64-73	D	
60-63	E	
35-59	FX	not counted
1-34	F	

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. 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".

16. 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.
	4. Harcum S.W., Kiss R.D. Editorial overview: Pharmaceutical biotechnology: the pandemic years - new modality development and biomanufacturing innovations in a maturing field. Curr Opin Biotechnol. 2022 Dec;78:102846. doi: 10.1016/j.copbio.2022.102846. 5. Zuba-Surma EK, Józkowicz A, Dulak J. Stem cells in pharmaceutical biotechnology. Curr Pharm Biotechnol. 2011 Nov;12(11):1760-73. doi: 10.2174/1389201111798377120. 6. Khavari F, Saidijam M, Taheri M, Nouri F. Microalgae: therapeutic potentials and applications. Mol Biol Rep. 2021 May;48(5):4757-4765. doi: 10.1007/s11033-021-06422-w. 7. Boulay JL, Miot S. Chemical biotechnology pharmaceutical biotechnology. Web alert. Curr Opin Biotechnol. 2000 Dec;11(6):515. doi: 10.1016/s0958-1669(00)00138-5. 8. Bhatia, Saurabh, Tanveer Naved, and Satish Sardana. Introduction to Pharmaceutical Biotechnology, Volume 3; Animal tissue culture and biopharmaceuticals. 2019.
Current electronic information resources (magazines, websites) for in-depth study of the educational component	1. European pharmacopeia [Electronic resource]: official website. - Access mode https://pheur.edqm.eu/home . 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). 3. National Pharmaceutical University. Department of Biotechnology [Electronic resource]: website of the Department of Biotechnology. – Access mode: http://biotech.nuph.edu.ua 4. Electronic archive of the NUPh library. http://lib.nuph.edu.ua ; e-mail library@nuph.edu.ua 5. Educational portal http://pharmel.kharkiv.edu - center of distance technologies of NUPh
Moodle distance learning system	https://pharmel.kharkiv.edu/moodle/course/view.php?id=4751

17. 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.