SYLLABUS OF THE EDUCATIONAL COMPONENT

TECHNOLOGIES OF MICROBIAL SYNTHESIS OF MEDICINAL PRODUCTS

for acquirers higher 4th course of full-time education forms acquisition education
Educational programs " Pharmacy "
Specialties 226 " Pharmacy , industrial pharmacy »
Industries of knowledge 22 " Protection health »
Second (master 's) level higher education

TEACHERS

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5. Abstract of the educational component: Microorganisms are producers of a number of biologically active compounds, many of which are pharmacologically active and, at the same time, less toxic compared to products of chemical synthesis. This causes a rapid increase in their use as active substances in the composition of medicines. Graduates of higher education in the pharmaceutical specialty need to be oriented in the theoretical foundations of technologies of microbial synthesis of medicinal substances and acquire practical abilities and skills in the application of such technologies , management of the processes of cultivation of microorganisms , quality control of the obtained target products, it is necessary to know both traditional and innovative methods of obtaining biologically active substances and pharmaceuticals - amino acids, enzymes, recombinant proteins, antibiotics and other drugs for medical purposes and dietary supplements - using producer organisms .
6. The purpose of teaching the educational component: assimilation by students of higher education of the theoretical foundations and practical abilities and skills of carrying out the process of microbial synthesis, assimilation of methods of cultivation of individual strains of industrial microorganisms, management of these processes and quality control of the obtained target products, assimilation of features and familiarization with the achievements of biotechnologies of pharmaceutical production means of the latest generation: recombinant proteins, vitamins, enzymes, amino acid, antibiotic drugs using producer organisms, which will allow effective realization of the scientific and creative potential of future specialists.

7. Competencies according to the educational program:

Soft- skills / General competences (GK):

GK02. ability to apply knowledge in practical situations, make informed decisions;

GK04. the ability to think abstractly, analyze and synthesize, learn and be modernly educated.

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

PC 1. The ability to carry out sanitary and educational work among the population for the purpose of prevention of common diseases, prevention of dangerous infectious, viral and parasitic diseases, as well as for the purpose of promoting timely detection and support of adherence to the treatment of these diseases in accordance with their medical and biological characteristics and microbiological features .

PC 15. The ability to organize and participate in the production of medicinal products in the conditions of pharmaceutical enterprises, 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 preparation of the necessary documentation. Determine the stability of medicines.

8. Program learning outcomes (PLO):

PLO 27. To justify the technology and organize the production of medicinal products at pharmaceutical enterprises and draw up technological documentation for the production of medicinal products at pharmaceutical enterprises .

9. Status of the educational component: selective.

10. Prerequisites of the educational component: "Biology with the basics of genetics", "General and inorganic chemistry", "Organic chemistry", "Physical and colloidal chemistry", "Biological chemistry", "Microbiology with the basics of epidemiology", "Pharmacognosy with the basics of resource science " , "Technology of industrial production of drugs" **.**

11. The scope of the educational component : 3 ECTS credits, 90 hours: 32 hours of classroom classes, of which 8 hours of lectures, 24 hours of practical classes, 58 hours of independent work.

12. Organization of training:

Teaching methods :

- *explanatory (informational and reproductive) method:* Lecture-based learning –lectures, video materials;
- *reproductive method:* traditional practical classes;
- *problem teaching:* Brainstorming –"brainstorming" method; Case- based learning –case method;
- *partial search method:* Game - based learning –game methods of learning (business games); Team-based learning –method of working in small groups.

Content of the educational component:

Content module 1. Objects, methods and technological processes of microbial synthesis of medicinal products .

Topic 1. Tasks and features of microbial synthesis. Objects and products of microbial synthesis.

Topic 2. Raw materials and nutrient media. The main stages of the process of microbial synthesis.

Topic 3. Methods of cultivation of microorganisms for the implementation of microbial synthesis technologies.

Topic 4. Technologies of microbial synthesis of amino acids, enzyme preparations.

Topic 5. Technologies of microbial synthesis of vitamins.

Topic 6. Technologies of microbial synthesis of antibiotics.

Topic 7. Technologies for obtaining recombinant cytokine proteins .

Organization of independent work:

Independent work includes the study of questions on the topics of the educational component that were not included in classroom classes, and the performance of tasks on these questions in order to consolidate the theoretical material .

13. Types and forms of control:

Types and forms of control:

Current control:

Control of knowledge in each lesson (on each topic): oral survey, writing test tasks, solving situational (calculation) problems, writing an essay.

Content module control: writing test tasks, answering theoretical questions.

Conditions for admission to control of the content module: the presence of a minimum number of points for taking the content module,

Semester control:

Semester control form : semester assessment.

Conditions for admission to semester control :

the current rating is more than 60 points, the presence of the minimum number of points for the control of the content module 1, the absence of unworked passes of practical classes, the fulfillment of all the requirements stipulated by the work program of the educational component.

14. Evaluation system for the educational component:

Evaluation <u>of mastering the topics</u> of the educational component <u>during classes:</u>

Subject number of the educational component	***Maximum number of points for the topic***	***Distribution of the maximum number of points per topic by type of work***	***Types of work for which the applicant receives points***
Content module 1			
Topic 1. Tasks and features of microbial synthesis. Objects and products of microbial synthesis	8	4	Testing
		4	Oral answer
Topic 2 . Raw materials and nutrient media. The main stages of the process of microbial synthesis	8	8	Testing
Topic 3. Methods of cultivation of microorganisms for the implementation of microbial synthesis technologies	8	4	Testing
		4	Solving situational (calculation) tasks
Topic 4. Technologies microbial synthesis of amino acids , enzymes drug in	8	4	Testing
		4	Writing an essay
Topic 5. Technologies of microbial synthesis of vitamins	1 2	6	Testing
		6	Writing an essay
Topic 6. Technologies of microbial synthesis of antibiotics	8	8	Testing
Topic 7. Technologies for obtaining recombinant cytokine proteins	8	8	Testing
Total points for the module:		***60***	

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:

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

Evaluation during control of the content module :

Types of work, for which the acquirer receives points	***Distribution of the maximum number of points for control of the content module by types of works***	***The maximum number of points for control of the content module***
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	

15. 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 Institute of Public Health ". Writing off during the assessment of the success of a higher education applicant during control measures in practical (seminar, laboratory) classes, control of content modules and the semester exam 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. The student of higher education is obliged to attend classes (POL "On the organization of the educational process of the National University 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. 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 the elimination of academic differences in curricula at the National Academy of Sciences " in accordance with the timetable for making up missed classes established at 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 Institute of Higher Education ". 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 in violation of deadlines without valid reasons are evaluated for 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 challenge (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 ".

Policy on the recognition of learning outcomes obtained through non-formal and/or informal education by higher education students . Applicants of higher education have the right to recognition of learning results acquired in informal and informal education in accordance with the POL "On the procedure for recognition of educational results obtained through informal and/or informal education by applicants of higher education at the National Institute of Public Health " .

As part of the academic freedom of the teacher, instead of performing types of work on the subject of the educational component, it is possible to enroll in the non-formal education of a student of higher education.

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

Mandatory literature	1. Khokhlenkova N.V. Workshop on pharmaceutical biotechnology: a study guide for students of higher education in pharmaceutical and biotechnological specialties / N.V. Khokhlenkova , L.S. Strelnikov , O.P. Sagittarius, O.S. Kalyuzhnaya , N.V. Dvinskikh , Yu.M. Azarenko . - 1st edition. - Kh.: National University of Applied Sciences , 2021. - 111 p. (electronic edition) 2. Pie T.P. Biochemical basics of microbial synthesis [Text]: textbook [for students . ZVO spec. 162 "Biotechnology and bioengineering" and related specialties. 091 "Biology", 226 "Pharmacy"] / T. P. Pirog , Yu. M. Penchuk ;

	National University of Food technologies. - Kyiv: Lira-K, 2020. - 258 p. 3. Microbiology: tutorial . for university students . teach app . / N. I. Filimonova , L. F. Silaeva , O. M. Dyka and others. ; in general ed. N. I. Filimonova . — 2nd edition. — Kharkiv: National Academy of Sciences and Arts : Golden Pages, 2019. — 676 p. 4. Technological equipment of the pharmaceutical and biotechnological industry [Text]: textbook . for universities of III-IV levels of accreditation / M.V. Stasevich [and others]; National Lviv Polytechnic University, National Science and Technology University . - Lviv: Novy Svit-2000, 2016. - 410 p.
Additional literature for in-depth study of the educational component	1. Kaprelyants L.V. Theoretical foundations of biotechnology, textbook - Kharkiv, FACT: 2020. - 296 p. 2. Krasnopolskyi , D.M. Pylypenko. Pharmaceutical biotechnology: present and future: study guide for students of biotechnological specialties / Yu.M. Krasnopolskyi , D.M. Pylypenko. - Kharkiv: "Drukarnia Madrid" LLC, 2022. - 151 p. 3. Veterinary biotechnology: a textbook . for students of higher educational institutions / M.D. Bezugliy, V.O. Golovko, I.Yu. Bisyuk et al. - Kh.: Gymnasium, 2012. - 464 p. 4. Yulevich O. I., Kovtun S. I., Gil M. I. Biotechnology: teaching . help under the editorship E. Gilya . Mykolaiv: Moscow State University, 2012. 476 p. 5. Fundamentals of biotechnology: a textbook for students. N.Yu. touch – Luhansk: DZ "LNU named after . Taras Shevchenko", 2011. - 153 p.
Actual electronic information resources (magazines, sites, etc.) for in-depth study of the educational component	1. Scientific library of the National Pharmaceutical University. [Electronic resource]: Scientific library of the National Academy of Sciences of Ukraine . – Access mode: http://lib.nuph.edu.ua 2. Website of the Department of Biotechnology of the National Academy of Sciences - Department of Biotechnology [Electronic resource]: - Access mode: http: biotech.nuph.edu.ua 3. Center for Distance Learning Technologies of the National Institute of Advanced Studies : http://pharmel.kharkiv.edu 4. Kharkiv State Scientific Library named after V.G. Korolenko. [Electronic resource] : – Mode of access : http://korolenko.kharkov.com
Moodle distance learning system	https :// pharmel . Kharkiv . edu / moodle / course / view . php ? ID = 3577

17. Material, technical and software support of the educational component:

Technical support – computer, video camera, multimedia projector, screen.

Software: Microsoft Word, Excel, Power Point , Acrobat rider , Google Workspace for Education Standard, ZOOM, MOODLE; 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 box AC2 -4E1, microscopes (MC-10, Ulab XSP-12B, GRANUM W10, MBS-10), steam sterilizer GK-20, air sterilizer ГП-80-01, spectrophotometer ULAB 101, thermostat TS 1/80 SPU, laboratory centrifuge OPN -8, laboratory utensils, dispensers, cultures of microorganisms, nutrient media for cultivation of microorganisms.