



MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Department of Biotechnology

PHARMACEUTICAL BIOTECHNOLOGY

(name of educational component)

**WORK PROGRAM
of educational component**

training for _____ second (master's) level _____
(Higher Educational Level Name)
in specialty _____ «226 Pharmacy, industrial pharmacy» _____
(Code and Specialty Name)
field of knowledge « _____ 22 Health care _____
(Code and Knowledge Field Name)
of educational program _____ «Pharmacy» _____
(Educational Program Name)

Kharkiv - 2023
(year of creation)

The work program of the educational component "Pharmaceutical biotechnology" in specialty 226 Pharmacy, industrial pharmacy of the educational program "Pharmacy" for applicants for higher education 4th year of study.

EDUCATIONAL COURSE TEAM:

Natalya KHOKHLENKOVA, head of department of biotechnology, Doctor of Pharm.Sc., professor.

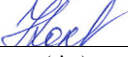
Olha KALIUZHNAIA, associate professor of the institution of higher education department of biotechnology, Ph.D, associate professor.

Alina SOLOVIOVA, asistant of the institution of higher education department of biotechnology, Ph.D, asistant.

(specify the LAST NAME, first name of the authors, their positions, scientific degrees and academic titles)

Work program has been considered and approved at the Department meeting
Department of biotechnology

Record from « 1 » 09 2023 № 1

Head of the Department  prof. Natalya KHOKHLENKOVA
(sig.) (first name LAST NAME)

Work program has been approved at the meeting of the Methodical Commission of technological educational components

Record from « 1 » 09 2023 № 1

Deputy Head of Methodical Commission  of technological educational components _____ prof. Olena RUBAN

1. Description of the educational component

Language of instruction: English

Status of the educational component: selective

Prerequisites for studying the educational component: the educational component is based on the study of 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, and industrial drug technology;

the educational component is the basis for studying the technological aspects of modern biotechnological production, which involves integration with the above educational components.

The subject matter of the educational component "Pharmaceutical Biotechnology" is the main provisions and trends in the development of pharmaceutical biotechnology in the world and in Ukraine; mastering the modern principles of production of active pharmaceutical ingredients and medicines using biotechnology methods - microbial synthesis, cellular technology, genetic engineering methods, familiarization with the main modern types of biotechnology production equipment.

Information content of the educational component. 3 ECTS credit 90 hours are assigned to the study of the educational component.

2. Objectives and tasks of the educational component

The purpose of teaching the educational component "Pharmaceutical biotechnology" is the assimilation by students of higher education of the theoretical foundations and practical skills and abilities of carrying out biotechnological processes, cultivation of individual strains of industrial microorganisms, management of processes of cultivation of microorganisms and quality control of the received target products, environmental safety of biotechnology products created on the basis of microorganisms, assimilation of features and familiarization with achievements biotechnologies for the production of pharmaceutical products of the latest generation: vaccines, hormones, immunomodulators, vitamins, enzymes, probiotics, antibiotics and other medical preparations and dietary supplements using producer organisms and other biological objects, which will make it possible to effectively realize 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 legal and procedural legislation and the corresponding order of the Ministry of Health of Ukraine.

The main tasks of the educational component "Pharmaceutical biotechnology" is:

- mastering the theoretical foundations of biotechnological processes, means and methods of obtaining biologically active substances using living objects and their enzyme systems;
- the formation of students of higher education in the practical use of biotechnological processes for the industrial production of valuable products of the vital activity of microorganisms and other biotechnological objects, their biomass, the production of useful substances and medicines, as well as preventive and diagnostic tools based on them, which are used in various in the fields of medicine and pharmacy;
- assimilation of the methodology of creation, standardization, evaluation of the quality and safety of medicines obtained by biotechnological methods on the basis of general laws of chemical and biological sciences for the performance of professional tasks of a pharmacy specialist;
- formation of systematized knowledge on handling, storage, transportation, use of information about biotechnological drugs and provision of information on these issues to consumers.

3. Competencies and planned learning outcomes

The educational component "Pharmaceutical Biotechnology" ensures that students of higher education acquire the following **competencies**:

- *integral*:

ability to solve typical and complex specialized tasks and critically comprehend and solve the practical problems in the professional pharmaceutical and/or research and innovation activity using provisions, theories and methods of the fundamental, chemical, technological, biomedical, socio-economic science; integrate knowledge and solve complex issues, formulate judgments in the presence of

incomplete or limited information, clearly and unambiguously to convey their conclusions and use their knowledge, reasonably substantiating them, to professional and non-professional audience.

- *special (professional, subject):*

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.

Integrative final program learning outcomes (PLO), the formation of which is facilitated by the educational component:

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.

As a result of studying the academic discipline, the student of education must

know:

- history and directions of development of pharmaceutical biotechnology;
- main producers and methods of obtaining APIs and medicinal products by biotechnological methods;
- traditional and innovative ways of obtaining biologically active substances by biotechnology methods;
- main stages of the biotechnological process;
- basic regulatory documents on standardization, production, quality control and compliance with environmental safety of medicinal products obtained by biotechnological methods, as well as biological objects - their producers.

be able:

- - to perform various technological operations of the biotechnological process of drug production;
- - to justify the conditions of cultivation of microorganisms, cells and tissues of plants and animals;
- - to carry out certain types of technological control of production and standardization of the obtained drugs (determination of antimicrobial activity of antibiotics, activity of enzyme preparations, concentration of viable cells, viability of microorganisms)
- - choose optimal storage conditions for medicinal products obtained by biotechnological methods;

4.The educational component structure

Names of content modules and topics	The amount of hours					
	Full-time study					
	the whole amount	including				
		L	Sem	Practical lessons	lab	Self study
<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>	<i>7</i>
Topic 1. Bioobjects and methods of pharmaceutical biotechnology.	12/11	1/1		4/3		7/7
Topic 2. The main stages of the biotechnological process.	13/12	2/2		4/3		7/7
Topic 3. Cellular technologies: objects and methods; ways of use.	10/11	1/1		2/3		7/7

Topic 4. Probiotics. Bacteriophages. General characteristics, drugs, production.	10/11	1/1		2/3		7/7
Topic 5. Biotechnological production of preparations of metabolites of microorganisms.	12/11	1/1		4/3		7/7
Topic 6. Production technology of immunopreparations.	10/11	1/1		2/3		7/7
Topic 7. Hormonal drugs obtained by biotechnological methods. Principles and stages of production, dosage forms. <i>Control of content module 1.</i>	21/20	1/1		4/3		16/16
The whole amount of hours for the content module 1	88/87	8/8		22/21		58/58
Semester credit/semester differential credit from module 1				2/3		
<i>The whole amount of hours for the course</i>	<i>90/90</i>	<i>8/8</i>		<i>24/24</i>		<i>58/58</i>

5. Content of the educational component

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

Topic 1. Bioobjects and methods of pharmaceutical biotechnology.

Biotechnology as a science, its goals and tasks. Definition of biotechnology. The structure of the world biotechnology market.

Basic methods of biotechnology. Dependence of the degree of complexity of production biotechnological processes on the nature of the biological object, the target product, its purpose and dosage form. Characteristics of traditional and modern methods of biotechnology. Concept of cellular and genetic engineering. Their essence and practical use.

Objects of biotechnology. Functions of biological objects. Concept of producers. Requirements for producers of biologically active substances.

Pharmaceutical biotechnology as a component of biotechnology. Manufacturing biotechnological processes that belong to pharmaceutical biotechnology. Types of drugs that are obtained on the basis of biological objects.

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

The main stages of the biotechnological process. Preparatory operations for biosynthesis. Methods and stages of seed preparation. Methods of equipment sterilization. The variety and characteristics of the preparation of nutrient media for the cultivation of producers.

Fermentation as a defining stage of the biotechnological process. Classification of enzymatic processes depending on the method of cultivation. Deep and surface fermentation.

Post-fermentation stages. Isolation and purification of the target product. Methods of separation of bioproducts from culture fluid. Methods of separation of the target product from the culture fluid. Methods of destruction of producer cells and extraction of the target product with its intracellular localization. Methods of concentration of culture fluid and purification of target products. Types of dosage forms of drugs obtained by biotechnological methods.

The main conditions of the biotechnological process.

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

Stages of development of biotechnology of medicinal plants. Objects of study, basic terms and definitions. Directions of development of tissue culture technologies of medicinal plants. Features and methods of cultivation of plant cells and tissues.

Protoplasts: a scheme for obtaining a culture of protoplasts. Application of isolated protoplasts.

Classification of animal tissue cultures. Use of primary and permanent cell cultures. Advantages and disadvantages of using cultures of animal cells and tissues, peculiarities of their cultivation.

Mechanisms of immune response. Concept of antigenic determinants. Advantages of using monoclonal antibodies. Normal and malignant cells: properties and advantages when choosing for cultivation. Emergence of hybridoma technologies. The main stages of hybridoma technology.

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

The purpose of using symbiont microorganisms in medicine. Concept of symbiosis of microorganisms. Variants of symbiosis: mutualism, parasitism, neutralism, commensalism. Human microflora (skin, mucous membranes, gastrointestinal tract). Species composition of normal intestinal microflora and its functions. The role of resident microflora for the host organism.

Medicines based on live cultures of bifido and lactic acid bacteria (lactobacterin, bifidumbacterin, colibacterin and bificol). Types of probiotics. Prebiotics.

Technological process of obtaining probiotic preparations. Requirements for producer strains. The essence of the main stages of production, equipment and methods used. General indicators of the quality of probiotic preparations. Biform production technology.

Bacteriophages. Definition, types of bacteriophages. Mechanism of interaction with a microbial cell. Distinguishing features (specificity, selectivity of action, lack of influence on normal flora). Practical use of bacteriophages. Technological process of obtaining bacteriophages. Indicators of quality control of the finished product.

Topic 5. Biotechnological production of preparations of metabolites of microorganisms.

Metabolites of microorganisms. Primary metabolites. The biological role of amino acids and their use in the pharmaceutical industry and as medicines.

Methods of obtaining amino acids. Microbiological synthesis of amino acids. Creation of amino acid superproducers.

Stages of production of glutamic acid and their features.

Biological role of vitamins. Classification of vitamins. Traditional methods of production (extraction from natural sources and chemical synthesis).

Vitamins B2 (riboflavin), B12, A, C, D. Main producers. Scheme and features of biosynthesis. The stage of bioconversion in the production of vitamin C.

Determination of enzymes. Distinguishing features of enzymes from other BARs. The structure of enzymes, their classification and sources of production.

Production of enzymes from vegetable and animal raw materials, by the method of microbial synthesis. Advantages of microorganisms as producers of enzymes. Technological process of obtaining enzymes by microbial synthesis.

The main parameters and features of solid-phase and suspension cultivation in the production of enzymes. Stages of the technological process and their essence.

Definition of antibiotics. The main features that determine the specificity of antibiotics in comparison with some other products of vital activity of organisms. Classification of antibiotics by origin and nature of action on the bacterial cell.

Methods of obtaining antibiotics. Scheme of industrial production of antibiotics by the method of microbial synthesis. Features of the process and influencing factors. Organisms are producers of antibiotics. Methods of obtaining active strains of producers. Types of nutrient media and their requirements. Seed preparation scheme.

Conditions for the microbiological synthesis of antibiotics and processes characteristic of the trophophase and idiophase of the development of producers.

Methods of separation of culture liquid from biomass, isolation of antibiotic from culture medium, cleaning and drying of the product. Obtaining a ready dosage form of an antibiotic. Indicators of the quality of antibiotic preparations.

Topic 6. Production technology of immunopreparations.

The subject and tasks of immunobiotechnology. Types of immunobiological drugs.

Immunobiological preparations for creating artificial active immunity. Classification of vaccines. The main stages of the technological process of manufacturing live, killed, antiviral vaccines, toxoids. Vaccine control indicators. Examples of vaccine preparations.

Immunobiological drugs that form artificial passive immunity. Types of serums. The main stages of the manufacturing process of hyperimmune heterologous serum.

Immunoglobulins. Types of immunoglobulins (homologous, heterologous). Technology for obtaining specific plasma immunoglobulins. Types of modern immunoglobulin preparations.

Monoclonal antibodies, methods of obtaining.

Quality indicators that are controlled in sera and immunoglobulins.

Topic 7. Hormonal drugs obtained by biotechnological methods. Principles and stages of production, dosage forms.

Methods of obtaining hormones. Hormones obtained by biotechnological methods.

Insulin, characteristics, origin, structure, production methods (synthetic-enzymatic, genetic-engineering), their essence. The method of obtaining human insulin using a recombinant microorganism. Technological scheme of production. Insulin preparations obtained by genetic engineering. Specific indicators of insulin quality.

Somatotropic hormone, characteristics, methods of obtaining. Stages of the genetic engineering method of obtaining a hormone. Stages of industrial production of the somatotropic drug and its quality indicators. Medicinal forms of somatotropin.

Hormones that are obtained by the method of microbiological transformation: progestins, sex hormones and hormones of the adrenal cortex (corticosteroids). Raw material sources, general principles of biotransformations, types of used microorganisms-transformers. Examples of dosage forms of steroid hormones.

Control of content module 1 is carried out in order to check the level of assimilation of theoretical material, acquisition of practical skills and skills from the educational component. Theoretical knowledge is controlled by a written answer to a theoretical question. Control of practical skills is carried out by solving test tasks.

Semester control of module 1 is conducted in the form of a semester undifferentiated assessment.

6. Topics of lectures

№	Topic name	The amount of hours
		Full-time study
1	Topic 1. Biobjects and methods of pharmaceutical biotechnology.	1
2	Topic 2. The main stages of the biotechnological process.	2
3	Topic 3. Cellular technologies: objects and methods; ways of use.	1
4	Topic 4. Probiotics. Bacteriophages. General characteristics, drugs, production.	1
5	Topic 5. Biotechnological production of preparations of metabolites of microorganisms.	1
6	Topic 6. Production technology of immunopreparations.	1
7	Topic 7. Hormonal drugs obtained by biotechnological methods. Principles and stages of production, dosage forms.	1
The whole amount of hours		8

7. Topics of seminars

Not provided for in the working program.

8. Topics of practical lessons

№	Name of topic	The amount of hours
		Full-time study
1	Topic 1. Biobjects and methods of pharmaceutical biotechnology.	4/3
2	Topic 2. The main stages of the biotechnological process.	4/3
3	Topic 3. Cellular technologies: objects and methods; ways of use.	2/3
4	Topic 4. Probiotics. Bacteriophages. General characteristics, drugs, production.	2/3
5	Topic 5. Biotechnological production of preparations of metabolites of microorganisms.	4/3
6	Topic 6. Production technology of immunopreparations.	2/3

7	Topic 7. Hormonal drugs obtained by biotechnological methods. Principles and stages of production, dosage forms. <i>Control of content module 1.</i>	4/3
8	Semester control (semester assessment).	2/3
	The whole amount of hours	24/24

9. Topics of laboratorial lessons

Not provided for in the working program.

10. Self-study work

№	Topic name	The amount of hours
		Full-time study
1	Topic 1. Bioobjects and methods of pharmaceutical biotechnology. The structure of the world biotechnology market. The most developed companies and their areas of specialization regarding medicinal products and their fields of application.	7
2	Topic 2. The main stages of the biotechnological process. Dependence of the degree of complexity of production biotechnological processes on the nature of the biological object, the target product, its purpose and dosage form. Methods of equipment sterilization. The variety and characteristics of the preparation of nutrient media for the cultivation of producers.	7
3	Topic 3. Cellular technologies: objects and methods; ways of use. Stages of development of biotechnology of medicinal plants. Directions of development of tissue cultures of medicinal plants. Advantages and disadvantages of using cultures of animal cells and tissues. Normal cells and cells of malignant neoplasms: properties and emergence of hybridoma technologies.	7
4	Topic 4. Probiotics. Bacteriophages. General characteristics, drugs, production. Species composition of normal intestinal microflora in different periods of human life and its functions. The role of resident microflora for the host organism. Improvement of medicinal forms of bacteriophages. Indicators of quality control of the finished product.	7
5	Topic 5. Biotechnological production of metabolites of microorganisms. The biological role of amino acids and their use in the pharmaceutical industry and as medicines. Creation of amino acid superproducers. Biological role of vitamins. Classification of vitamins. Traditional methods of production (extraction from natural sources and chemical synthesis). Distinguishing features of enzymes from other BARs. Structure of enzymes. Peculiarities of solid-phase and suspension cultivation in the production of enzymes. Classifications of antibiotics. Classification of antibiotics according to the nature of action on the bacterial cell. Methods of obtaining active strains of producers. Types of nutrient media and their requirements.	7
8	Topic 6. Production technology of immunopreparations. Types of modern immunoglobulin preparations.	7
9	Topic 7. Hormonal drugs obtained by biotechnological methods. Principles and stages of production, dosage forms. Hormones that are obtained by the method of microbiological transformation: progestins, sex hormones and hormones of the adrenal cortex (corticosteroids). Raw material sources, general principles of biotransformations, types of used microorganisms-transformers. Examples of dosage forms of steroid hormones.	16

Control of content module 1. Preparation for control of content module 1. Semester control is conducted in the form of a semester assessment.	
The whole amount of hours	58

Tasks for self-study work

1. Elaboration of lecture material and preparation for practical classes.
2. Familiarization with the history of the development of cell technologies and the contribution of modern scientists to the development of plant and animal cell biotechnology.
3. Learning how to create aseptic conditions when working with biological objects (preparation of air, premises, equipment, personnel).
4. Acquaintance with the types of nutrient media for the cultivation of cells and tissues, their constituent components. Learn the differences in media for plant and animal cell lines.
5. Acquaintance with the history of the emergence and use of probiotics and bacteriophages.
6. Learning modern methods of biological determination of bacteriophage activity.
7. Familiarization with the mechanisms of intensification of the processes of obtaining products of cellular metabolism.
8. Familiarization with the development of biotechnological methods of obtaining enzymes.
9. Familiarization with the principles of composition and preparation of nutrient media for the cultivation of BAR-producing microorganisms.
10. Acquaintance with the history of the discovery of antibiotics and the contribution of modern scientists to the development of biotechnological methods of obtaining antibiotics.
11. Acquaintance with the history of the creation of immunopreparations.
12. Learning the reactions of immunity, their role in the immune response and diagnosis of infectious diseases.
13. Familiarization with the development of blood fractionation methods.
14. Learning ways to ensure the safety of blood products.
15. Familiarization with the history of the creation of insulin production technology.
16. Familiarization with innovative technologies in the production of drugs based on hormones by biotechnological methods.

11. Criteria and evaluation order of educational outcomes

The criteria for evaluating the knowledge and skills of higher education students from the educational component "Fundamentals of research in biotechnology" were developed in accordance with the "Regulations on the procedure for evaluating the results of higher education students at the National Pharmaceutical University A2.2-25-031-B".

The evaluation 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.

Criteria for evaluating the knowledge and skills of students of higher education in correspondence form of education in laboratory and seminar classes

Assessment of current educational activities (held during each lesson) – control of theoretical knowledge, practical skills and abilities. When mastering each topic of the content modules for the current educational activity, higher education applicants are awarded points for all types of activities, which are added up at the end of studying the content module.

Evaluation criteria	Scores
1	2
➤ showed a comprehensive and deep knowledge of theoretical material on the topic of the class, which is set out in the texts of lectures, compulsory and	7.0

<p>additional literature, gave comprehensive answers to theoretical questions of the teacher</p> <ul style="list-style-type: none"> ➤ answered 90%-100% of the test tasks correctly; ➤ has studied the methodological recommendations for the practical lesson and mastered the methodology of practical work; ➤ correctly completed the practical task; ➤ correctly formulated conclusions based on the results of the work performed. 	
<ul style="list-style-type: none"> ➤ showed full knowledge of the theoretical material on the topic of the class, which is set out in the texts of lectures, compulsory and additional literature, and answered theoretical questions of the teacher with minor deficiencies; ➤ correctly answered 74%-89% of the test tasks; ➤ has worked out the methodological recommendations for the practical lesson, but has not fully mastered the methodology of practical work; ➤ correctly completed the practical task, but made minor mistakes that do not affect the quality of the result; ➤ formulated conclusions based on the results of the work performed with minor inaccuracies. 	6.0
<ul style="list-style-type: none"> ➤ showed knowledge of theoretical material on the topic of the lesson to the extent that is considered necessary and sufficient to apply knowledge in standard situations; ➤ answered theoretical questions with errors that were corrected with the help of the teacher; ➤ correctly answered 60%-73% of the test tasks; ➤ did not work out the methodological recommendations for the practical lesson in full, made gross mistakes in teaching the methodology of practical work; ➤ correctly completed the practical task, but with the help of the teacher, needs to rely on the sample; ➤ made mistakes in formulating conclusions based on the results of the work performed. 	5.0
<ul style="list-style-type: none"> ➤ did not familiarize himself with the theoretical material on the topic of the class, which is set out in the texts of lectures, compulsory and additional literature; ➤ did not answer theoretical questions of the teacher; ➤ answered less than 60% of the test tasks correctly; ➤ performed certain methodological actions incorrectly, performed the task not independently (following the instructor's instructions) or not in full; ➤ did not formulate conclusions based on the results of the work performed. 	0-4.0

The independent work of a higher education student is monitored during each practical lesson, during the control of the content module.

In the event that the applicant comes to class unprepared, he or she must be present at the class. After working with the recommended literature and / or electronic sources on the topic of the lesson and an individual conversation with the teacher on the topic of the lesson, the higher education applicant is allowed to practice.

The sum of the points of the current control is the sum of the points received by the higher education applicant during the study of all topics of the module and the control of the content module on the educational component.

Criteria for evaluating the knowledge and skills of higher education applicants on the control of the content module

Candidates of higher education who have completed all types of work provided for in the curriculum and have scored at least the minimum number of points while studying the topics of the content module are admitted to the control of the content module (CCM). CCM is carried out in the last lesson of the content module and is evaluated in points.

Evaluation criteria	Scores
<p><i>theoretical task:</i></p> <ul style="list-style-type: none"> ➤ gave a comprehensive answer to the theoretical question; <p><i>practical task:</i></p> <ul style="list-style-type: none"> ➤ answered 90-100% of the test questions; 	43-51

<p>theoretical task:</p> <ul style="list-style-type: none"> ➤ gave a correct but incomplete answer to a theoretical question; <p>practical task:</p> <ul style="list-style-type: none"> ➤ answered 74-89% of test questions; 	34-42
<p>theoretical task:</p> <ul style="list-style-type: none"> ➤ gave answers to theoretical questions with errors or not at all; <p>practical task:</p> <ul style="list-style-type: none"> ➤ answered 60-73% of test questions; 	25-33
<p>theoretical task:</p> <ul style="list-style-type: none"> ➤ did not answer the theoretical question; <p>practical task:</p> <ul style="list-style-type: none"> ➤ answered less than 60% of the test questions. 	0-24

For those applicants who want to improve their performance in the educational component on the ECTS scale and increase the rating of the module, this is possible at the last session of the module during the semester assessment.

Scheme of accrual and distribution of points

Current control and independent work								
Content module 1								
T1	T2	T3	T4	T5	T6	T7	T7	Sem. con.
PL1	PL2	PL3		PL4	PL5		PL6 CCM1	PL7
4-7	4-7	4-7	4-7	12-18	4-7	4-7	24-40	
60.0-100.0								

T1, T2 ... T7 – topics of the module.

PL1 ...PL7 - numbers of seminar classes.

CCM.. – control of the content module.

Semester control - semester control.

12.Forms of progress and semester supervision of academic achievements

Current control is conducted during each laboratory and seminar session in accordance with specific goals and during the 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.

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

Content module control is held in 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 held at the last lesson of the module.

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 at the last lesson of the module during the semester assessment.

Form of control- semester credit

13.Methodological support

1. Educational work program of the educational component.
2. Work program of the educational component.
3. Syllabus of the educational component.
4. Calendar plan of lectures and practical classes.
5. Lectures in multimedia format.

6. Videos on topics.
7. Interactive teaching methods (transfer of information, discussion, learning about processes, problem solving, simulation and non-simulation technologies, etc.)
8. Methodological recommendations on the topics of practical classes.
9. Test tasks for current knowledge control.
10. Tasks for independent work.
11. Questions for preparation for the control of content modules.
12. Training equipment, technical means of training.

15. Reading suggestions

The main reading suggestions

1. Pharmaceutical Biotechnology in Drug Development / Muhammad Sajid Hamid Akash. – Academic press, 2023.

Supplementary reading suggestions

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: 10.2174/138920111798377120.
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.

16 Electronic resources, including the Internet

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