MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS
Educational Institution
«BELARUSIAN STATE MEDICAL UNIVERSITY»

Контрольный экземпляр

APPROVED
by Rector of the Educational Institution «Belarusian State Medical University»
_____ S.P.Rubnikovich
01.12.2025
Reg. # UD-0912-01-33/2526/edu.

PHARMACEUTICAL BIOTECHNOLOGY

Curriculum of the educational institution in the academic discipline for the specialty

7-07-0912-01 «Pharmacy»

2025

Curriculum is based on the educational program «Pharmaceutical Biotechnology», approved 26.06.2025, registration # УД-0912-01-33/2526/уч.; on the educational plan in the specialty 7-07-0912-01 «Pharmacy», approved 16.04.2025, registration # 7-07-0912-01/2526/mf.

COMPILERS:

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RECOMMENDED FOR APPROVAL:

by the Department of Pharmaceutical Technology with advanced training and retraining course of the Educational Institution «Belarusian State Medical University»
(protocol # 14 of 16.05.2025);

by the Scientific and Methodological Council of the Educational Institution «Belarusian State Medical University»
(protocol # 10 of 26.06.2025)

EXPLANATORY NOTE

«Pharmaceutical Biotechnology» – the educational discipline of the module «Pharmaceutical Technology», which contains systematic scientific knowledge about the methods of obtaining medicines using biological systems and processes.

The purpose of the educational discipline «Pharmaceutical Biotechnology» is the formation of specialized competencies for students to participate in the industrial production of medicines, including biological (immunobiological) medicines.

The objectives of the educational discipline «Pharmaceutical Biotechnology» are to form students' scientific knowledge about biological objects as means of production of medicinal products, methods of their improvement; a typical scheme of biotechnological production; the main groups of biotechnological medicinal products and their production technologies based on the vital activity of microorganisms, animal and plant cells; the influence of various parameters on the efficiency of the technological process and the quality of the final product; skills and abilities necessary for the implementation of technological processes for the production of biotechnological medicines; assessment of the quality of raw materials, nutrient media, intermediates and target products; regulation and improvement of the biotechnological process in order to obtain a high-quality final product; assessment of compliance of biotechnological production with GMP rules, environmental safety requirements, in relation to the used on the production of bio-producing objects and target products. Нет в программе на русском

Relations to other educational disciplines

The knowledge, skills, and abilities acquired during the study of the educational discipline «Pharmaceutical Biotechnology» are necessary for the successful study of the following academic disciplines: «Industrial Technology of Drugs», «Pharmaceutical Development with the Fundamentals of Biopharmaceutics», «Standardization of Medicines», «Pharmaceutical Ecology».

Studying the educational discipline «Pharmaceutical Biotechnology» should ensure the formation of students' specialized competency: take part in the industrial production of medicines and biologically active food additives.

As a result of studying the educational discipline «Pharmaceutical Biotechnology» the student should

know:

basic terms and concepts of biotechnology;

bio-objects and methods of their improvement;

the main groups of medicines obtained by methods of biotechnology (biotechnological medicines);

a typical scheme of biotechnological production;

technologies for the production of medicines based on the vital activity of microorganisms, animal and plant cells;

innovative ways to create medicines based on the use of genomics, proteomics and bioinformatics data;

be able to:

to take into account the influence of various factors on the efficiency of the technological process and the quality of the final product, to maintain optimal conditions for the biosynthesis of the target product;

to ensure the conditions for the aseptic conduct of the biotechnological process and its compliance with modern requirements for the organization of production;

to substantiate the technological and equipment design of biotechnological production;

use regulatory and technical legal acts regulating the production and quality assurance of medicines obtained by biotechnological methods;

ensure compliance with the rules of industrial hygiene, environmental protection, occupational safety and health;

master:

the nomenclature of medicines obtained by biotechnological methods;

basic methods of modern experimental biotechnology used for drug biosynthesis;

the technology of manufacturing nutrient media for fermentation;

the skills of calculating the modes of sterilization of nutrient media for industrial fermentation;

the rules for choosing the fermentation method and the process hardware, depending on the type of producer (microorganisms, isolated plant or animal cells);

practical skills in working with regulatory and technical regulations governing the production and quality assurance of medicines obtained by biotechnological methods.

Total number of hours for the study of the discipline is 120 academic hours, of which 72 classroom hours and 48 hours of student independent work. Classroom hours according to the types of studies: lectures – 21 hours (including 6 hours of supervised student independent work (SSIW)), laboratory classes –51 hours.

Intermediate assessment is carried out according to the syllabus of the specialty in the form of examination (6 semester).

Form of higher education – full-time.

ALLOCATION OF ACADEMIC TIME ACCORDING TO SEMESTERS OF STUDY

Code, name of the specialty	Semester	Total number of academic hours	Number of classroom hours				Out-of-class self-studies	Form of intermediate assessment
			Number of classroom hours	including				
				class lectures	SSIW	laboratory		
7-07-0912-01 «Pharmacy»	6	120	72	15	6	51	48	Examination

THEMATIC PLAN

Section (topic) name	Number of class hours	
	lectures (incl. SSIW)	laboratory
1. General issues of pharmaceutical biotechnology	**10,5**	**30**
1.1. Pharmaceutical biotechnology as a science and field of production	1,5	3
1.2. Improvement of biological objects	3	6
1.3. Genomics and proteomics. Medicines for gene therapy	1,5	3
1.4. Molecular mechanisms of intracellular regulation of metabolism and their use in the biosynthesis of target products	1,5	6
1.5. The biotechnological process of drug production and its features	1,5	12
1.6. Post-fermentation stages: isolation, concentration and chemical purification of the target product	1,5	
2. Biotechnology of medicines	**10,5**	**21**
2.1. Biotechnology of antibiotics, probiotics, amino acids	1,5	3
2.2. Production of enzyme preparations and vitamins	1,5	3
2.3. Biotechnology of recombinant proteins (using the example of protein and polypeptide hormones)	1,5	3
2.4. Biotechnology of steroid hormones	1,5	3
2.5. Immunobiotechnology	1,5	6
2.6. Interferons and interleukins: biological role, methods of production	1,5	
2.7. Features of cell culture in advanced complex eukaryotes. Phytobiotechnology	1,5	3
Total hours	**21**	**51**

CONTENT OF THE EDUCATIONAL DISCIPLINE

1. General issues of pharmaceutical biotechnology

1.1. Pharmaceutical biotechnology as a science and field of production

The main stages of biotechnology development. The relationship between biotechnology and fundamental disciplines. General characteristics of medicines obtained by biotechnology methods. Classification of biological objects. Microorganisms as a biological objects. The microbial cell as the main biological agent of biotechnology, its advantages. Macrobioobjects of animal origin. Biological objects of plant origin. Enzymes and multienzyme complexes in biotechnological production.

1.2. Improvement of biological objects

The genetic basis for the improvement of biological objects.

Traditional methods: selection. Spontaneous mutations and directed mutagenesis. Mutagens, the mechanism of their action. Types of mutations.

Genetic engineering as a field of knowledge about the purposeful change of the properties of biological objects. Sections of genetic engineering: genomic, chromosomal, genetic engineering.

Cellular engineering as the main direction of genomic engineering. The use of cellular engineering methods to create new biological active substances (BAS) products. Protoplast fusion technology and its capabilities. Cellular engineering of animal cells. Hybridomas, importance for the production of modern medicines.

Genetic engineering. The basic principles and stages of deoxyribonucleic acid (DNA) recombination technology. Enzymes used in genetic engineering: restrictases, DNA polymerase, reverse transcriptase, DNA ligase, alkaline phosphatase, terminal transferase.

Search and identification of the structural gene encoding the target product. Determination of the nucleotide sequence by analyzing the amino acid sequence of the protein molecule encoded by the gene. DNA sequencing, basic principles and methods: chemical according to Maxam and Gilbert, enzymatic Sanger method, hybridization method, chip method, pyrosequencing.

Preparation and development of the gene encoding the target product: the restrictase method, synthesis based on mRNA (messenger ribonucleic acid), solid-phase chemical-enzymatic synthesis from deoxyribonucleotides followed by amplification in polymerase chain reaction (PCR).

Creation of recombinant DNA. Methods of joining DNA fragments: restriction-ligase method of ‘sticky ends’, connector method, linker method. Vector in recombinant DNA technology: purpose, basic principles of action. Requirements for vector molecules. Classification of vectors by function: cloning, expressing, integrative. Types of vectors: plasmids, vectors based on the DNA of bacteriophages and other viruses, cosmids, phasmids, transposons, shuttle vectors. Classification of vectors by recipient systems.

The main methods of introducing recombinant DNA into the target cell are natural (conjugation, transduction) and artificial (transformation, transfection). Chemical and biochemical methods for increasing the permeability of cell walls in cells of various organisms.

Identification and selection of cells carrying recombinant DNA. Marker genes: selective and reporter, their role and characteristics. The method of inactivating the insertion marker.

Problems of expression of foreign genes in recombinant cells and ways to overcome them. Regulation of gene expression in prokaryotes and eukaryotes.

Genomic libraries: purpose, varieties, basic principles and methods of creation. Screening and methods of identification of the target gene in the clone database of the genomic library.

The concept of superproducers: causes of instability, ways to maintain activity. Molecular mechanisms of protection of the producer cell from a toxic target product. Problems of stabilization of industrial strains.

Immobilized biological objects. Methods of immobilization of biological objects, media used. The use of immobilized biological objects to obtain target products.

Methods and basic principles of conservation of various biological objects; rules for their storage and transportation. International and national collections of cultures of plant, animal cells and individual strains of microorganisms, their importance for the development of biotechnology.

1.3. Genomics and proteomics. Medicines for gene therapy

The main directions of development and importance for medicine and pharmacy. Antisense nucleic acids – molecular aspects of their biological activity and application prospects. Bioinformatics. The use of information technology and artificial intelligence in biotechnology. Medicines for gene therapy of hereditary and non-hereditary diseases.

1.4. Molecular mechanisms of intracellular regulation of metabolism and their use in the biosynthesis of target products

Induction and repression of enzyme synthesis. Inhibition of enzymes based on the feedback principle. Retroinhibition of the metabolic product. Strict amino acid control of the metabolism of microorganisms (stringent response phenomenon). Regulation of assimilation of nitrogen-containing compounds. Catabolic repression. Intracellular transport and secretion of biotechnological products in microorganisms.

1.5. The biotechnological process of drug production and its features

The stages of the biotechnological process, the goals and objectives of each stage. Raw materials and nutrient substrates in the production of medicines. Molecular mechanisms of the influence of errors in the composition of nutrient media on the metabolism of producers.

Equipment for cultivation of BAS producers. Fermenter (bioreactor): device, types of fermenters. The criterion for selecting enzymes for the implementation of specific goals.

Pre-fermentation stages: preparation and sterilization of nutrient media; preparation of technological equipment and air.

Fermentation. Deconservation, scaling and cultivation of seed material. Types of fermentation processes and their implementation. The conditions of the process. Processing of culture liquid is the preliminary stage of isolation of the target product.

1.6. Post-fermentation stages: isolation, concentration and chemical purification of the target product

Post-fermentation stages: isolation of the target product by extraction, precipitation, ion exchange method. Concentration and chemical purification of the target product (ultrafiltration, gel filtration, chromatographic methods, etc.).

The main parameters of control and management of biotechnological processes.

Environmental aspects of biotechnological production of BAS. Disposal of liquid, solid and gaseous waste from industrial biotechnology. Biotechnological methods of wastewater treatment.

2. Biotechnology of medicines

2.1. Biotechnology of antibiotics, probiotics, amino acids

The biological role of antibiotics as secondary metabolites. The origin of antibiotics and the evolution of their functions. Methods of creating antibiotic products and ways to increase their productivity. Mechanisms for protecting super-producers from their own antibiotics. Bacterial antibodies. Actinomycete antibiotics.

Antibiotics of mycelial fungi. Semi-synthetic antibiotics. Industrial production of anti-biotics using the example of penicillin. Equipment design and conditions of the processes. Mechanisms of bacterial resistance to antibiotics. Targeted biotransformation and chemical transformation of β-lactam structures. New generations of cephalosporins, penicillins, effective against resistant microorganisms. Carbapenems. Monobactams. Combined drugs: amoxicillin and clavulanic acid, cefotaxime and sulbactam, piperacillin and tazobactam, ceftazidim and avibactam. Biosynthesis and organosynthesis in the creation of new antibiotics. Antitumor antibiotics.

The resident microbiota of the gastrointestinal tract. The causes of dysbiosis. Probiotics in the fight against dysbiosis. Bifidobacteria, lactic acid bacteria. Non-pathogenic strains of E. coli that produce bactericides. Obtaining ready-made forms of probiotics. Monopreparations and preparations based on mixed cultures.

The biological role of amino acids. Areas of application of amino acids as medicines. Methods of obtaining amino acids. Producers of amino acids. General principles of designing amino acid producing strains to ensure supersynthesis of the target product. Biosynthesis of glutamic acid. Production of L-amino acids from racemic mixtures. Production of L-aspartic acid.

2.2. Production of enzyme preparations and vitamins

Enzymes produced by microbial cells: proteases, amylases, lipases, etc. Methods of obtaining, isolating and standardizing. Immobilized enzymes as industrial biocatalysts, scope of application. Carriers for enzyme immobilization, methods of immobilization.

The biological role of vitamins. Traditional methods of production: isolation from natural sources and chemical synthesis. Microbiological synthesis of vitamins and its advantages. Producers, biosynthesis schemes (for example, vitamins B2, B12, vitamin C, ergosterol and vitamins of group D). Intensification of biosynthesis.

2.3. Biotechnology of recombinant proteins (using the example of protein and polypeptide hormones)

The construction of recombinant producer strains and the production of protein and polypeptide hormones with their help. Insulin. Extraction from animal raw materials, species specificity, problems of shortage of raw materials. Genetically engineered human insulin. The technology of obtaining genetically engineered human insulin through proinsulin and synthesis of individual chains. Human growth hormone: production by recombinant microorganisms.

2.4. Biotechnology of steroid hormones

Traditional sources of steroid hormones. Advantages of biotransformation over chemical transformation. Strains of microorganisms with the ability to transform (bioconversions) steroids. Microbiological synthesis of hydrocortisone, obtained from it by bioconversion of prednisone. Industrial implementation of the biotransformation process of steroids.

2.5. Immunobiotechnology

The main components and ways of functioning of the immune system. Types of immunity: specific and nonspecific, cellular and humoral, innate and acquired. Strengthening the immune response with the help of immunopreparations.

Classification of immunotropic drugs depending on the nature of the effect on the immune system.

Classical and modern vaccines: classification, characteristics, production technology. Medicines for the treatment and prevention of viral AIDS (acquired immunodeficiency syndrome).

Immunoglobulin preparations (polyclonal antibodies). The characteristics. The technology of obtaining. Areas of application.

Monoclonal antibodies. Obtaining using hybrid and genetically engineered technologies. The use of monoclonal antibodies in the diagnosis and therapy of diseases. The use of monoclonal antibodies to ensure targeted delivery of active substances molecules to target organs. Receiving immunotherapeutic thrombolytics and anticoagulants, anticancer drugs.

2.6. Interferons and interleukins: biological role, methods of production

Interferons. Classification, functions in the body, inducers of interferons. Methods of obtaining human interferons.

Interleukins. The biological role. Methods of production.

2.7. Features of cell culture in advanced complex eukaryotes. Phytobiotechnology

Concepts of the Hayflick limit, immortal cells, and totipotency. Cultivation of plant cells and tissues. Cultures of callus cells. Phytohormones: classification, biological role. The use of special vectors in plant DNA recombination technology. Preparation of drugs using plant cell cultures.

EDUCATIONAL DISCIPLINE «PHARMACEUTICAL BIOTECHNOLOGY» CURRICULAR CHART

Section, topic #	Section (topic) name	Number of class hours		Supervised student independent work	Literature	Practical skills	Form of control	
		lectures	laboratory				of practical skills	of current / intermediate assessment
6 semester								
	Lectures	**15**	**-**	**6**				
1.	Pharmaceutical biotechnology as a science and a field of production	1,5	-	-	1, 3, 4, 12			
2.	Improvement of biological objects by methods of selection, directed mutagenesis, and cellular engineering	1,5	-	-	2, 3, 4, 12			
	Improvement of biological objects by methods of genetic engineering. Study of the basic principles of recombinant DNA technology	1,5	-	-	1, 2, 3, 4, 12			
3.	Genomics and proteomics. Medicines for gene therapy	-	-	1,5	8, 9, 12			Computer testing
4.	Molecular mechanisms of intracellular regulation of metabolism of biological objects and their use in biosynthesis of target products	1,5	-	-	3, 4, 12			
5.	The biotechnological process of drug production and its features	1,5	-	-	1, 5, 6, 10,11, 12			
6.	Post-fermentation stages: isolation, concentration and chemical purification of the target product	-	-	1,5	1, 5, 6, 12			Presentation, report
7.	Biotechnology of antibiotics, probiotics, amino	1,5	-	-	3, 4, 5,			

	acids				12			
8.	Production of enzyme preparations and vitamins	-	-	1,5	3, 4, 6, 12			Presentation, report
9.	Biotechnology of recombinant proteins (using the example of protein and polypeptide hormones)	1,5	-	-	3, 4, 6, 12			
10.	Biotechnology of steroid hormones	1,5	-	-	5, 6, 12			
11.	Immunobiotechnology	1,5	-	-	1, 4, 7, 12			
12.	Interferons and interleukins: biological role, methods of production	-	-	1,5	1, 4, 7, 12			Computer testing
13.	Features of cell culture in advanced complex eukaryotes. Phytobiotechnology	1,5	-	-	3, 4, 12			
	Laboratory lessons	**-**	**51**	**-**				
1.1	Pharmaceutical biotechnology as a science and field of production	-	3	-	3, 4, 12	Possession of the nomenclature of medicines obtained by biotechnological methods	Report on laboratory work with oral defense	Testing
1.2	Improvement of biological objects by methods of selection, directed mutagenesis, and cellular engineering	-	3	-	1, 2, 3, 4, 12	The use of bioinformatics resources in the integrated EMBL-EBI database to address issues of genomics and proteomics of a specific biological object	Report on laboratory work with oral defense	Express-interview
	Improvement of biological objects by methods of genetic engineering. Study of the basic principles of recombinant DNA technology		3					Defense of the abstract (report)
1.3	Genomics and proteomics. Medicines for gene therapy	-	3	-	8, 9, 12	The use of bioinformatics resources in the integrated EMBL-EBI database to address issues of genomics and	Report on laboratory work with oral defense	Interview

						proteomics of a specific biological object		
1.4	Molecular mechanisms of intracellular regulation of metabolism of biological objects and their use in the biosynthesis of target products		3					Defense of the abstract (report)
	Final lesson on topics «Improvement of biological objects by methods of selection, directed mutagenesis, and cellular engineering», «Improvement of biological objects by methods of genetic engineering. Study of the basic principles of recombinant DNA technology», «Genomics and proteomics. Medicines for gene therapy», «Molecular mechanisms of intracellular regulation of metabolism of biological objects and their use in the biosynthesis of target products»	-	3	-	2, 3, 4, 8, 9, 12			Interview, situational problem solving*, colloquium
1.5	The biotechnological process of drug production and its features. Pre-fermentation stages	-	3	-	1, 5, 6, 10, 11, 12	Organization and provision of conditions for the aseptic conduct of the biotechnological process. Compliance with the rules of industrial hygiene, occupational safety and health	Report on laboratory work with oral defense	Interview
	The biotechnological process of drug production and its features. Fermentation	-	3	-	1, 5, 6, 10, 11, 12	Calculation of the qualitative and quantitative composition of nutrient media for fermentation.	Report on laboratory work with oral defense	Testing

						Calculation of sterilization modes of nutrient media for industrial fermentation. Calculation of filter media parameters (pore size) for purification of liquid nutrient media from mechanical impurities		
1.6	The biotechnological process of drug production and its features. Post-fermentation stages	-	3	-	1, 5, 6, 10, 11, 12	Determination and selection of the fermentation method depending on the type of producer (microorganisms, isolated plant or animal cells). The use of technical documentation for the selection and operation of hardware and instrumentation for fermentation, depending on the type of producer	Report on laboratory work with oral defense	Colloquium, interview, situational problem solving *
	Final lesson on topics «The biotechnological process of drug production and its features. Pre-fermentation stages», «The biotechnological process of drug production and its features. Fermentation», «The biotechnological process of drug production and its features. Post-fermentation stages»	-	3	-	1, 5, 6, 10, 11, 12			
2.1	Biotechnology of antibiotics, probiotics, amino acids	-	3	-	3, 4, 5, 12	Work with regulatory and technical regulations governing the production and quality assurance of medicines obtained by biotechnological methods	Report on laboratory work with oral defense	Control work

2.2	Production of enzyme preparations and vitamins	-	3	-	3, 4, 6, 12			Defense of the report
2.3	Biotechnology of recombinant proteins (using the example of protein and polypeptide hormones)	-	3	-	3, 4, 6, 12	Assessment of the possibility of using biotechnology methods for the biosynthesis of various drugs	Laboratory work with oral defense	Defense of the abstract (report)
2.4	Biotechnology of steroid hormones	-	3	-	5, 6, 12	Assessment of the possibility of using biotechnology methods for the biosynthesis of various drugs	Report on laboratory work with oral defense	Situational problem solving
2.5	Immunobiotechnology. Immunoglobulin preparations (polyclonal antibodies): characteristics, technology, field of application. Technology of traditional and modern vaccines. Medicines for the treatment and prevention of viral AIDS	-	3	-	4, 7, 12	Work with regulatory and technical regulations governing the production and quality assurance of medicines obtained by biotechnological methods	Report on laboratory work with oral defense	Testing
2.6.	Immunobiotechnology. Technology of monoclonal antibodies. Receiving immunotherapeutic thrombolytics and anticoagulants, anti-cancer drugs. Interferons and interleukins: biological role, production methods	-	3	-	4, 7, 12	Work with regulatory and technical regulations governing the production and quality assurance of medicines obtained by biotechnological methods	Report on laboratory work with oral defense	Testing
2.7	Features of cell culture in advanced complex eukaryotes. Phytobiotechnology	-	3	-	3, 4, 12	Assessment of the possibility of using biotechnology methods for the biosynthesis of various drugs	Report on laboratory work with oral defense	Control work
	Total hours:	**15**	**51**	**6**				Exam

*This is a mandatory form of current certification.

INFORMATION AND INSTRUCTIONAL UNIT

LITERATURE

Basic (relevant):

1. Pharmaceutical Biotechnology : Fundamentals and Applications / V. Adams, R. R. Alloway, J. M. Beals [et al.]; edited by J. A. Daan, R. D. Crommelin, B. M. Sindelar. – Springer, 2024. – 707 p.

Additional:

2. Technological process organization in biotechnological industry : study guide / N. S. Golyak – Minsk : BSMU, 2021. – 24 p.

3. Objects and methods of pharmaceutical biotechnology : study guide / N. S. Golyak – Minsk : BSMU, 2021. – 28 p.

4. Glick, Bernard R. Molecular biotechnology : principles and applications of recombinant DNA / Bernard R. Glick, Jack J. Pasternak, and Cheryl L. Patten. – 6th ed. – ASM Press, 2022. – 896 p.

5. Wittmann, C. Industrial Biotechnology : Microorganisms (Advanced Biotechnology Book 3) / C. Wittmann, J. C. Liao. – Wiley, 2017. – 724 p.

6. Wittmann, C. Industrial Biotechnology: Products and Processes (Advanced Biotechnology Book 4) / C. Wittmann, J. C. Liao. – Wiley, 2016. – 605 p.

7. Plotkin's Vaccines / S. A. Plotkin, W. A. Orenstein, P. A. Offit [et al.] – Elsevier, 2018. – 2331 p.

8. Brown, T. A. Gene Cloning and DNA Analysis : An Introduction / T. A. Brown. –Wiley-Blackwell, 2016. – 376 p.

9. National Center for Biotechnology Information. GenBank Overview (https://www.ncbi.nlm.nih.gov/genbank/)

Normative regulatory acts:

10. European Medicine Agency. Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Public Health. EudraLex - Volume 4 – 2018.

11. WHO good manufacturing practices: main principles for pharmaceutical products. In: WHO guidelines, good practices, related regulatory guidance and GXP training materials, Geneva, World Health Organization, 2016

Electronic courseware for the educational discipline «Pharmaceutical Biotechnology»:

12. https://etest.bsmu.by/course/view.php?id=950.

METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF STUDENT INDEPENDENT WORK IN THE ACADEMIC DISCIPLINE

The time allocated for independent work can be used by students for:

preparing for lectures and laboratory classes;

preparing for colloquiums, tests and exam in the academic discipline;

studying the topics (issues) designed for independent work;

problem solving;

preparing thematic reports, abstracts, presentations;

performing practical tasks;
compiling a review of scientific literature on a given topic;
execution of information and demonstration materials (stands, posters, graphs, tables, newspapers, etc.);
making models, laboratory teaching aids;
compilation of a thematic selection of literature sources, Internet sources.

METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF SUPERVISED STUDENT INDEPENDENT WORK IN THE ACADEMIC DISCIPLINE

Approximate list of tasks for supervised student independent work:

preparation and presentation of abstracts;
presentation of reports;
studying topics and problems that have not been discussed at the lectures;
computer testing.

Forms of control of supervised student independent work:

computer testing;
presentation, report.

LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competence assessment:
defense of the abstract (report);
express-interview;
interview;
colloquium;
situational problem solving;
testing;
control work;
report on laboratory work with oral defense.

LIST OF AVAILABLE TEACHING METHODS

Traditional method;
Active (interactive) methods:
Problem-Based Learning (PBL);
Team-Based Learning (TBL);
Research-Based Learning (RBL).

LIST OF PRACTICAL SKILLS

Name of practical skills	Form of practical skills control
1. Possession of the nomenclature of medicines obtained by biotechnological methods	Report on laboratory work with oral defense
2. Organization and provision of conditions for the aseptic conduct of the biotechnological process	Report on laboratory work with oral defense

Name of practical skills	Form of practical skills control
3. Compliance with the rules of industrial hygiene, occupational safety and health	Report on laboratory work with oral defense
4. The use of bioinformatics resources in the integrated EMBL-EBI database to address issues of genomics and proteomics of a specific biological object	Report on laboratory work with oral defense
5. Assessment of the possibility of using biotechnology methods for the biosynthesis of various drugs	Report on laboratory work with oral defense
6. Calculation of the qualitative and quantitative composition of nutrient media for fermentation	Report on laboratory work with oral defense
7. Calculation of sterilization modes of nutrient media for industrial fermentation	Report on laboratory work with oral defense
8. Calculation of filter media parameters (pore size) for purification of liquid nutrient media from mechanical impurities	Report on laboratory work with oral defense
9. Determination and selection of the fermentation method depending on the type of producer (microorganisms, isolated plant or animal cells)	Report on laboratory work with oral defense
10. The use of technical documentation for the selection and operation of hardware and instrumentation for fermentation, depending on the type of producer	Report on laboratory work with oral defense
11. Work with regulatory and technical regulations governing the production and quality assurance of medicines obtained by biotechnological methods	Report on laboratory work with oral defense

LIST OF EQUIPMENT USED

1. Microscope;
2. electronic scales;
3. compact incubator thermostat 100-240 V, 50/60 Hz, 18 L;
4. pH meter;
5. viscometer;
6. PM 2111 - solar photometer;
7. spectrophotometer;
8. dry-air sterilizer;
9. table shaker;
10. water bath.

PROTOCOL OF THE CURRICULUM APPROVAL
BY OTHER DEPARTMENTS

Title of the discipline requiring approval	Department	Amendments to the curriculum in the academic discipline	Decision of the department, which designed the curriculum (date, protocol #)
1. Pharmaceutical Ecology	Pharmaceutical Chemistry	There are no offers	Protocol # 10 of 26.06.2025
2. Industrial Technology of Drugs	Pharmaceutical Technology	There are no offers	Protocol # 10 of 26.06.2025
3. Pharmaceutical Development with the Fundamentals of Biopharmaceutics	Pharmaceutical Technology	There are no offers	Protocol # 10 of 26.06.2025
4. Standardization of medicines	Pharmaceutical Chemistry	There are no offers	Protocol # 10 of 26.06.2025

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Senior Lecturer of the Department of Pharmaceutical Technology with Advanced Training and Retraining Course of the Educational Institution «Belarusian State Medical University», MSc _____ O.A.Sushinskaya

Curriculum content, composition and the accompanying documents comply with the established requirements.

Head of the Office of Educational Activities of the Educational Institution «Belarusian State Medical University» I.L.Kotovich
24.06.2025

Methodologist of the Educational and Methodological Department of the Office of Educational Activities of the Educational Institution «Belarusian State Medical University» S.V.Zaturanova
24.06.2025