

DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

Department of Drug Technology and Biopharmaceutics



APPROVED

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2023

EDUCATIONAL PROGRAM

on discipline

«PHARMACEUTICAL BIOTECHNOLOGY»

**for training specialists of the second (master's) degree of higher education
of the specialty 226 Pharmacy, industrial pharmacy
the specialization 226.01 Pharmacy
the branch of study 22 Health care
for the 5th year students of Faculty of Pharmacy
of the full-time and part-time forms of education
MC 30.3**

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Department of Drug Technology and
Biopharmaceutics
Minutes No.13
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Head of the department
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Approved
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on chemical and pharmaceutical disciplines
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INTRODUCTION

Program for studying the discipline "Pharmaceutical Biotechnology"

according to the draft Standard of higher education of the *second (master's) level*

field of knowledge 22 "*Health*"

specialty 226 "*Pharmacy, industrial pharmacy*"

educational program of *Master of Pharmacy*

Discipline description (abstract)

The discipline "Pharmaceutical Biotechnology" belongs to the cycle of disciplines of professionally-oriented training of specialists in the specialty "Pharmacy, Industrial Pharmacy" and includes 1 content module.

The discipline "Pharmaceutical Biotechnology" together with other pharmaceutical disciplines and social sciences plays an important role in providing special technological training for professional activities.

Discipline "Pharmaceutical Biotechnology", designed for higher education, provides theoretical knowledge and develops practical skills in the development and production of drugs by biotechnological methods, general requirements to biotechnological products of different groups, modern trends in pharmaceutical biotechnology.

The educational program reflects the main directions of theory and practice of biotechnological aspects of medicines, substantiates the methods of production of biotechnological products.

Structure of the educational discipline	Number of credits, hours, of them			Academic year / semester	Type of control	
	Total	Class hours				Self-education
		Lectures	Laboratory classes			
Pharmaceutical Biotechnology	3 credits ECTS/ 90 hours	8	30	52	5 year, IX semester Credit	

The subject of the discipline is the main provisions and trends in the development of pharmaceutical biotechnology in Ukraine and the world; modern principles of production of medicines in various dosage forms with the use of biotechnology methods - microbial synthesis, cell technologies, methods of genetic engineering, the main modern types of equipment for biotechnological productions.

Interdisciplinary links:

- the discipline is based on the study of biophysics, physical and physico-chemical methods of analysis; inorganic, analytical, biological, physical and colloidal chemistry; normal physiology; human anatomy; pathological physiology with the basics of pathological anatomy;

- summarizes the knowledge gained in the study of disciplines: drug technology, biochemistry, pharmacology, pharmacotherapy, etc;

- the discipline lays the foundations for the training of future specialists, promotes the formation of pharmaceutical and technical thinking;

- together with other pharmaceutical disciplines and social sciences, the discipline plays an important role in providing special training for professional activities.

1. Purpose and tasks of discipline

1.1. The purpose of teaching discipline "Pharmaceutical Biotechnology" is the assimilation of higher education acquisitions of the main stages of the creation and production of medicinal products by biotechnological methods, general requirements for biotechnological medicines of various groups, modern directions of development of pharmaceutical biotechnology, environmental safety of biotechnology products, vaccines, hormones, immunomodulators, vitamins, vitamins, enzymes, probiotic, antibiotic and many other medical treatment preparations obtained using organisms-producers and other biobjects, which makes it possible to fully implement scientific and creative potential in future specialists.

1.2. The main tasks of studying the discipline "Pharmaceutical biotechnology" are:

- mastering the theoretical bases of biotechnological processes, means and methods for obtaining biologically active substances with the help of living objects and their enzyme systems;
- formation of higher education acquisitions for the practical use of biotechnological processes to obtain an industrial method of medicinal products used in various fields of medicine and pharmacy;
- assimilation of the methodology for creation, standardization, quality assessment and safety of medicines received by biotechnological methods based on general patterns of chemical-biological sciences to perform professional tasks of a specialist in pharmacy;
- formation of systematized knowledge on handling, storage, transportation, use of information on biotechnological preparations and providing information on these issues for patients.

1.3 Competence and learning outcomes, the formation of which contributes to discipline (interconnection with the normative content of preparation of higher education applications, formulated in terms of study results in the Standard).

According to the requirements of the Standard, discipline provides acquisition by students of competencies: **general and professional**.

General competence (GC):

GC01. Ability to abstract thinking, analysis and synthesis.

GC02. Knowledge and understanding of the subject area; understanding of professional activity.

GC03. Ability to communicate in the national language both orally and in writing.

GC04. The ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity.

GC05. The ability to evaluate and ensure the quality of the work performed.

GC06. Ability to work in a team.

GC09. Ability to use information and communication technologies

Professional competence (PC)

PC01. Ability to integrate knowledge and solve complex pharmacy/industrial pharmacy problems in broad or multidisciplinary contexts.

PC02. The ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.

PC03. Ability to solve pharmacy problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility.

PC 06. The ability to develop and implement a quality management system for pharmaceutical enterprises in accordance with the requirements of current Standards, to conduct quality audits and risk management for the quality of pharmaceutical products.

PC07. The ability to carry out sanitary and educational work among the population for the purpose of prevention and prevention of common, dangerous infectious, viral and parasitic diseases, promotion of timely detection and support of adherence to the treatment of these diseases according to their medico-biological characteristics and microbiological features.

PC08. The ability to provide rational use and counseling regarding prescription and non-prescription drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic, and physicochemical properties and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.

PC12. The ability to ensure the proper storage of medicines and other products of the pharmacy assortment in accordance with their physical and chemical properties and the rules of Good Storage Practices in health care institutions.

PC17. The ability to carry out pharmaceutical development, determine the stability of medicinal products and participate in the production of medicinal products in the conditions of pharmaceutical enterprises in accordance with the requirements of Good Manufacturing Practice with the appropriate development and preparation of the necessary documentation.

PC19. The ability to organize and carry out quality control of medicinal products in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods, technological instructions, etc.; carry out standardization of medicinal products in accordance with current requirements; to prevent the distribution of low-quality, falsified and unregistered medicinal products.

Program learning outcomes (PLO), the formation of which is facilitated by the educational discipline:

PLO01. Possess specialized conceptual knowledge in the field of pharmacy and related fields, taking into account modern scientific achievements, and be able to apply them in professional activities.

PLO03. Possess specialized knowledge and abilities/skills for solving professional problems and tasks, including for the purpose of improving knowledge and procedures in the field of pharmacy.

PLO04. Communicate freely in the national and English languages orally and in writing to discuss professional problems and results of activities, presentation of scientific research and innovative projects.

PLO05. Assess and ensure the quality and efficiency of activities in the field of pharmacy in standard and non-standard situations; adhere to the principles of deontology and ethics in professional activity.

PLO06. Develop and make effective decisions to solve complex/complex problems of pharmacy personally and based on the results of joint discussion; formulate the goals of one's own activity and the activity of the team, taking into account social and industrial ones

interests, general strategy and existing limitations, determine optimal ways to achieve goals.

PLO07. Analyze the necessary information on the development and production of medicinal products, using professional literature, patents, databases and other sources; systematize, analyze and evaluate it, in particular, using statistical analysis.

PLO08. Develop and implement innovative projects in the field of pharmacy, as well as related interdisciplinary projects taking into account technical, social, economic, ethical, legal and environmental aspects.

PLO09. Formulate, argue, clearly and concretely convey to specialists and non-specialists, including those seeking higher education, information based on one's own knowledge and professional experience, the main trends in the development of world pharmacy and related industries.

PLO11. Determine the advantages and disadvantages of drugs of natural and synthetic origin of various pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic and pharmacodynamic features and the type of dosage form. Recommend medicinal products and other products of the pharmacy assortment with the provision of advisory assistance and pharmaceutical care.

PLO13. Record cases of side effects when using medicinal products of natural and synthetic origin; evaluate factors that can affect the processes of absorption, distribution, deposition, metabolism and excretion of drugs and are determined by the condition and characteristics of the human body and the pharmaceutical characteristics of drugs.

PLO15. Predict and determine the influence of environmental factors on the quality and consumer characteristics of medicines and other products of the pharmacy assortment, organize their storage in accordance with their physical and chemical properties and the rules of Good Storage Practices.

PLO19. Develop technological documentation for the manufacture of medicinal products, choose a rational technology, manufacture medicinal products in various dosage forms according to the prescriptions of doctors and the requirements (orders) of treatment and prevention institutions, prepare them for release.

PLO20. Carry out pharmaceutical development of medicinal products of natural and synthetic origin in the conditions of industrial production.

PLO23. Determine the main chemical and pharmaceutical characteristics of medicinal products; choose and/or develop quality control methods for the purpose of their standardization using physical, chemical, physicochemical, biological, microbiological and pharmacotechnological methods in accordance with current requirements.

PLO26. Plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of proper pharmaceutical practices.

PLO27. To contribute to the preservation of health, in particular the prevention of diseases, the rational prescription and use of medicinal products.

2. Information scope of discipline

For study of discipline is given 3 ECTS credits - 90 hours.

Content module 1. Fundamentals of biotechnological processes. Technology of medicinal products obtained on the basis of bioobjects.

3. Structure of discipline

Topic	Lectures	Laboratory classes	Self-educational work	Individual work
Content module 1. Fundamentals of biotechnological processes. Technology of medicinal products obtained on the basis of bioobjects				
Topic 1. General principles of production of medicinal products by biotechnology	2	6	16	

Topic 2. Biotechnological production of antibiotics	1	2	10	-
Topic 3. Technology of probiotics and bacteriophages	0,5	2	5	
Topic 4. Biotechnological production of microorganisms metabolites - amino acids and vitamins	0,5	2	5	
Topic 5. Biotechnological production of enzymes	0,5	2	-	
Topic 6. Biotechnological production of hormones	0,5	2	5	
Topic 7. Immunobiological medicines. Vaccines. Serum. Immunoglobulins and diagnostic means on their basis	1	6	3	
Topic 8. Production of drugs from blood. Blood plasma. Plasma proteins.	0,5	4	6	
Topic 9. Biotechnological production of medicinal plant raw materials	0,5	2	2	
Topic 10. Auxiliary substances obtained by biotechnology methods. Preservatives and surfactants. Production of ethanol	0,5	2	-	
Topic 10. Features of quality control methods of biotechnological medicines. Biosimiliaries.	0,5	2	-	
Total hours of discipline - 90/3 Credits ESTS	8	30	52	
Final control				Залік

4. Thematic plan of lectures

No	Topic	Number of hours
Content module 1. Fundamentals of biotechnological processes. Technology of medicinal products obtained on the basis of bioobjects		
1	Topic 1. Pharmaceutical biotechnology as an integral part of biotechnology. Bioobjects and methods of biotechnology. The main stages of the biotechnological process.	2
2	Topic 2. Biotechnological drugs obtained by microbial synthesis. Antibiotics, probiotics, bacteriophages and preparations of metabolites of microorganisms.	2
3	Topic 3. Immunobiological drugs (vaccines, serums, immunoglobulins) and blood products. General characteristics and technological aspects of obtaining.	2
4	Topic 4. Biotechnological drugs obtained by methods of cell technology and genetic engineering.	2
Total		8

5. Thematic plan of laboratory classes

No	Topic	Number of hours
Content module 1. Fundamentals of biotechnological processes. Technology of medicinal products obtained on the basis of bioobjects		
1	Pharmaceutical biotechnology as an integral part of biotechnology. Basic terms of pharmaceutical biotechnology	2
2	Bioobjects and the main stages of the biotechnological process	2

3	Regulatory documents regulating the production of medicines by biotechnology methods	2
4	Biotechnological production of antibiotics	2
5	Technology of probiotics and bacteriophages	
6	Biotechnological production of preparations of metabolites of microorganisms - amino acids and vitamins	2
7	Biotechnological production of enzymes	2
8	Biotechnological production of hormones	2
9-10	Immunobiological medicines. Vaccines. Serums. Immunoglobulins and diagnostics based on them	4
11-12	Production of blood products. Blood plasma. Blood plasma proteins	4
13	Biotechnological production of medicinal plant raw materials	2
14	Excipients obtained by biotechnological methods. Antimicrobial preservatives and surfactants. Production of ethanol	2
15	Biosimilars. Features of quality control methods of biotechnological medicines	2
Total		30

6. Thematic plan of self-educational work

No	Topic	Number of hours	Type of control
Content module 1. Fundamentals of biotechnological processes. Technology of medicinal products obtained on the basis of bioobjects			
1	Producers of biologically active substances, requirements for producers	5	Current control at laboratory classes
2	Regulatory documents of pharmaceutical biotechnology	6	
3	Cellular and genetic engineering, their essence and practical use	5	
4	Classification of antibiotics by the nature of the action on the bacterial cell	5	
5	Obtaining finished dosage forms of antibiotics. Quality parameters of antibiotics	5	
6	Species composition of normal intestinal microflora in different periods of human life and its functions	5	
7	Biological role of vitamins, their classification and function	5	
8	Hormones, types of their classifications and functions	5	
9	Types of immunity. Immunogenic drugs for creation artificial active and passive immunity	5	
10	Fluids of the internal environment of the body. Homeostasis. Blood composition.	6	
Total		52	

7. Individual tasks

Not provided by the curriculum.

8. Teaching methods: explanatory-illustrated (multimedia lectures with elements of discussion communication with applicants for higher education), reproductive, research, part-search (independent search work, work with literature).

The following teaching methods are used:

- verbal - explanation, conversation, instruction, lecture, discussion;
- visual - demonstration of videos, visual equipment, illustrations;
- practical methods - laboratory and practical work;
- inductive methods - generalization of search and research results.

Preference is given to active and interactive methods and multimedia learning (multimedia lectures, educational films).

Types of educational activities of students according to the curriculum are:

- a) lectures;
- b) laboratory classes;
- c) self-educational work of students.

The lecture course includes the teaching of the most important topics based on the achievements of domestic and foreign science in the field of biotechnological research.

Laboratory classes in pharmaceutical biotechnology are conducted on the basis of theoretical principles of drug technology, modern requirements for dosage forms, knowledge of the properties of medicines and excipients. In laboratory classes, students acquire skills and abilities to apply biotechnological research. Classes include elements of teaching and research work.

The basis of laboratory classes is self-educational work of students. To deepen the theoretical knowledge, an oral consideration of certain issues is planned, which is recommended to be conducted in the form of a discussion.

In the process of conducting laboratory tasks, students must follow the rules of safety, instruction in which is conducted in the first laboratory lesson and supervised by teachers in each lesson.

Laboratory classes include:

- consideration of theoretical issues;
- watching educational videos;
- performance of practical tasks;
- analysis and interpretation of the obtained results.

The main stages of the laboratory class:

Preparatory - motivation of the topic, control of the initial level of knowledge (basic and basic), the issuance of tasks for practical work.

Control of the initial level of knowledge involves an oral analysis of the main issues on the topic and writing a test.

Main stage - students receive tasks for work, work in groups (4-5 students), draw up protocols.

Final - control of mastering the material by solving situational problems, oral presentations about the work done. General assessment of each student's work, remarks during the class, tasks for independent work.

At laboratory classes, students fill out a diary in the form of protocols, which record the results of work performed.

9. Control methods. Control methods include current and final semester control.

10. The current control is carried out during the training sessions and aims to verify the assimilation of educational material by students.

Current control: oral examination, test control, control of practical skills, acceptance of protocols of practical work. Current control is carried out at each laboratory class in accordance with specific objectives.

The form of assessment of current educational activities is standardized and includes control of

theoretical and practical training.

The control of theoretical training is carried out by performing test tasks, situational tasks, and practical skills by assessing the quality and completeness of practical tasks and the ability to interpret the results.

At each laboratory class, the student answers test tasks on the topic of the laboratory lesson, standardized questions, knowledge of which is necessary to understand the current topic; demonstrates knowledge, skills and practical abilities in accordance with the topic of the laboratory class. The grade for the laboratory class is determined by the sum of the results of test control and performance of practical tasks. Students' self-educational work is assessed during the current control of the topic in the relevant class. A student who has missed classes is allowed to work off academic debt by the deadline.

11. Final control is carried out in order to assess learning outcomes at a certain educational and qualification level and at some of its completed stages in a national scale and ECTS scale. The form of final control on pharmaceutical biotechnology in accordance with the curriculum is a credit.

Credit is a form of final control, which consists in assessing the student's mastery of educational material in the discipline for the semester solely on the basis of the results of current control.

12. Scheme of accrual and distribution of points received by students

During the assessment of mastering each topic for the current educational activity of the student, grades are set on a 4-point (traditional) scale, taking into account the approved criteria. The student must receive a grade on each topic.

The results of the current control are an indicator of the level of students' mastery of the educational program and the performance of self-educational work.

The maximum number of points that a student can score for the current academic activity is 200 points.

The minimum number of points that a student must score for the current educational activity is 120.

The calculation of the number of points is based on the grades obtained by the student in the traditional scale during the study of the discipline by calculating the arithmetic mean (CA), rounded to two decimal places. The value obtained is converted into points as follows:

$$X = \frac{CA \times 200}{5}$$

The calculation of the average grade for current activities into a multi-point scale for the discipline, ending with a credit, is given in the table.

Table

Calculation of the average score for current activities in a multi-point scale

4- points scale	200- points scale	4- points scale	200- points scale	4- points scale	200- points scale	4- points scale	200- points scale	4- points scale	200- points scale
5	200	4.45	178	3.92	157	3.37	135		
4.97	199	4.42	177	3.89	156	3.35	134		
4.95	198	4.4	176	3.87	155	3.32	133		
4.92	197	4.37	175	3.84	154	3.3	132		
4.9	196	4.35	174	3.82	153	3.27	131		
4.87	195	4.32	173	3.79	152	3.25	130		
4.85	194	4.3	172	3.77	151	3.22	129		
4.82	193	4.27	171	3.74	150	3.2	128		

4.8	192		4.24	170		3.72	149		3.17	127
4.77	191		4.22	169		3.7	148		3.15	126
4.75	190		4.19	168		3.67	147		3.12	125
4.72	189		4.17	167		3.65	146		3.1	124
4.7	188		4.14	166		3.62	145		3.07	123
4.67	187		4.12	165		3.57	143		3.02	121
4.65	186		4.09	164		3.55	142		3	120
4.62	185		4.07	163		3.52	141		Less than 3	Not enough
4.6	184		4.04	162		3.5	140			
4.57	183		4.02	161		3.47	139			
4.52	181		3.99	160		3.45	138			
4.5	180		3.97	159		3.42	137			
4.47	179		3.94	158		3.4	136			

Points from the discipline are independently converted into both the ECTS scale and the 4-point scale. ECTS scale scores are not converted to a 4-point scale and vice versa.

The points of students studying in one specialty, taking into account the number of points scored of the discipline are ranked on the ECTS scale as follows:

Point by ECTS	Statistical index
A	The best 10% of students
B	The following 25% of students
C	The following 30% of students
D	The following 25% of students
E	The last 10% of students

Points from the discipline for students who have successfully completed the program are converted into a traditional 4-point scale according to the absolute criteria listed in the table below.

Points from the discipline	Score on a 4-point scale
From 170 to 200 points	5
From 140 to 169 points	4
From 139 points to the minimum number of points that a student must score	3
Below the minimum number of points that a student must score	2

The ECTS score is not converted to the traditional scale, as the ECTS scale and the 4-point scale are independent.

The objectivity of the assessment of students' learning activities is checked by statistical methods (correlation coefficient between ECTS assessment and assessment in a national scale).

13. Methodical support:

- Lecture material (multimedia presentations, lecture texts, calendar-thematic plan of lectures).
- Calendar-thematic plans of laboratory classes.

- Questions for laboratory classes and self-educational work.
- Methodical recommendations for laboratory classes.
- Videos.
- Internet resources.

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