MINISTRY OF HEALTH OF UKRAINE

ODESSA NATIONAL MEDICAL UNIVERSITY

Department of Pharmaceutical Chemistry and Drug Technology

APPROVED

Vice-rector for scientific and pedagogical work

_____ Eduard BURYACHKIVSKY

September 1st, 2024

WORKING PROGRAM IN THE DISCIPLINE «PHARMACEUTICAL BIOTECHNOLOGY»

Level of higher education: second (master's degree)

Field of knowledge: 22 «Health care»

Specialty: 226 «Pharmacy, industrial pharmacy»

Educational and professional program: Pharmacy, industrial pharmacy

2024

The working program is based on the educational and professional program "Pharmacy, industrial pharmacy" for the training of specialists of the second (master's) level of higher education in the specialty 226 "Pharmacy, industrial pharmacy" of the field of knowledge 22 "Health care", approved by the Scientific Council of ONMedU (protocol no. 10 of June 27, 2024).

Developers: PhD, doc. Fizor N.S., ass. Shyshkin I.O.

The work program was approved at the meeting of the Department of Pharmaceutical Chemistry and Drug Technology
Protocol No. 1 dated August 29, 2024.

Head of the department _____ Volodymyr GELMBOLDT

Agreed with the EPP guarantor _____ Liana UNHURIAN

Approved by the subject cycle methodical commission for pharmaceutical disciplines of ONMedU
Protocol No. 1 dated August 30, 2024

Head of the subject cycle methodical commission for pharmaceutical disciplines of ONMedU

_____ Natali FIZOR

Reviewed and approved at the department meeting _____
_____
Protocol № ___ from "___" _____ 20__.

Head of the department _____ _____
(signature) *(First name Surname)*

Reviewed and approved at the department meeting _____
_____
Protocol № ___ from "___" _____ 20__.

Head of the department _____ _____
(signature) *(First name Surname)*

1. Description of the academic discipline:

Name of indicators	Field of knowledge, specialty, specialization, level of higher education	Characteristics of the academic discipline
Total number: Credits: 3 Hours: 90 Content modules: 1	Field of knowledge 22 "Health care" Specialty 226 "Pharmacy, industrial pharmacy" Level of higher education second (master's)	*Full-time education* *Elective discipline*
		Year of preparation: 5
		Semesters X
		Lectures (0 h.)
		Practical (30 h.)
		Independent work (60 h.)
		The form of final control is credit

2. The purpose and tasks of the educational discipline

Goal: acquaint applicants with the subject of biotechnology of medicines, with new scientific achievements in the field of genetic engineering, cell engineering, culture of isolated tissues and cells, production of antibiotics and vaccines, enzyme biotechnology, biotechnological processes in the pharmaceutical and processing industry, the connection of biotechnology with energy and ecology, and animal and human cloning.

Tasks:

1. to form an idea of the chemical unity of the environment among the acquirers;
2. plant biotechnology, cloning of plant organisms, production of virus-free plants, production of transgenic plants for the production of medicinal products;
3. biotechnology of microorganisms, genetic engineering, gene cloning, recombinant DNA construction, vectors;
4. possibilities of cloning animal organisms, individual organs and tissues, production of antibiotics and vaccines, hormones, monoclonal antibodies, vitamins;
5. possibilities of using viruses, bacteria, plant and animal cells to obtain medicines;
6. general methodology for obtaining medicinal products;
7. peculiarities of the use of existing genetic vectors in molecular cloning - methods of screening and selection of cells containing recombinant DNA;
8. peculiarities of selection and purification of the target product;
9. methods of obtaining recombinant medicinal products: interferon, somatotropin, monoclonal antibodies, vaccines, antibiotics;
10. choose the most suitable object for research and production in the field of biotechnology;
11. to orientate in molecular genetic methods that can be applied to study the properties of producer organisms;
12. calculate the production capabilities of bioreactors with different cultivation conditions on various substrates;
13. prepare nutrient media, disinfect the workplace and sterilize nutrient media for plant cloning;
14. clone plants, obtain sterile explants and grow plants from them;
15. be able to distinguish between natural and artificially created chemicals;
16. study the impact of new materials on the natural environment and the possibilities of their utilization;
17. master the theoretical foundations of the course.

The process of studying the discipline is aimed at forming elements of the following competencies:

General competencies (GC):

- GC 01. Ability to think abstractly, analyze and synthesize, learn and be modernly trained.
- GC 02. Knowledge and understanding of the subject area and understanding of professional activity.
- GC 03. Ability to communicate in the national language both orally and in writing.
- GC 04. The ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity.
- GC 05. The ability to evaluate and ensure the quality of the work performed.
- GC 06. Ability to work in a team.
- GC 10. The ability to act socially responsibly and consciously.
- GC 11. Ability to apply knowledge in practical situations.
- GC 12. The desire to preserve the environment.
- GC 13. Ability to show initiative and entrepreneurship.
- GC 14. Ability to adapt and act in a new situation.
- GC 15. Knowledge and understanding of the subject area and understanding of professional activity.
- GC 16. The ability to conduct experimental research at the appropriate level.

Professional competencies (PC):

- PC 01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC 02. Ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.
- PC 08. The ability to consult on prescription and non-prescription drugs and other products of the pharmacy assortment; pharmaceutical care during the selection and sale of medicinal products of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use guided by data on the health status of a specific patient.
- PC 12. Ability to ensure proper storage of natural and synthetic medicinal products and other pharmacy products in accordance with their physicochemical properties and Good Storage Practice (GSP) rules in healthcare facilities.
- PC 16. The ability to organize and carry out the production activities of pharmacies for the manufacture of medicinal products in various dosage forms according to the prescriptions of doctors and the requirements (orders) of medical and preventive institutions, including the justification of technology and the selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).
- PC 17. The ability to carry out pharmaceutical development and participate in the production of medicinal products of natural and synthetic origin in the conditions of pharmaceutical enterprises in accordance with the requirements of Good Manufacturing Practice (GMP).
- PC 24. Ability to use knowledge of regulatory and legislative acts of Ukraine and recommendations of proper pharmaceutical practices in professional activities.
- PC 25. The ability to demonstrate and apply in practical activities communicative communication skills, fundamental principles of pharmaceutical ethics and deontology, based on moral obligations and values, ethical standards of professional behavior and responsibility in accordance with the Code of Ethics of Pharmaceutical Workers of Ukraine and WHO guidelines.
- PC 26. The ability to organize and participate in the production of medicinal products in the conditions of pharmaceutical enterprises, in particular the selection and justification of the technological process, equipment in accordance with the requirements of Good Manufacturing

Practice (GMP) with the appropriate development and execution of the necessary documentation. Determine the stability of medicines.

Program learning outcomes (PLO):

- PLO 01. Have and apply specialized conceptual knowledge in the field of pharmacy and related fields, taking into account modern scientific achievements.
- PLO 03. Have specialized knowledge and skills/skills for solving professional problems and tasks, including for the purpose of further development of knowledge and procedures in the field of pharmacy.
- PLO 04. 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.
- PLO 07. Collect 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.
- PLO 19. 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 medical and preventive institutions, prepare them for release.
- PLO 20 – Carry out pharmaceutical development of medicinal products of natural and synthetic origin in the conditions of industrial production.
- PLO 25. Observe the norms of the sanitary and hygienic regime and the requirements of safety equipment when carrying out professional activities.
- PLO 27. To perform professional activities using creative methods and approaches.
- PLO 30. Adhere to the norms of communication in professional interaction with colleagues, management, consumers, work effectively in a team.
- PLO 36. Plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of proper pharmaceutical practices.
- PLO 38. To substantiate the technology and organize the production of medicinal products at pharmaceutical enterprises and draw up technological documentation for the production of medicinal products at pharmaceutical enterprises.
- PLO 43. To organize the necessary level of individual safety (own and the persons he cares for) in the event of typical dangerous situations in the individual field of activity.

As a result of studying the academic discipline, the student of higher education should:

to know:

1. requirements of GMP, GRP, other proper pharmaceutical practices and regulatory documents (orders, instructions, etc.) regarding the development and manufacture of biotechnological pharmaceutical drugs;
2. basic terms and concepts of pharmaceutical biotechnology;
3. the main regulatory documents related to production, quality control, compliance with environmental safety, storage, international and domestic standards in relation to medicinal products obtained by biotechnological methods, as well as biological objects and their producers;
4. main achievements in modern pharmaceutical biotechnology and bionanotechnology;
5. modern biotechnological methods of obtaining medicines: genetic engineering, protein engineering, engineering enzymology;
6. technologies for the production of BAVs and drugs based on the vital activity of microorganisms;
7. the main principles underlying modern methods of diagnosing diseases and analyzing medicinal substances (enzyme immunoassay, polymerase chain reaction, etc.);
8. devices and principles of operation of modern laboratory and industrial biotechnological equipment;

9. conditions for carrying out the biotechnological process and its compliance with modern requirements for the organization of pharmaceutical production.

be able to:

1. calculate the required number of components for the preparation of nutrient media used for pharmaceutical purposes;
2. evaluate the parameters of biosynthesis in the fermenter (productivity, average rate of synthesis of the target product, yield of the target product from a given volume of culture liquid, etc.) and adjust the process to ensure the best conditions for the production of drugs;
3. justify the choice of the method and carry out the isolation of the target product from the culture liquid, as well as from biomass;
4. carry out continuous control and standardization of received medicinal products (for example: determining the activity of antibiotics, enzymes, cell viability, etc.);
5. carry out immobilization of biological objects. Be able to critically assess the need for immobilization of bioobjects and be able to evaluate the effectiveness of applied immobilization methods under specific conditions of pharmaceutical production;
6. ensure and control aseptic conditions of modern production of biotechnological pharmaceuticals;
7. carry out optimization of the biotechnological process in the conditions of pharmaceutical drug production.
8. take into account the impact of biotechnological factors on the efficiency of the technological process and maintain optimal conditions for the biosynthesis of the target product in the conditions of pharmaceutical drug production;
9. use the main types of ND (SPhU, laboratory, research and industrial regulations, etc.) as well as modern scientific literature.

3. Content of the academic discipline

Topic 1. General issues of biotechnology for the production of medicinal products.

Introduction to pharmaceutical biotechnology. History of development. Biotechnology of medicines. Biotechnics. Connection of biotechnology with fundamental sciences. Biomedical technologies (concept). The main directions of development of pharmaceutical biotechnology.

Topic 2. Bioobjects as a means of production of medicinal, prophylactic and diagnostic products.

Bioobjects as a means of production of medicinal, prophylactic and diagnostic products. Macroorganisms, microorganisms. Enzymes as industrial biocatalysts. Improvement of biological objects by methods of mutagenesis and selection. Improvement of biological objects by methods of cellular engineering.

Topic 3. Pharmaceutical biotechnology of plants.

Cultures of plant cells, the technology of manufacturing medicinal substances from them. Development of methods of cultivation of plant tissues and isolated cells as an achievement of biotechnological science. Immobilization of plant cells. Problems of excretion of the target product from immobilized cells.

Topic 4. Pharmaceutical biotechnology of phospholipids.

Eicosanoids (prostanoids) and their biological and pharmaceutical role. Arachidonic acid and other polyunsaturated acids as a starting product for obtaining prostaglandins. Obtaining them from other natural sources - microorganisms, including fungi and protozoa. Technological scheme for the production of phospholipids.

Topic 5. Pharmaceutical biotechnology of protein medicinal compounds.

Recombinant proteins belonging to different groups of physiologically active compounds. Insulin. Sources of receipt. Species specificity. Immunogenic impurities. Prospects of implantation of insulin-producing cells.

Topic 6 Pharmaceutical biotechnology of obtaining amino acids.

Definition of the concept of amino acid. Classification of amino acids and requirements for primary metabolites of amino acids in pharmaceutical production. Biotechnological methods of obtaining amino acids in the industrial production of drugs. Microorganisms are producers of amino acids. Microbiological synthesis. Producers.

Topic 7 Pharmaceutical biotechnology of vitamins and coenzymes.

Biological role of vitamins and coenzymes. Coenzymes as derivatives of vitamins. Classification of vitamins and coenzymes. Traditional methods of production (extraction from natural sources and chemical synthesis). Microbiological synthesis of vitamins and construction of producer strains by methods of genetic engineering.

Topic 8. Pharmaceutical biotechnology of obtaining steroid hormones.

Traditional sources of steroid hormones. Problems of transformation of steroid structures. Advantages of biotransformation over chemical transformation. Pharmaceutical biotechnology of production of insulin preparations. Pharmaceutical biotechnology of production of human growth hormones (somatotropic hormone). Pharmaceutical biotechnology of human erythropoietin production. Strains of microorganisms that have the ability to transform (bioconversion) steroids.

Topic 9. Pharmaceutical biotechnology of obtaining antibiotics.

Antibiotics as biotechnological products. Screening methods of producers. Biological role of antibiotics as secondary metabolites. Origin of antibiotics and evolution of their functions. The possibility of screening low-molecular-weight bioregulators when selecting for antibiotic function (immunosuppressants, inhibitors of enzymes of animal origin, etc.).

Topic 10. Pharmaceutical biotechnology of obtaining immunobiotechnological preparations.

The main components and ways of functioning of the immune system. Immunomodulatory agents: immunostimulators and immunosuppressants (immunosuppressants). Strengthening of the immune response with the help of immunobiopreparations. Vaccines based on recombinant protective antigens or live hybrid carriers, their production technology. Antisera to infectious agents, to microbial toxins. Technological scheme of production of vaccines and serums. Non-specific strengthening of the immune response. Recombinant interleukins, interferons, etc. Mechanisms of biological activity. Thymic factors. Bone marrow transplantation. Production technology of immunobiopreparations. Suppression of the immune response with the help of immunobiopreparations.

Topic 11. Biotechnology for the production of yeast pharmaceutical preparations.

Production technology of yeast preparations, production technology of various yeast strains. Technological stages of growing yeast. Technology of fermentation production. Methods of yeast analysis. Cell autolysis. Technology of obtaining nucleic acids from yeast. Yeast RNA isolation technology. Technological methods of obtaining high-molecular yeast RNA. Biotechnology of obtaining preparations based on yeast double-helical RNA (Ridostin). The technology of obtaining preparations based on yeast β-glucans (Zymocel). Biotechnology of obtaining preparations based on the hydrolysis of yeast RNA. Methods of obtaining sodium nucleanate from yeast. Enzymes secreted from yeast and the technology of their production. Alcohol production technology.

Topic 12. Pharmaceutical biotechnology of manufacturing nanopreparations.

Nanoparticles. Production technology of liposomal forms of antimicrobial, neurotropic, ophthalmic, etc. drugs Production technology of liposomal adjuvants and vaccines (antiviral, antibacterial, ribosomal, antitumor vaccines). Technological aspects of the production of liposomal preparations.

Lipid substances. Technology of obtaining a lipid film. Liposome production technology. Liposome resuspension technology. Quality control of drugs.

Topic 13. Requirements for production and quality control of biotechnological preparations. GMP requirements for the pharmaceutical production of biotechnological drugs. Personnel requirements. Requirements for industrial premises and technological equipment of biotechnological production. Requirements for industrial production. Basic requirements for animals. Requirements for quality control of biopharmaceutical drugs. Technological aspects of the production of substances obtained by the method of biotechnology.

4. The structure of the academic discipline

Names of topics	Number of hours of full-time education			
	In total	including		
		Lectures	practical	IWS
Topic 1. General questions of the biotechnology of drug production.	8	0	2	6
Topic 2. Bioobjects as a means of production of medicinal, prophylactic and diagnostic products.	8	0	2	6
Topic 3. Pharmaceutical biotechnology of plants.	8	0	2	6
Topic 4. Pharmaceutical biotechnology of phospholipids.	8	0	2	6
Topic 5. Pharmaceutical biotechnology of protein medicinal compounds.	6	0	2	4
Topic 6 Pharmaceutical biotechnology of obtaining amino acids.	6	0	2	4
Topic 7 Pharmaceutical biotechnology of vitamins and coenzymes.	6	0	2	4
Topic 8. Pharmaceutical biotechnology of obtaining steroid hormones.	6	0	2	4
Topic 9. Pharmaceutical biotechnology of obtaining antibiotics.	6	0	2	4
Topic 10. Pharmaceutical biotechnology of obtaining immunobiotechnological preparations.	8	0	4	4
Topic 11. Biotechnology of production of pharmaceutical preparations of yeast.	6	0	2	4
Topic 12. Pharmaceutical biotechnology of manufacturing nanopreparations.	6	0	2	4
Topic 13. Requirements for production and quality control of biotechnological preparations.	6	0	2	4
Final control	2	0	2	0
Total hours:	**90**	**0**	**30**	**60**

5. Topics of lectures / seminars / practical / laboratory lessons

5.1. Topics of lectures

Lecture lessons are not provided.

5.2. Topics of practical classes

№ i/o	Topic name	Number of hours

1	Objects and methods of pharmaceutical biotechnology. Analytical research methods in pharmaceutical biotechnology.	2
2	Biotechnological methods of obtaining proteins.	2
3	Pharmaceutical biotechnology of phospholipids, obtaining, use.	2
4	Recombinant DNA biotechnology.	2
5	Pharmaceutical biotechnology of plants.	2
6	Pharmaceutical biotechnology of obtaining amino acids.	2
7	Pharmaceutical biotechnology of obtaining vitamins and coenzymes.	2
8	Pharmaceutical biotechnology of obtaining hormonal drugs.	2
9	Pharmaceutical biotechnology of obtaining antibiotics.	2
10	Production technology of immunobiological preparations.	2
11	Biotechnology of production of pharmaceutical preparations from yeast.	2
12	Technology of manufacturing nanopreparations. Liposomal forms of drugs.	2
13	Technology of manufacturing nanopreparations. Liposomal forms of adjuvants and vaccines.	2
14	Requirements for production and quality control of biotechnological preparations.	2
15	Final control.	2
In total		**30**

6. Independent work

№ i/o	**Types of IWS**	**Number of hours**
1	Preparation for practical classes.	60
In total		**60**

7. Teaching methods.

Practical classes: conversation, solving situational problems, conducting control of knowledge, abilities and skills of higher education students, posing a general problem by the teacher and discussing it with the participation of higher education students, performing control tasks, their verification, evaluation. Performance of laboratory work, in which students of higher education, under the guidance of a teacher, conduct educational experiments in specially equipped educational laboratories using equipment adapted to the conditions of the educational process.

Independent work: independent work with recommended basic and additional literature, with electronic information resources, independent work with a bank of test tasks.

8. Forms of control and assessment methods
(Including criteria for evaluating learning outcomes)

Current control: testing, oral survey, problem solving.

Final control: credit.

1. Assessment of the current educational activity in a practical session:

1. Assessment of theoretical knowledge on the topic of the lesson:
   - methods: survey, testing, solving a situational problem
   - maximum score – 5, minimum score – 3, unsatisfactory score – 2.
2. Assessment of practical skills on the subject of the lesson:
   - methods: assessment of the correctness of the performance of practical skills
   - maximum score – 5, minimum score – 3, unsatisfactory score – 2.

The grade for one practical lesson is the arithmetic average of all components and can only have an integer value (5, 4, 3, 2), which is rounded according to the statistical method.

Criteria for current assessment in a practical lesson

Assessment	Assessment criteria
«5»	The applicant actively participates in the discussion of the most difficult questions on the topic of the lesson, gives at least 90% correct answers to standardized test tasks, answers written tasks without errors, performs practical work and draws up a protocol.
«4»	The applicant participates in the discussion of the most difficult questions on the topic, gives at least 75% correct answers to standardized test tasks, makes some minor mistakes in the answers to written tasks, performs practical work and draws up a protocol.
«3»	The applicant participates in the discussion of the most difficult questions on the topic, gives at least 60% correct answers to standardized test tasks, makes significant mistakes in answers to written tasks, performs practical work and draws up a protocol.
«2»	The applicant does not participate in the discussion of complex questions on the topic, gives less than 60% correct answers to standardized test tasks, makes gross mistakes in answers to written tasks or does not give answers to them at all, does not perform practical work and does not draw up a protocol.

Only those applicants who have fulfilled the requirements of the training program in the discipline, have no academic debt, their average score for the current educational activity in the discipline is at least 3.00, and they have passed the test control based on the tests "STEP-2" are admitted to the final control in the form of an exam. - 2" at least 90% (50 tasks).

The test control is conducted in the Educational and Production Complex of Innovative Technologies of Learning, Informatization and Internal Monitoring of the Quality of Education of the University in the last class before the exam.

Assessment of the results of the students' training during the final control – exam.

Content of assessed activity	Scores
The answer to a theoretical question	2
The answer to a theoretical question	2
Solution of the calculation problem	1

Criteria for assessment the results of the students' training during final control - exam

Assessment	Assessment criteria
Perfectly «5»	The applicant worked systematically during the semester, showed during the exam versatile and in-depth knowledge of the program material, is able to successfully perform the tasks provided for in the program, mastered the content of the main and additional literature, realized the relationship of individual sections of the discipline, their importance for the future profession, showed creative abilities in understanding and using educational program material, demonstrated the ability to independently update and replenish knowledge; the level of competence is high (creative).
Good «4»	The applicant has demonstrated complete knowledge of the educational program material, successfully performs the tasks provided for by the program, has mastered the basic literature recommended by the program, has shown a sufficient level of knowledge in the discipline and is capable of their independent updating and renewal in the course of further education and professional activity; the level of competence is sufficient (constructive and variable).

Satisfactorily «3»	The applicant who has demonstrated knowledge of the main curriculum material in the amount necessary for further education and subsequent work in the profession, copes with the tasks provided for by the program, made some mistakes in the answers on the exam and when completing the exam tasks, but has the necessary knowledge to overcome the mistakes made mistakes under the guidance of a scientific and pedagogical worker; level of competence - average (reproductive).
Unsatisfactorily «2»	The applicant did not demonstrate sufficient knowledge of the main educational program material, made fundamental mistakes in the performance of tasks provided for by the program, cannot use the knowledge in further studies without the help of a teacher, did not manage to master the skills of independent work; the level of competence is low (receptive-productive).

9. Distribution of points received by higher education applicants

The obtained average score for the academic discipline for applicants who successfully mastered the work program of the academic discipline is converted from a traditional four-point scale to points on a 200-point scale, as shown in the table:

Conversion table of a traditional assessment into a multi-point scale

Traditional four-point scale	Multipoint 200-point scale
Perfectly («5»)	185 – 200
Good («4»)	151 – 184
Satisfactorily («3»)	120 – 150
Unsatisfactorily («2»)	Less than 120

A multi-point scale (200-point scale) characterizes the actual success of each applicant in mastering the educational component. The conversion of a traditional assessment (average score for an academic discipline) into a 200-point one is performed by the information and technical department of the University.

According to the obtained points on a 200-point scale, the achievements of the applicants are evaluated according to the ECTS rating scale. Further ranking according to the ECTS rating scale makes it possible to evaluate the achievements of students in the educational component who are studying in the same course of the same specialty, in accordance with the points they received.

The ECTS scale is a relative-comparative rating, which establishes the applicant's belonging to the group of better or worse among the reference group of fellow students (faculty, specialty). An "A" grade on the ECTS scale cannot be equal to a " perfectly " grade, a "B" grade to a "good" grade, etc. When converting from a multi-point scale, the limits of grades "A", "B", "C", "D", "E" according to the ECTS scale do not coincide with the limits of grades "5", "4", "3" according to the traditional scale. Acquirers who have received grades of "FX" and "F" ("2") are not included in the list of ranked acquirers. The grade "FX" is awarded to students who have obtained the minimum number of points for the current learning activity, but who have not passed the final examination. A grade of "F" is given to students who attended all lessons in the discipline, but did not receive an average score (3.00) for the current academic activity and were not admitted to the final examination.

Applicants who study on one course (one specialty), based on the number of points scored in the discipline, are ranked on the ECTS scale as follows:

Conversion of the traditional grade from the discipline and the sum of points on the ECTS scale

Assessment on the ECTS scale	Statistical indicator
A	Top 10% students
B	The next 25% students
C	The next 25% students

D	The next 25% students
E	The next 25% students

10. Methodical support:

- Working program of the academic discipline
- Syllabus of the academic discipline
- Textbooks:
- Multimedia presentations
- Situational tasks
- Methodical development of practical lessons
- Electronic bank of test tasks by subdivisions of the discipline.

11. Questions for final control

1. Describe the methods of culturing isolated cells and tissues.
2. Methods of storage of antibiotic-producing microorganisms.
3. How are the three quality control standards for measuring component content calculated?
4. Describe the chemical methods of enzyme immobilization, the reasons for the loss of enzyme activity.
5. Characteristics of pharmaceutical biotechnology facilities.
6. Preparation of pharmacologically active enzyme preparations (precipitation with organic solvents, salting out, selective denaturation, chromatography).
7. Methods of assessing the content of impurities (specific and total content) by the method of thin-layer chromatography.
8. Basic requirements of the process, cultivation of microorganisms - producers of proteins and enzymes.
9. Explain the phenomenon of protein electrophoresis based on the properties of protein molecules.
10. Describe the equipment for air sterilization when receiving pharmaceutical substances and finished preparations.
11. Microbiological and biochemical control of the processes of microbiological synthesis during the production of antibiotics.
12. Features of zone electrophoresis and an example of its use for the analysis of biological objects. The principle of automatic concentration of substances at the start during electrophoresis in a polyacrylamide gel.
13. Analyze the scheme for obtaining recombinant insulin.
14. Suspension or cancellation of accreditation of the testing laboratory.
15. What are the quality standards of SSU ISO 9000 (8 principles) based on?
16. Carbohydrates, monosaccharides, polysaccharides and their significance for biotechnology.
17. Describe the main methods of precipitation, separation and concentration of pharmaceutical biotechnology products.
18. Give an assessment of centrifugation methods, including density gradient centrifugation, when obtaining products of pharmaceutical biotechnology.
19. Basic tasks of cell engineering, requirements for cultural nutrient media.
20. Electrophoresis, the essence of the method. Isoelectric focusing of protein molecules.
21. Procedure for internal laboratory quality control of analytical work. External quality control of analytical works.
22. Fundamentals of pharmaceutical biotechnology.
23. High performance liquid chromatography (HPLC). The use of HPLC in the analysis of pharmaceutical products obtained by the biotechnological method.
24. Purpose and principle of the system of laboratory quality control of analytical works.
25. Basic concepts and tasks of genetic engineering in pharmaceutical biotechnology.
26. Describe the significance of carbohydrates: mono- and polysaccharides for biotechnology.
27. Analyze the basic requirements for culture media for the cultivation of viruses and the culture of cells producing biotechnological products.

28. Possibilities and perspectives of pharmaceutical.
29. Fluorescence spectroscopy, the essence of the method. Yablonsky diagram, methods of analysis of protein structures.
30. Procedure for developing a quality management system. Quality planning. How does the quality management system work and what advantages do it provide to the manufacturer?
31. Analyze the use of the sterilizing filtration method in pharmaceutical biotechnology.
32. What are the quality standards of SSU ISO 9000 based on (8 principles)?
33. Industrial devices for dry air and steam sterilization of equipment and primary packaging of pharmaceutical preparations.
34. To evaluate modern methods of genetic engineering in pharmaceutical biotechnology.
35. To analyze the reasons for the instability of recombinant producers.
36. To evaluate the role of biotechnological production of vaccines in modern times and to give a classification.
37. Give an assessment of the effectiveness of medicinal forms of vitamins, describe their classification and properties. To characterize strains producing vitamins.
38. Analyze the main critical points and identify risk factors in the production of human interferon.
39. Stages and criteria of accreditation of testing laboratories.
40. Give an assessment of the effectiveness of dosage forms of antibiotics, describe their classification and properties. Describe antibiotic-producing strains.
41. Rights and responsibilities of testing laboratories.
42. Evaluate modern methods of genetic engineering in pharmaceutical biotechnology.
43. Evaluate the main advantages of nanotechnology products. Describe the principles of technological process validation using the example of obtaining liposomes.
44. Means of sterilization of nutrient media. List the equipment for sterilization of environments.
45. The main features of the technology of modern pharmaceutical biotechnological productions and trends in its development.
46. Evaluate recombinant strains that produce antibiotics and state the advantages of recombinant producers.
47. Determine the main requirements for quality control of the production of vitamin substances and the finished drug.
48. Statistical analysis and its problems. What do the control charts look like, what indicators are included in them? What data is entered in the control charts between the two charts? What variants of conclusions can be made based on the analysis of control charts?
49. Hydrodynamic method of distribution of protein molecules. Estimation of the molecular weight of biomolecules.
50. Reasons for a decrease in the enzymatic activity of immobilized enzymes. Choice of immobilization method.
51. Selection of microorganisms in the production of antibiotics and vitamins.
52. Expansion of the field of accreditation of testing laboratories.
53. Analyze the advantages of nanoparticle-based dosage forms compared to free dosage forms.
54. Engineering enzymology and its role.
55. Cross-linking agents, requirements, physicochemical properties for enzyme immobilization.
56. Purpose and principle of the system of laboratory quality control of analytical work.
57. Give an assessment of ultrafiltration and gel filtration methods for obtaining pharmaceutical biotechnology products.
58. Give examples of air sterilization equipment, production equipment and inventory.
59. Basic principles of regulation of metabolism and growth rate of microorganisms.
60. Justify the system of laboratory control of probiotic preparations.

12. Recommended literature.

Basic:

1. S. Spada. G. Walsh Directory of Approved Biopharmaceutical Products 1st Edition . – CRC Press, 2019. – 336 p.
2. C. Kokare PHARMACEUTICAL BIOTECHNOLOGY 1st Edition. – Nirali Prakashan, 2017. – 274.
3. Лихач А. В. Промислова біотехнологія / А. В. Лихач. – МНАУ. – 2016. – 116 с.

Additional:

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