MINISTRY OF SCIENCE AND HIGHER EDUCATION OF THE RUSSIAN FEDERATION
Federal State Autonomous Educational Institution of Higher Education
**"Far Eastern Federal University"**
(FEFU)
INSTITUTE OF LIFE SCIENCES AND BIOMEDICINE (SCHOOL)

# APPRAISAL FUND

*in the discipline (module) " Medical and Pharmaceutical Biotechnology"*

Vladivostok
2023

The list of forms of assessment used at various stages of the formation of competencies in the course of mastering the discipline (module) " Medical and Pharmaceutical Biotechnology"

| No p/n | Supervised sections/topics of the discipline | Code and name of the achievement indicator | Learning Outcomes | Evaluation tools | |
|---|---|---|---|---|---|
| | | | | Current control | Intermediate certification |
| 1 | Section 1. General Biotechnology<br>Section 2. Private biotechnology | PC-2.1<br>Develops technological documentation for the industrial production of medicines | Knows:<br>−the specifics of the production of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use, determined by the nature of the product and production technology;<br>−methodological materials on technological preparation of production;<br>−licensing requirements for the production of medicines;<br>−the main regulatory documents related to the production, quality control, environmental safety, storage of biotechnological means obtained by biotechnological methods, as well as to biological objects and their producers | UO-2<br>Questions of the colloquium<br>PR-1<br>test | exam |
| | | | Can:<br>−use new methods and techniques in the development, production and circulation of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use;<br>−make adjustments to the draft action plans submitted for approval to accelerate the development of advanced technological solutions in the production processes of medicines obtained by biotechnological methods | PR-7<br>Supporting synopsis<br>PR-4 abstract<br>MA-3 report | exam |
| | | | Owns:<br>−skills of practical work with regulatory documentation, laboratory, pilot regulations, etc.; | PR-6<br>Practical tasks | exam |

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| | | | −skills in taking measures to accelerate the development of advanced biotechnological processes in production;<br>−skills in the introduction of new methods and techniques in the field of development, production and circulation of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use;<br>−skills in implementing proposals to improve technologies for the production of new medicines obtained by biotechnological methods | | |
| | | PC-2.2<br>Carries out the conduct of the technological process in the industrial production of medicines | Knows:<br>−The main producers and methods of obtaining biotechnological medicinal substances, their physical, chemical and pharmacological properties;<br>−biotechnological processes in the production and resources of natural biocenoses as sources of biologically active substances (BAS);<br>−modern achievements of biological sciences and biomedical technologies for the manufacture of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use;<br>−methods of optimization of biotechnological processes associated with the production of medicines;<br>Prospects for the technical development of a pharmaceutical organization. | UO-2<br>Questions of the colloquium<br>PR-1<br>test | exam |
| | | | Can:<br>−carry out biotechnological processes for the production and manufacture of medicines;<br>−obtain finished dosage forms from medicines of biotechnological origin;<br>−carry out the isolation and purification of biologically active substances from biomass and culture liquid;<br>regulate and improve the biotechnological process in order to obtain a high-quality final product | PR-7<br>Supporting synopsis<br>PR-4 abstract<br>MA-3 report | exam |

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| | | | Owns:<br>−the ability to develop and maintain the technological process in the industrial production of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use;<br>−the ability to carry out technological processes in the production and manufacture of medicines and biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use | | |
| | | PC-2.3<br>Carries out control of the technological process in the industrial production of medicines | Knows:<br>−the main regulatory documents related to the production, quality control, compliance with environmental safety, storage of biotechnological means obtained by biotechnological methods, as well as to biological objects - their producers;<br>−methods for determining the benignity of microorganisms-producers, determining the concentration of viable cells and their enzymatic activity;<br>−requirements for the production, standardization, quality control and compliance with the environmental safety of medicines obtained by biotechnological methods;<br>−analytical methods and methods of visual control of the technological process of production of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use | UO-2<br>Questions of the colloquium<br>PR-1<br>test | exam |
| | | | Can:<br>−develop and evaluate regulatory and recording documentation related to technological processes;<br>carry out step-by-step control and standardization of the resulting drugs (determination of the antimicrobial activity | PR-7<br>Supporting synopsis<br>PR-4 abstract<br>MA-3 report | exam |

| | | | | | |
|---|---|---|---|---|---|
| | | | of antibiotics, the activity of enzyme preparations, the viability of microorganisms;<br>−ensure compliance with industrial hygiene, environmental protection, occupational health and safety;<br>−choose the optimal storage conditions for therapeutic and diagnostic drugs and evaluate their quality during long-term storage | | |
| | | | Owns:<br>Requirements forcontrol in accordance with the Rules of Good Manufacturing Practice of the Eurasian Economic Union. | PR-6<br>Practical tasks | exam |

Scale for assessing the level of achievement of learning outcomes for current and intermediate certification *in the discipline "Medical and Pharmaceutical Biotechnology"*

| *Points (rating score)* | Levels of achievement Training | | *Requirements for formed competencies* |
|---|---|---|---|
| | Current and intermediate certification | *Intermediate certification* | |
| *100 – 86* | *Increased* | "credited" / "Excellent" | Freely and confidently finds reliable sources of information, operates with the information provided, has excellent skills in analyzing and synthesizing information, knows all the basic methods of solving problems provided by the curriculum, knows typical mistakes and possible difficulties in solving a particular problem and is able to choose and effectively apply an adequate method for solving a specific problem.<br>trouble |
| *85 – 76* | *Base* | "credited" / "Good" | In most cases, he is able to identify reliable sources of information, process, analyze and synthesize the proposed information, choose a method for solving the problem and solve it. Makes single serious mistakes in solving problems, experiences difficulties in rare or complex cases of problem solving, does not know typical mistakes and possible difficulties in solving one or another trouble |
| *75 – 61* | *Threshold* | "credited" / "Satisfyingly " | Makes mistakes in determining the reliability of sources of information, is able to correctly solve only typical, most common problems in<br>a specific area (process information, choose a method for solving a problem and solve it) |
| *60 – 0* | *Level Not reached* | "not credited" / "Dissatisfied" | He does not know a significant part of the program material, makes significant mistakes, hesitantly, with great difficulty, performs practical work. |

## Current certification in the discipline (module) "Medical and Pharmaceutical Biotechnology"

The current certification of students in the discipline "*Biotechnology"* is carried out in accordance with the local regulations of FEFU and is mandatory.

Current certification of the discipline is carried out in the form of control measures to assess the actual learning outcomes of students and is carried out by the leading teacher.

For each object, a description of the evaluation procedures is given in relation to the appraisal tools used.

### Assessment tools for ongoing control

### Questions for colloquia

**Topic 1. Antibiotics**

1. Isolation of soil microorganisms as objects for screening of biologically active compounds. Cultivation and study of morphological characteristics of microorganisms.
2. Brief theoretical foundations of cultivation and determination of morphological characteristics of microorganisms used in the screening of biologically active substances.
3. Natural biologically active substances and the main approaches for their screening.
4. The systematic position of microorganisms-producers of biologically active substances *(Bacillus, Actinomyces, Fungi),* the specificity of the compounds they produce. Isolation from the soil, cultivation and study of morphological characteristics of microorganisms. The main methods of storage of microorganisms.
5. Features of biosynthesis of microorganisms-producers of antibiotics.
6. Search and characterization of microorganisms-producers of antibiotics.
7. Comparison of morphological characteristics of the main producers in surface and deep cultivation.
8. Microbiological methods for determining antibiotic activity.
9. Microbiological methods for determining sensitivity to antibiotics and their concentration.
10. Study of antibiotic sensitivity.
11. Determination of the concentration (activity) of antibiotics.
12. Diffusion method into agar.
13. Method of serial dilution.
14. Standardization of methods for determining the concentration of antibiotics and sensitivity to them.

15. Isolation of antibiotics from culture fluid, determination of the authenticity of antibiotics and their quantitative analysis.

16. Methods of antibiotic isolation.

17. Methods of analysis.

18. Qualitative analysis.

19. Determination of the antibiotics homomycin and galtamicin in culture fluid extracts using TLC on Silufol plates.

20. Quantification of antibiotics.

21. Determination of fusidic acid.

22. Study of morphological characteristics of microorganisms-producers of biologically active substances in different phases of growth during deep cultivation; selection of optimal parameters of biosynthesis.

23. Theoretical foundations of antibiotic biosynthesis.

24. Producer as a self-regulating system.

25. Technological scheme of the process of microbial synthesis.

26. Seed.

27. Fermentation, stages of growth and biosynthesis.

28. The composition of the medium and fermentation conditions.

29. Controlled fermentation processes.

30. Study of micromorphological features of biologically active substances producers at different stages of cultivation (trophophase, idiophase) with the choice of optimal conditions for the process of antibiosynthesis of the antibiotic.

31. Determination of the optimal parameters for the biosynthesis of the antitumor antibiotic rubomycin.

**Topic 2. Amino acids**

1. The use of amino acids in medicine.
2. Superproducer strains.
3. Technology for the production of amino acids.
4. Fermentation of threonine; identification and determination of the content of this amino acid in the culture liquid.
5. The process of fermentation of threonine in the fermenter under conditions of intensive aeration and pH-stating with fractional supply of carbon and nitrogen sources to the medium on a signal from the pH sensor.
6. Determination of amino acids by TLC.

**Topic 3. Vitamins and coenzymes**

7. Biotechnological use of microorganisms in the production of vitamin C.
8. Transformation of D-sorbitol into L-sorbose by microorganisms of the species *Gluconobacter oxydans.*
9. Biotechnological use of microorganisms in the preparation of ubiquinone-10.
10. Characteristics of ubiquinones.

11. Industrial production of ubiquinones.
12. Methods for isolating and quantifying ubiquinones.
13. Methods of extraction of ubiquinones from biological objects.
14. Chromatographic methods for the isolation of ubiquinones.
15. Quantification of ubiquinone-10 from the biomass of *Gluconobacter oxydans bacteria.*

**Topic 4. Steroid hormones**

1. The use of biotechnological methods in the production of steroid hormones.
2. Microbiological transformations.
3. Biotransformation of hydrocortisone to prednisolone using immobilized A. *globiformis* cells.
4. Determination of the optimal conditions for the process of biotransformation **of hydrocortisone** to **prednisolone.**
5. Determination of the degree of biotransformation.
6. Dehydrogenation reactions.
7. Oxidative cleavage of the side chain of sitosterol ρ and the formation of blood pressure by biotransformer microorganisms.
8. Microbiological transformation of steroid hormones using immobilized *Arthrobacter globiformis* cells.

**Topic 5. Probiotics**

1. Preparations based on live cultures of lactic acid bacteria.
2. Human microflora.
3. Determination of the concentration of viable cells of lactobacilli, bifidobacteria and enterococci.
4. Preparation of nutrient media for accounting for lactobacilli, bifidobacteria and enterococci.
5. Conducting microscopic examination of these crops.
6. Determination of the concentration of viable cells.
7. Determination of active and titratable acidity.

**Topic 6. Biological products of plant origin**

1. Preparations based on plant biomass obtained *in vitro.*
2. Callus technologies.
3. Obtaining callus cell culture and assessing its quality.
4. Obtaining a primary callus.
5. Determination of the mitotic index.
6. Determination of extractives.
7. Carrying out high-quality reactions to glycosides, steroid compounds, starch.

**Topic 7. Immobilized biological objects**

1. Benefits of immobilizing isolated enzymes and whole microbial cells.
2. Immobilization of *E. coli* cells , a producer of penicillinacylase, and the

production of 6-APK.

3. Preparation of calcium alginate gel.
4. Immobilization in a solid carrier of E. *coli* cells producing penicillinacylase.
5. Qualitative and quantitative determination of 6-APC formed from benzylpenicillin.
6. Influence of immobilization conditions on the productivity of microbial cells.
7. Immobilization of microbial cells in PAAG.
8. Study of the influence of immobilization conditions on the productivity of microbial cells.

**Topic 8. Recombinant proteins**

1. Theoretical aspects of obtaining species-specific human proteins using recombinant strains.
2. Analysis of E. *coli* cell culture for the presence of an insulin-producing vector.
3. Isolation and analysis of plasmid DNA.
4. Cell destruction and separation of the plasmid vector (DNA).
5. Electrophoretic analysis of plasmid DNA in agarose.

**Topic 9. Vaccine**

1. Classification of vaccines.
2. Live vaccines.
3. Inactivated vaccines.
4. Technology for obtaining measles vaccine.
5. Preparation of the vaccine strain.
6. Infection of the vaccine strain with a seed virus.
7. Control of the specific activity of the measles virus.

To prepare answers to the questions of the colloquium, it is necessary to work out the recommended basic and additional literature.

## Biotechnology Test Questions

1. Activation of an insoluble carrier in case of immobilization of a biological object is necessary for:

– enhancing the efficiency of the inclusion of the enzyme in the gel;
– increase the sorption of the enzyme;
– increase the activity of the enzyme;
– formation of a covalent bond.

2. Activated sludge used in the treatment of industrial effluents of pharmaceutical production:

– sorbent;
– a mixture of sorbents;
– a mixture of microorganisms obtained by genetic engineering methods;

– natural complex of microorganisms.

3. The biosynthesis of antibiotics used as drugs is enhanced and occurs earlier on the media:

– rich in nitrogen sources;
– carbon-rich;
– rich in phosphorus sources;
– nutrient-poor.

4.Biotechnologists use restriction enzyme, which recognizes and cuts DNA, as follows:

– both complementary strands of DNA at the same time;
– one of the complementary strands of DNA;
– with a specific sequence of 2-3 pairs of nucleotides;
– with a specific sequence of 5-6 pairs of nucleotides.

5. The marker gene is necessary for a biotechnologist to:

– increasing the activity of the recombinant;
– formation of competent host cells;
– modification of the site of interaction of restriction enzymes with the substrate;
– selection of recombinants.

6. A plasmid-based vector is preferable to a phage-based DNA vector due to:

– large sizes;
– less toxicity;
– high frequency of inclusion;
– lack of lysis of the host cell.

7. Isolation and purification of biosynthesis and organic synthesis products have fundamental differences at certain stages of the process:

– at all stages;
– on the finite;
– on the former;
– There are no fundamental differences.

8.Genomics in antimicrobial drug screening allows you to anticipate:

– the cost of drugs;
– spectrum of antimicrobial action;
– the presence of side effects;
– the rate of development of resistance;
– Methods of selection.

9. Hybridization of protoplasts is possible if the cells of the original plants have:

– sexual compatibility;
– sexual incompatibility;

– Compatibility is not essential.

10. For the preparation of nutrient media in the production of antibiotics, it is advisable to use water:

– Distilled;
– Sterile;
– Drinking;
– from open water bodies after appropriate treatment.

11. Suspension cultures are most suitable for protoplasting:

– in the lag phase;
– in the phase of accelerated growth;
– in the logarithmic phase;
– in the phase of slow growth;
– in the stationary phase;
– in the phase of dying off.

12. Protection of aminoglycoside producers from their own antibiotic is determined by

– low ribosome affinity;
– active release;
– temporary enzymatic inactivation;
– compartment.

13. Producer cells are immobilized if the target product:

– water-soluble;
– insoluble in water;
– localized inside the cell;
– is the biomass of cells.

14. What raw materials are used as a source of nitrogen in the production of penicillin?

– corn extract;
– soybean flour;
– ammophos;
– corn flour.

15. β-lactam antibiotics include:

– Penicillins;
– cyclosporines;
– carbapenems;
– cephalosporins;
– macrolides.

16. Mycobacteria - the causative agents of modern tuberculosis infection are

resistant to chemotherapy due to:

– compensatory mutations;
– slow growth;
– intracellular localization;
– one-copy operon;
– weakening of the immunity of the host organism

17. The target for physical and chemical mutagens in the cell of biological objects is:

– DNA;
– DNA polymerase;
– RNA polymerase;
– ribosome;
– messenger RNA.

18. Monoclonal antibodies in production receive:

– in the fractionation of antibodies of organisms;
– fractionation of lymphocytes;
– with the help of hybridoma technology.

19. Combining the genomes of cells of different species and genera is possible with somatic hybridization:

– only in natural conditions;
– only in artificial conditions;
– in natural and artificial conditions.

20.The relaxation of restrictions on the use of recombinant microorganisms producing human hormones in industry was made possible by:

– improvement of methods for isolating genetically engineered recombinants from the environment;
– advanced training of personnel working with recombinants;
– established experimentally weak viability of the producer;
– experimental confirmation of the loss of foreign genes.

21. The main advantage of enzymatic bioconversion of steroids over chemical transformation is:

– availability of reagents;
– selectivity of effects on certain functional groups of the steroid;
– shortening the process time;
– obtaining fundamentally new compounds.

22. The peculiarity of peptide tissue growth factors is:

– tissue specificity;
– species specificity;

– the formation of their endocrine glands;
– their formation outside the endocrine glands.

23. The following definitions correspond to the concept of "biological object":
– an organism on which new biologically active compounds are tested;
– an organism that causes contamination of biotechnological equipment;
– enzyme used for analytical purposes;
– an organism that produces biologically active compounds;
– enzyme-industrial catalyst.

24. The occurrence of multiple resistance of tumors to antitumor agents is due to:
– membrane impermeability;
– enzymatic inactivation;
– decrease in affinity of intracellular targets;
– active ejection (pump mechanism).

25. GMP rules provide for the production of the following groups of antibiotics in separate rooms and on separate equipment:
– penicillins;
– aminoglycosides;
– Tetracycline;
– macrolides;
– polyenes.

26.The GMP rules provide for validation when:
– replacement of a biological object with a more productive one;
– changes in the composition of the nutrient medium;
– the end of the calendar year;
– Quarterly;
– when updating the staff of the enterprise.

27. The advantage of genetically engineered insulin is its:
– high activity;
– lower allergenicity;
– less toxicity;
– Greater stability.

28. The advantages of immobilization of cells with increased membrane permeability are:
– long-term preservation of viability;
– greater binding to the carrier;
– increasing the rate of diffusion of the substrate;
– Increasing the yield rate of the target product.

29. Advantages of obtaining species-specific proteins for humans by microbiological synthesis (choose from the following):

– simplicity of equipment;
– economy;
– absence of scarce raw materials;
– removal of ethical problems.

30. The advantage of RIA in comparison with the determination of insulin by a drop in the concentration of glucose in the blood of animals is:

– lower cost of analysis;
– uselessness of scarce reagents;
– ease of mastering the method.

31. When isolating enzymes, the efficiency of centrifugation depends on:

– molecular weight of the enzyme;
– number of subunits;
– the presence of a coenzyme.

32. When treating industrial effluents during peak hours, the following destructor strains shall be used (choose from the following):

– natural microorganisms;
– permanent components of activated sludge;
– stable genetically engineered strains.

33. The reason for the high efficacy of antibiotic drugs unazin and augmentin is:

– low toxicity (compared with ampicillin and amoxicillin);
– low cost;
– action on β-lactam-resistant strains of bacteria;
– prolongation of the effect.

34. The reason for the impossibility of direct expression of the human gene in the cell of prokaryotes:

– high concentration of nucleases;
– inability to replicate plasmids;
– lack of transcription;
– impossibility of splicing.

35. Proteomics characterizes the state of a microbial pathogen by:

– enzymatic activity;
– growth rate;
– expression of individual proteins;
– being at a specific stage of the growth cycle.

36. Direct transfer of foreign DNA into protoplasts is possible using:

– microinjections;

– Transformation;
– packaging in liposomes;
– cultivation of protoplasts on appropriate nutrient media.

37. The developed technology for the production of recombinant erythropoietin is based on the expression of the gene in:
– bacterial cells;
– yeast cells;
– plant cells;
– culture of animal cells.

38. Regulated fermentation in the process of biosynthesis is achieved with a certain method of cultivation:
– Periodic;
– Continuous;
– weaning-topping;
– semi-periodic.

39. Retroinhibition in biosynthesis of biologically active substances is:
– suppression of the last enzyme of the metabolic chain;
– suppression of the initial enzyme of the metabolic chain;
– inhibition of all enzymes of the metabolic chain.

40. Signal transduction is:
– signal transmission from the cell membrane to the genome;
– initiation of protein synthesis;
– post-translational changes in protein;
– isolation of lytic enzymes.

41. Screening of enzymes for the production of semi-synthetic β-lactams is necessary due to:
– enzyme instability;
– patenting of previously obtained enzymes;
– the high cost of commercial drugs;
– different substrate specificity.

42. A complete enzyme complex is called:
– apoenzyme;
– coenzyme;
– holoenzyme;
– cofactor.

43. Methods for storing microbial biological objects may be as follows:
– on bulk materials;
– under a layer of oil;

– in saline;
– on a nutrient agar medium;
– in alcohol solutions;
– at ultra-low temperatures.

44. The sterile air supplied to the fermenter performs the following functions:
– provides microorganisms with oxygen;
– serves as a heat sink;
– removes gaseous metabolic products;
– prevents foaming;
– maintains the pH of the medium at an optimal level;
– increases the rate of mass transfer processes.

45.The term "normal flora" characterizes:
– probiotics;
– eubiotics;
– microbiotics;
– lactic acid bacteria.

46. The term "vector" in genetic engineering corresponds to:
– plasmid with a foreign gene;
– a foreign gene included in a chromosome;
– a section of the cell membrane that is not protected by a cell wall;
– host cell chromosome;
– phage DNA with a foreign gene.

47. Process air for biotechnological production shall be sterilized in the following way:
– Heating;
– filtering;
– Irradiation.

48. Transferases shall carry out:
– catalysis of redox reactions;
– transfer of functional groups to the water molecule;
– catalysis of the addition reaction by double bonds;
– catalysis of functional group transfer reactions.

49. An increase in the yield of the target product during the biotransformation of the steroid is achieved with:
– increasing the intensity of mixing;
– increase in the intensity of aeration;
– increase in fermentation temperature;
– increase in fermentation time;

– increase in the concentration of the steroid substrate in the fermentation medium;

– purposeful change in the chemical structure of the steroid substrate.

50. Specify the correct sequence of operations for the preparation of process air:

– cooling of air in the heat exchanger;

– compression of air in the compressor;

– purification of atmospheric air from suspended particles;

– separation from condensate;

– maintaining the set temperature and humidity in the head filter, cold sterilization;

– Sterilization of air in an individual filter.

51. The condition for the preservation of protoplasts (in relation to the method of cell engineering) is:

– low temperature;

– the presence of PEG (polyethylene oxide) in the medium;

– the presence of a buffer in the environment;

– hypertensive environment.

52. FUC as a precursor in the biosynthesis of penicillin add:

– before fermentation;

– at the beginning of fermentation;

– 2-3 days after the start of fermentation;

– every day for a 5-day process.

53. The function of pheromones is:

– antimicrobial activity;

– antiviral activity;

– changes in the behavior of an organism with a specific receptor;

– antitumor activity.

54. Objectives of immobilization of enzymes in biotechnological production (choose from the following):

– increase in specific activity;

– stability improvements;

– expansion of the substrate spectrum;

– Reuse.

55. Embryonic tissues are used in the preparation of vaccines against:

– Flu;

– Polio;

– Rabies;

– typhoid fever;

– Cory.

## IX. APPRAISAL FUNDS

Professional competencies of graduates and indicators of their achievement:

| Task type | Code and name of professional competence (the result of mastering) | Code and name of the competency achievement indicator |
|---|---|---|
| Professional Career | PC-2<br>Able to take part in the selection, justification of the optimal technological process and its implementation in the production of medicines for medical use | PC-2.1<br>Develops technological documentation for the industrial production of medicines |
| | | PC-2.2<br>Carries out the conduct of the technological process in the industrial production of medicines |
| | | PC-2.3<br>Carries out control of the technological process in the industrial production of medicines |

| Code and name of the competency achievement indicator | Name of the assessment indicator (the result of training in the discipline) |
|---|---|
| PC-2.1<br>Develops technological documentation for the industrial production of medicines | Knows:<br>−the specifics of the production of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use, determined by the nature of the product and production technology;<br>−methodological materials on technological preparation of production;<br>−licensing requirements for the production of medicines;<br>−the main regulatory documents related to the production, quality control, environmental safety, storage of biotechnological means obtained by biotechnological methods, as well as to biological objects and their producers |
| | Can:<br>−use new methods and techniques in the development, production and circulation of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use;<br>−make adjustments to the draft action plans submitted for approval to accelerate the development of advanced technological solutions in the production processes of medicines obtained by biotechnological methods |
| | Owns:<br>−skills of practical work with regulatory documentation, laboratory, pilot regulations, etc.;<br>−skills in taking measures to accelerate the development of advanced biotechnological processes in production;<br>−skills in the introduction of new methods and techniques in the field of development, production and circulation of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use;<br>−skills in implementing proposals to improve technologies for the production of new medicines obtained by biotechnological methods |

| Code and name of the competency achievement indicator | Name of the assessment indicator (the result of training in the discipline) |
|---|---|
| PC-2.2<br>Carries out the conduct of the technological process in the industrial production of medicines | Knows:<br>−the main producers and methods of obtaining biotechnological medicinal substances, their physical, chemical and pharmacological properties;<br>−biotechnological processes in the production and resources of natural biocenoses as sources of biologically active substances (BAS);<br>−modern achievements of biological sciences and biomedical technologies for the manufacture of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use;<br>−methods of optimization of biotechnological processes associated with the production of medicines;<br>−Prospects for the technical development of a pharmaceutical organization. |
| | Can:<br>−carry out biotechnological processes for the production and manufacture of medicines;<br>−obtain finished dosage forms from medicines of biotechnological origin;<br>−carry out the isolation and purification of biologically active substances from biomass and culture liquid;<br>−regulate and improve the biotechnological process in order to obtain a high-quality final product |
| | Owns:<br>−the ability to develop and maintain the technological process in the industrial production of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use;<br>−the ability to carry out technological processes in the production and manufacture of medicines and biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use |
| PC-2.3<br>Carries out control of the technological process in the industrial production of medicines | Knows:<br>−the main regulatory documents related to the production, quality control, compliance with environmental safety, storage of biotechnological means obtained by biotechnological methods, as well as to biological objects - their producers;<br>−methods for determining the benignity of microorganisms-producers, determining the concentration of viable cells and their enzymatic activity;<br>−requirements for the production, standardization, quality control and compliance with the environmental safety of medicines obtained by biotechnological methods;<br>−analytical methods and methods of visual control of the technological process of production of biological (including immunobiological) active pharmaceutical ingredients and medicines for medical use |
| | Can:<br>−develop and evaluate regulatory and recording documentation related to technological processes; |

| Code and name of the competency achievement indicator | Name of the assessment indicator (the result of training in the discipline) |
|---|---|
| | −carry out step-by-step control and standardization of the resulting drugs (determination of the antimicrobial activity of antibiotics, the activity of enzyme preparations, the viability of microorganisms;<br>−ensure compliance with industrial hygiene, environmental protection, occupational health and safety;<br>−choose the optimal storage conditions for therapeutic and diagnostic drugs and evaluate their quality during long-term storage |
| | Owns:<br>−control requirements under the Rules of Good Manufacturing Practice of the Eurasian Economic Union. |

## The list of forms of assessment used at various stages of the formation of competencies in the course of mastering the discipline of the module

### Examples of current control tasks

### Interview Questions

**Topic 1. Antibiotics**

1. Isolation of soil microorganisms as objects for screening of biologically active compounds. Cultivation and study of morphological characteristics of microorganisms.
2. Brief theoretical foundations of cultivation and determination of morphological characteristics of microorganisms used in the screening of biologically active substances.
3. Natural biologically active substances and the main approaches for their screening.
4. The systematic position of microorganisms-producers of biologically active substances *(Bacillus, Actinomyces, Fungi),* the specificity of the compounds they produce. Isolation from the soil, cultivation and study of morphological characteristics of microorganisms. The main methods of storage of microorganisms.
5. Features of biosynthesis of microorganisms-producers of antibiotics.
6. Search and characterization of microorganisms-producers of antibiotics.
7. Comparison of morphological characteristics of the main producers in surface and deep cultivation.
8. Microbiological methods for determining antibiotic activity.
9. Microbiological methods for determining sensitivity to antibiotics and their concentration.
10. Study of antibiotic sensitivity.
11. Determination of the concentration (activity) of antibiotics.
12. Diffusion method into agar.

13. Method of serial dilution.

14. Standardization of methods for determining the concentration of antibiotics and sensitivity to them.

15. Isolation of antibiotics from culture fluid, determination of the authenticity of antibiotics and their quantitative analysis.

16. Methods of antibiotic isolation.

17. Methods of analysis.

18. Qualitative analysis.

19. Determination of the antibiotics homomycin and galtamicin in culture fluid extracts using TLC on Silufol plates.

20. Quantification of antibiotics.

21. Determination of fusidic acid.

22. Study of morphological characteristics of microorganisms-producers of biologically active substances in different phases of growth during deep cultivation; selection of optimal parameters of biosynthesis.

23. Theoretical foundations of antibiotic biosynthesis.

24. Producer as a self-regulating system.

25. Technological scheme of the process of microbial synthesis.

26. Seed.

27. Fermentation, stages of growth and biosynthesis.

28. The composition of the medium and fermentation conditions.

29. Controlled fermentation processes.

30. Study of micromorphological features of biologically active substances producers at different stages of cultivation (trophophase, idiophase) with the choice of optimal conditions for the process of antibiosynthesis of the antibiotic.

31. Determination of the optimal parameters for the biosynthesis of the antitumor antibiotic rubomycin.

**Topic 2. Amino acids**

16. The use of amino acids in medicine.

17. Superproducer strains.

18. Technology for the production of amino acids.

19. Fermentation of threonine; identification and determination of the content of this amino acid in the culture liquid.

20. The process of fermentation of threonine in the fermenter under conditions of intensive aeration and pH-stating with fractional supply of carbon and nitrogen sources to the medium on a signal from the pH sensor.

21. Determination of amino acids by TLC.

**Topic 3. Vitamins and coenzymes**

22. Biotechnological use of microorganisms in the production of vitamin C.

23. Transformation of D-sorbitol into L-sorbose by microorganisms of the

species *Gluconobacter oxydans.*

24. Biotechnological use of microorganisms in the preparation of ubiquinone-10.
25. Characteristics of ubiquinones.
26. Industrial production of ubiquinones.
27. Methods for isolating and quantifying ubiquinones.
28. Methods of extraction of ubiquinones from biological objects.
29. Chromatographic methods for the isolation of ubiquinones.
30. Quantification of ubiquinone-10 from the biomass of *Gluconobacter oxydans bacteria.*

**Topic 4. Steroid hormones**

9. The use of biotechnological methods in the production of steroid hormones.
10. Microbiological transformations.
11. Biotransformation of hydrocortisone to prednisolone using immobilized A. *globiformis* cells.
12. Determination of the optimal conditions for the process of biotransformation **of hydrocortisone** to **prednisolone.**
13. Determination of the degree of biotransformation.
14. Dehydrogenation reactions.
15. Oxidative cleavage of the side chain of[sitosterol ρ] and the formation of blood pressure by biotransformer microorganisms.
16. Microbiological transformation of steroid hormones using immobilized *Arthrobacter globiformis* cells.

**Topic 5. Probiotics**

8. Preparations based on live cultures of lactic acid bacteria.
9. Human microflora.
10. Determination of the concentration of viable cells of lactobacilli, bifidobacteria and enterococci.
11. Preparation of nutrient media for accounting for lactobacilli, bifidobacteria and enterococci.
12. Conducting microscopic examination of these crops.
13. Determination of the concentration of viable cells.
14. Determination of active and titratable acidity.

**Topic 6. Biological products of plant origin**

8. Preparations based on plant biomass obtained *in vitro.*
9. Callus technologies.
10. Obtaining callus cell culture and assessing its quality.
11. Obtaining a primary callus.
12. Determination of the mitotic index.
13. Determination of extractives.
14. Carrying out high-quality reactions to glycosides, steroid compounds, starch.

**Topic 7. Immobilized biological objects**

9. Benefits of immobilizing isolated enzymes and whole microbial cells.
10. Immobilization of *E. coli* cells , a producer of penicillinacylase, and the production of 6-APK.
11. Preparation of calcium alginate gel.
12. Immobilization in a solid carrier of E. *coli* cells producing penicillinacylase.
13. Qualitative and quantitative determination of 6-APC formed from benzylpenicillin.
14. Influence of immobilization conditions on the productivity of microbial cells.
15. Immobilization of microbial cells in PAAG.
16. Study of the influence of immobilization conditions on the productivity of microbial cells.

**Topic 8. Recombinant proteins**

6. Theoretical aspects of obtaining species-specific human proteins using recombinant strains.
7. Analysis of E. *coli* cell culture for the presence of an insulin-producing vector.
8. Isolation and analysis of plasmid DNA.
9. Cell destruction and separation of the plasmid vector (DNA).
10. Electrophoretic analysis of plasmid DNA in agarose.

**Topic 9. Vaccine**

8. Classification of vaccines.
9. Live vaccines.
10. Inactivated vaccines.
11. Technology for obtaining measles vaccine.
12. Preparation of the vaccine strain.
13. Infection of the vaccine strain with a seed virus.
14. Control of the specific activity of the measles virus.

To prepare answers to the questions of the colloquium, it is necessary to work out the recommended basic and additional literature.

## Biotechnology Test Questions

2. Activation of an insoluble carrier in case of immobilization of a biological object is necessary for:

– enhancing the efficiency of the inclusion of the enzyme in the gel;
– increase the sorption of the enzyme;
– increase the activity of the enzyme;
– formation of a covalent bond.

2. Activated sludge used in the treatment of industrial effluents of pharmaceutical production:

– sorbent;
– a mixture of sorbents;
– a mixture of microorganisms obtained by genetic engineering methods;
– natural complex of microorganisms.

3. The biosynthesis of antibiotics used as drugs is enhanced and occurs earlier on the media:
– rich in nitrogen sources;
– carbon-rich;
– rich in phosphorus sources;
– nutrient-poor.

4.Biotechnologists use restriction enzyme, which recognizes and cuts DNA, as follows:
– both complementary strands of DNA at the same time;
– one of the complementary strands of DNA;
– with a specific sequence of 2-3 pairs of nucleotides;
– with a specific sequence of 5-6 pairs of nucleotides.

5. The marker gene is necessary for a biotechnologist to:
– increasing the activity of the recombinant;
– formation of competent host cells;
– modification of the site of interaction of restriction enzymes with the substrate;
– selection of recombinants.

6. A plasmid-based vector is preferable to a phage-based DNA vector due to:
– large sizes;
– less toxicity;
– high frequency of inclusion;
– lack of lysis of the host cell.

7. Isolation and purification of biosynthesis and organic synthesis products have fundamental differences at certain stages of the process:
– at all stages;
– on the finite;
– on the former;
– There are no fundamental differences.

8.Genomics in antimicrobial drug screening allows you to anticipate:
– the cost of drugs;
– spectrum of antimicrobial action;
– the presence of side effects;
– the rate of development of resistance;
– Methods of selection.

9. Hybridization of protoplasts is possible if the cells of the original plants have:

– sexual compatibility;

– sexual incompatibility;

– Compatibility is not essential.

10. For the preparation of nutrient media in the production of antibiotics, it is advisable to use water:

– Distilled;

– Sterile;

– Drinking;

– from open water bodies after appropriate treatment.

11. Suspension cultures are most suitable for protoplasting:

– in the lag phase;

– in the phase of accelerated growth;

– in the logarithmic phase;

– in the phase of slow growth;

– in the stationary phase;

– in the phase of dying off.

12. Protection of aminoglycoside producers from their own antibiotic is determined by

– low ribosome affinity;

– active release;

– temporary enzymatic inactivation;

– compartment.

14. Producer cells are immobilized if the target product:

– water-soluble;

– insoluble in water;

– localized inside the cell;

– is the biomass of cells.

14. What raw materials are used as a source of nitrogen in the production of penicillin?

– corn extract;

– soybean flour;

– ammophos;

– corn flour.

17. β-lactam antibiotics include:

– Penicillins;

– cyclosporines;

– carbapenems;

– cephalosporins;
– macrolides.

18. Mycobacteria - the causative agents of modern tuberculosis infection are resistant to chemotherapy due to:
– compensatory mutations;
– slow growth;
– intracellular localization;
– one-copy operon;
– weakening of the immunity of the host organism

17. The target for physical and chemical mutagens in the cell of biological objects is:
– DNA;
– DNA polymerase;
– RNA polymerase;
– ribosome;
– messenger RNA.

18. Monoclonal antibodies in production receive:
– in the fractionation of antibodies of organisms;
– fractionation of lymphocytes;
– with the help of hybridoma technology.

19. Combining the genomes of cells of different species and genera is possible with somatic hybridization:
– only in natural conditions;
– only in artificial conditions;
– in natural and artificial conditions.

20.The relaxation of restrictions on the use of recombinant microorganisms producing human hormones in industry was made possible by:
– improvement of methods for isolating genetically engineered recombinants from the environment;
– advanced training of personnel working with recombinants;
– established experimentally weak viability of the producer;
– experimental confirmation of the loss of foreign genes.

21. The main advantage of enzymatic bioconversion of steroids over chemical transformation is:
– availability of reagents;
– selectivity of effects on certain functional groups of the steroid;
– shortening the process time;
– obtaining fundamentally new compounds.

22. The peculiarity of peptide tissue growth factors is:

– tissue specificity;
– species specificity;
– the formation of their endocrine glands;
– their formation outside the endocrine glands.

23. The following definitions correspond to the concept of "biological object":

– an organism on which new biologically active compounds are tested;
– an organism that causes contamination of biotechnological equipment;
– enzyme used for analytical purposes;
– an organism that produces biologically active compounds;
– enzyme-industrial catalyst.

24. The occurrence of multiple resistance of tumors to antitumor agents is due to:

– membrane impermeability;
– enzymatic inactivation;
– decrease in affinity of intracellular targets;
– active ejection (pump mechanism).

25. GMP rules provide for the production of the following groups of antibiotics in separate rooms and on separate equipment:

– penicillins;
– aminoglycosides;
– Tetracycline;
– macrolides;
– polyenes.

26.The GMP rules provide for validation when:

– replacement of a biological object with a more productive one;
– changes in the composition of the nutrient medium;
– the end of the calendar year;
– Quarterly;
– when updating the staff of the enterprise.

27. The advantage of genetically engineered insulin is its:

– high activity;
– lower allergenicity;
– less toxicity;
– Greater stability.

28. The advantages of immobilization of cells with increased membrane permeability are:

– long-term preservation of viability;
– greater binding to the carrier;

– increasing the rate of diffusion of the substrate;
– Increasing the yield rate of the target product.

29. Advantages of obtaining species-specific proteins for humans by microbiological synthesis (choose from the following):
– simplicity of equipment;
– economy;
– absence of scarce raw materials;
– removal of ethical problems.

30. The advantage of RIA in comparison with the determination of insulin by a drop in the concentration of glucose in the blood of animals is:
– lower cost of analysis;
– uselessness of scarce reagents;
– ease of mastering the method.

31. When isolating enzymes, the efficiency of centrifugation depends on:
– molecular weight of the enzyme;
– number of subunits;
– the presence of a coenzyme.

32. When treating industrial effluents during peak hours, the following destructor strains shall be used (choose from the following):
– natural microorganisms;
– permanent components of activated sludge;
– stable genetically engineered strains.

33. The reason for the high efficacy of antibiotic drugs unazin and augmentin is:
– low toxicity (compared with ampicillin and amoxicillin);
– low cost;
– action on β-lactam-resistant strains of bacteria;
– prolongation of the effect.

34. The reason for the impossibility of direct expression of the human gene in the cell of prokaryotes:
– high concentration of nucleases;
– inability to replicate plasmids;
– lack of transcription;
– impossibility of splicing.

35. Proteomics characterizes the state of a microbial pathogen by:
– enzymatic activity;
– growth rate;
– expression of individual proteins;
– being at a specific stage of the growth cycle.

36. Direct transfer of foreign DNA into protoplasts is possible using:

– microinjections;
– Transformation;
– packaging in liposomes;
– cultivation of protoplasts on appropriate nutrient media.

37. The developed technology for the production of recombinant erythropoietin is based on the expression of the gene in:

– bacterial cells;
– yeast cells;
– plant cells;
– culture of animal cells.

39. Regulated fermentation in the process of biosynthesis is achieved with a certain method of cultivation:

– Periodic;
– Continuous;
– weaning-topping;
– semi-periodic.

39. Retroinhibition in biosynthesis of biologically active substances is:

– suppression of the last enzyme of the metabolic chain;
– suppression of the initial enzyme of the metabolic chain;
– inhibition of all enzymes of the metabolic chain.

40. Signal transduction is:

– signal transmission from the cell membrane to the genome;
– initiation of protein synthesis;
– post-translational changes in protein;
– isolation of lytic enzymes.

41. Screening of enzymes for the production of semi-synthetic β-lactams is necessary due to:

– enzyme instability;
– patenting of previously obtained enzymes;
– the high cost of commercial drugs;
– different substrate specificity.

42. A complete enzyme complex is called:

– apoenzyme;
– coenzyme;
– holoenzyme;
– cofactor.

43. Methods for storing microbial biological objects may be as follows:

– on bulk materials;
– under a layer of oil;
– in saline;
– on a nutrient agar medium;
– in alcohol solutions;
– at ultra-low temperatures.

44. The sterile air supplied to the fermenter performs the following functions:
– provides microorganisms with oxygen;
– serves as a heat sink;
– removes gaseous metabolic products;
– prevents foaming;
– maintains the pH of the medium at an optimal level;
– increases the rate of mass transfer processes.

45.The term "normal flora" characterizes:
– probiotics;
– eubiotics;
– microbiotics;
– lactic acid bacteria.

46. The term "vector" in genetic engineering corresponds to:
– plasmid with a foreign gene;
– a foreign gene included in a chromosome;
– a section of the cell membrane that is not protected by a cell wall;
– host cell chromosome;
– phage DNA with a foreign gene.

47. Process air for biotechnological production shall be sterilized in the following way:
– Heating;
– filtering;
– Irradiation.

48. Transferases shall carry out:
– catalysis of redox reactions;
– transfer of functional groups to the water molecule;
– catalysis of the addition reaction by double bonds;
– catalysis of functional group transfer reactions.

49. An increase in the yield of the target product during the biotransformation of the steroid is achieved with:
– increasing the intensity of mixing;
– increase in the intensity of aeration;

– increase in fermentation temperature;

– increase in fermentation time;

– increase in the concentration of the steroid substrate in the fermentation medium;

– purposeful change in the chemical structure of the steroid substrate.

50. Specify the correct sequence of operations for the preparation of process air:

– cooling of air in the heat exchanger;

– compression of air in the compressor;

– purification of atmospheric air from suspended particles;

– separation from condensate;

– maintaining the set temperature and humidity in the head filter, cold sterilization;

– Sterilization of air in an individual filter.

51. The condition for the preservation of protoplasts (in relation to the method of cell engineering) is:

– low temperature;

– the presence of PEG (polyethylene oxide) in the medium;

– the presence of a buffer in the environment;

– hypertensive environment.

52. FUC as a precursor in the biosynthesis of penicillin add:

– before fermentation;

– at the beginning of fermentation;

– 2-3 days after the start of fermentation;

– every day for a 5-day process.

53. The function of pheromones is:

– antimicrobial activity;

– antiviral activity;

– changes in the behavior of an organism with a specific receptor;

– antitumor activity.

54. Objectives of immobilization of enzymes in biotechnological production (choose from the following):

– increase in specific activity;

– stability improvements;

– expansion of the substrate spectrum;

– Reuse.

55. Embryonic tissues are used in the preparation of vaccines against:

– Flu;

– Polio;

– Rabies;
– typhoid fever;
– Cory.

## Bank of test tasks

1. The emergence of genomics as a scientific discipline became possible after:
(a) Establishing the structure of DNA; b) the creation of the concept of the gene;
c) differentiation of regulatory and structural regions of the gene;
d) complete genome sequencing in a number of organisms.
2. The materiality of the gene in a pathogenic organism - the product encoded by the genome is necessary:
a) for cell reproduction; b) to maintain life;
c) for invasion into tissues; d) to inactivate an antimicrobial substance.
3. House keeping genes in a pathogenic microorganism are expressed:
a) in the infected organism of the host b) always
c) only on artificial nutrient media d) under the influence of inductors
4. Proteomics characterizes the state of a microbial pathogen:
a) by enzymatic activity b) by growth rate
c) by the expression of individual proteins; d) by being at a specific stage of the growth cycle;
5. To obtain protoplasts from fungal cells, the following is used:
a) lysozyme b) trypsin
c) "snail enzyme" d) pepsin
6. The formation of protoplasts from microbial cells can be monitored using the following methods:
a) viscosymetry b) colorimetry
c) phase-contrast microscopy d) electron microscopy
7. To obtain protoplasts from bacterial cells, the following is used:
a) lysozyme b) "snail enzyme" c) trypsin d) papain
8. Combining the genomes of cells of different species and genera is possible with somatic hybridization:
a) only in natural conditions; b) only in artificial conditions;
c) in natural and artificial conditions
9. High stability of protoplasts is achieved during storage:
a) in the cold; b) in a hypertensive environment;
c) in an environment with the addition of antioxidants; d) under anaerobic conditions.
10. Polyethylene glycol (PEG) applied to the suspension of protoplasts:
(a) Facilitate their merger; b) prevents their merger;

c) increases the stability of the suspension; d) prevents microbial contamination.

11. Suspension cultures are most suitable for protoplasting:

a) in the lag phase; b) in the phase of accelerated growth;

c) in the logarithmic phase; d) in the phase of slow growth; e) in the stationary phase;

12. Hybridization of protoplasts is possible if the cells of the original plants have:

(a) Sexual compatibility; b) sexual incompatibility;

c) compatibility is not essential.

13. The advantages of genetically engineered insulin are:

(a) High activity; b) lower allergenicity;

c) less toxicity; d) greater stability.

14. Advantages of obtaining species-specific proteins for humans by microbiological synthesis:

(a) Simplicity of equipment; b) cost-effectiveness;

c) absence of scarce raw materials; d) removal of ethical problems.

15. The developed technology for the production of recombinant erythropoietin is based on the expression of the gene:

a) in bacterial cells; b) in yeast cells;

c) in plant cells; d) in the culture of animal cells.

16. The peculiarity of peptide tissue growth factors shall be:

a) tissue specificity; b) species specificity;

c) the formation of endocrine glands; d) formation outside the endocrine glands;

17. The advantage of ELISA over the determination of insulin by a drop in the concentration of glucose in the blood of animals:

(a) Lower cost of analysis; b) uselessness of scarce reagents; c) ease of development;

d) in the absence of influence on the results of the analysis of other proteins; e) the duration of the analysis time.

18. When assessing the quality of genetically engineered insulin, it is necessary to pay special attention to the test for:

(a) Sterility; b) toxicity; c) allergenicity; d) pyrogenicity.

19. The main advantage of semi-synthetic erythromycin derivatives - azitro-, roxitro-, clarithromycin over a natural antibiotic is due to:

(a) Less toxicity; b) bactericidal activity;

c) activity against intracellularly localized parasites; d) action on mushrooms.

20. Antibiotics with self-promoted penetration into the pathogen cell:

(a) Beta-lactams; b) aminoglycosides; c) macrolides; d) glycopeptides.

21. The appearance of multiple tumor resistance to antitumor agents is due to:

(a) Membrane impermeability; b) enzymatic inactivation;

c) a decrease in the affinity of intracellular targets; d) active release.

22. The practical significance of the semisynthetic aminoglycoside amikacin is due to:

(a) Activity against anaerobic pathogens; b) lack of nephrotoxicity;

c) resistance to protective enzymes in bacteria that inactivate other aminoglycosides;

d) activity against pathogenic fungi.

23. The effect of polyenes - nystatin and amphotericin B on fungi, but not on bacteria, is explained:

a) features of ribosomes in fungi; b) the presence of mitochondria;

c) the presence of chitin in the cell wall; d) the presence of ergosterol in the membrane.

24. The fungicidal nature of nystatin and amphotericin B polyenes is due to:

a) interaction with DNA; b) activation of lytic enzymes;

c) the formation of water channels in the membrane and the loss of low molecular weight metabolites and inorganic metabolites by the cell

Ions;

d) suppression of electronic transport systems.

25. Protection of aminoglycoside producers from their own antibiotic:

(a) Low ribosome affinity; b) active release;

c) temporary enzymatic inactivation; d) compartment.

26. Signal transduction:

(a) Signal transduction from the cell membrane to the genome; b) initiation of protein synthesis;

c) post-granulation changes in protein; d) isolation of lytic enzymes.

27. Of the secondary metabolites of microorganisms, the inhibitor of signal transduction shall be:

a) streptomycin; b) nystatin; c) cyclosporine A; d) erythromycin.

28. Transferases shall carry out:

a) catalysis of redox reactions; b) transfer of functional groups to the water molecule;

c) catalysis of addition reactions by double bonds;

d) catalysis of functional group transfer reactions to the substrate.

29. Fourth-generation cephalosporin resistant to beta-lactamases of gram-negative bacteria:

a) cephalexin; b) cefazolin; c) cefpir; d) cefaclor.

30. Fourth-generation cephalosporin resistant to betalactamases of gram-positive bacteria:

a) cefazolin; b) ceftriaxone; c) cephaloridine; d) cefepime.

31. Penicillin acylase is used:

a) when checking the factory series of penicillin for sterility;

b) when assessing the effectiveness of penicillin structures against resistant bacteria;

c) in the production of semi-synthetic penicillins;

d) when relieving allergic reactions to penicillin.

32. Penicillin acylinacylase catalyzes:

a) cleavage of the betalactam ring; b) cleavage of the thiazolidine ring;

c) cleavage of the lateral radical in C-b; d) demethylation of the thiazolidine ring.

33. Monoclonal antibodies shall be obtained in production:

a) in the fractionation of antibodies of organisms; b) fractionation of lymphocytes;

c) with the help of hybridomas; d) chemical synthesis.

34. The target for physical and chemical mutagens in the cell of biological objects shall be:

(a) DNA; b) DNA polymerase;

c) RNA polymerase; d) ribosome; e) messenger RNA.

35. The activated sludge used in the treatment of wastewater from biotechnological industries shall be:

a) sorbent; b) a mixture of sorbents; c) a mixture of microorganisms obtained by genetic engineering methods;

d) a natural complex of microorganisms.

36. When treating industrial effluents during rush hours, destructor strains shall be used:

(a) Natural microorganisms; b) permanent components of activated sludge;

c) stable genetically engineered strains; d) unstable genetically engineered strains.

37. The constant presence of destructor strains in aeration tanks is ineffective; Periodic introduction of them

Commercial drugs are caused by:

(a) Their slow rate of reproduction; b) their displacement by representatives of the microflora of activated sludge;

c) loss of plasmids, where the genes of oxidative enzymes are localized; d) safety problems.

38. The function of pheromones shall be:

(a) Antimicrobial activity; b) antiviral activity;

c) a change in the behavior of an organism that has a specific receptor;

d) thermoregulatory activity; e) antitumor activity.

39. Isolation and purification of products of biosynthesis and organic synthesis shall have fundamental differences in

Stages of the process:

(a) All; b) final; c) the former; d) there are no fundamental differences.

40. The main advantage of enzymatic bioconversion of steroids over chemical transformation:

(a) Availability of reagents; b) selectivity of the effect on certain functional groups of the steroid;

c) reduction of process time; d) obtaining fundamentally new compounds.

41. An increase in the yield of the target product during the biotransformation of the steroid shall be achieved:

a) with an increase in the intensity of mixing; b) with an increase in the intensity of aeration;

c) when the fermentation temperature rises; d) with the exclusion of microbial contamination;

e) with an increase in the concentration of the steroid substrate in the fermentation medium.

42. The director (chief engineer) of a pharmaceutical enterprise shall be, in accordance with the requirements of GMP:

(a) Engineer-economist; b) a lawyer; c) pharmacist; d) a doctor.

43. The construction and installation rules shall provide for the production in separate premises and on separate equipment:

(a) Penicillins; b) aminoglycosides; c) tetracyclines;

d) macrolides; e) polyenes.

44. The property of betalactams, due to which they should, according to the construction and installation work, be produced in separate rooms:

(a) General toxicity; b) chronic toxicity;

c) embryotoxicity; d) allergenicity.

45. GLP regdaments:

(a) Laboratory tests; b) planning of prospecting works;

c) a set of tests for preclinical trials; d) methods of mathematical data processing.

46. According to the SSR, the duties of ethics committees include:

a) control over the sanitary condition of medical institutions;

b) protection of the rights of patients on whom new medicinal products are tested;

c) approval of the prescribed treatment regimens;

d) control over compliance with internal regulations.

47. The reason for the impossibility of direct expression of a human gene in a prokaryotic cell:

(a) High concentration of nucleases; b) the impossibility of replication of plasmids;

c) lack of transcription; d) not the possibility of splicing.

48. Direct transfer of foreign DNA into protoplasts is possible using:

(a) Microinjections; b) transformations; c) packaging in liposomes;

d) cultivation of protoplasts on appropriate nutrient media.

49. The substrates of restriction enzymes used by a genetic engineer shall be:

(a) Homopolysaccharides; b) heteropolysaccharides;

c) nucleic acids; d) proteins.

50. Gene marker, essential in genetic engineering:

a) to incorporate the vector into the host cells; b) for the selection of colonies formed by cells into which the vector has penetrated;

c) to include the "working gene" in the vector; d) to increase the stability of the vector.

51. The concept of "sticky ends" in relation to genetic engineering reflects:

(a) Complementarity of nucleotide sequences; b) interaction of nucleic acids and histones;

c) reaction of SN groups with each other with the formation of disulfide bonds;

d) hydrophobic interaction of lipids.

52. The search for new restriction enzymes for use in genetic engineering is explained by:

(a) Differences in catalytic activity; b) different places of impact on the substrate;

c) species specificity; d) high cost.

53. The success of genetic engineering in the creation of recombinant proteins is greater than in the creation of recombinant antibiotics, which is explained by:

(a) Simpler protein structure;

b) the difficulty of selecting host cells for the biosynthesis of antibiotics;

c) a large number of structural genes included in the biosynthesis of antibiotics;

d) problems of safety of the production process.

54. The ligase enzyme shall be used in genetic engineering because:

a) fastens the vector to the shell of the host cell;

b) catalyzes the incorporation of the vector into the chromosome of the host cells;

c) catalyzes the covalent binding of the carbohydrate-phosphorus chain of the DNA of the gene to the DNA of the vector;

d) catalyzes the closure of peptide bridges in the peptidoglycan of the cell wall.

55. A biotechnologist "marker gene" shall:

a) to increase the activity of the recombinant; b) for the formation of competent host cells;

c) to modify the place of interaction of restriction enzymes with the substrate; d) for the selection of recombinants.

56. The easing of restrictions on the use of recombinant microorganisms producing human hormones in industry has been made possible by:

(a) Improving methods for isolating genetically engineered recombinants from the environment;

b) advanced training of personnel working with recombinants;

c) the experimentally established weak viability of the recombinant;

d) experimental confirmation of the mandatory loss of foreign genes.

57. A plasmid-based vector is preferable to a phage-based DNA vector due to:

a) large size; b) less toxicity;

c) a higher frequency of inclusion; d) lack of lysis of the host cell.

58. Activation of an insoluble carrier in case of immobilization of the enzyme shall be necessary:

a) to enhance the incorporation of the enzyme into the gel; b) to increase the sorption of the enzyme;

c) to increase the activity of the enzyme; d) for the formation of a covalent bond.

59. Immobilization of individual enzymes is limited to such a circumstance as:

a) high lability of the enzyme; b) the presence of a coenzyme in the enzyme;

c) the presence of subunits in the enzyme; d) belonging of the enzyme to hydrolases.

60. Immobilization of whole cells of producers of medicinal substances shall be irrational in the case of:

a) high lability of the target product (medicinal substance);

b) use of the target product only in injectable form;

c) intracellular localization of the target product;

d) high hydrophilicity of the target product;

61. Immobilization of producer cells shall be appropriate if the target product:

a) soluble in water; b) insoluble in water;

c) localized inside the cell; d) it is the biomass of cells.

62. The objectives of immobilization of enzymes in biotechnological production shall be:

a) increase in specific activity; b) increasing stability;

c) expansion of the substrate spectrum; d) repeated use.

63. The target protein product is localized inside the immobilized cell. To achieve its selection, not

By disrupting systems, you can:

(a) By strengthening active emission systems; b) weakening the barrier functions of the membrane;

c) by attaching a leader sequence from an external protein to the protein; d) increasing the rate of protein synthesis.

64. A column bioreactor for immobilizing whole cells should be different from a reactor for immobilizing enzymes:

(a) A large column diameter; b) removal of gases;

c) faster movement of the solvent; d) the shape of the particles of the insoluble carrier.

65. A technology based on the immobilization of a biological object shall reduce the presence in the drug

of the following impurities:

(a) Traces of heavy metals; b) proteins;

c) mechanical particles; d) traces of organic solvents.

66. The economic advantage of biotechnological production based on immobilized

biological objects, before the traditional one is due to:

(a) Less labour; b) cheaper raw materials;

c) repeated use of a biological object; d) acceleration of the production process.

67. The biosynthesis of antibiotics used as medicinal substances is enhanced and occurs earlier on

Environments:

(a) Rich in nitrogen sources; b) rich in carbon sources;

c) rich sources of phosphorus; d) nutrient-poor.

68. Regulated fermentation in the process of biosynthesis shall be achieved by the method:

(a) Periodic; b) continuous;

c) weaning-topping; d) semi-periodic.

69. Retroinhibition by the final product in the biosynthesis of biologically active substances shall be:

a) suppression of the last enzyme in the metabolic chain;

b) suppression of the initial enzyme in the metabolic chain;

c) suppression of all enzymes in the metabolic chain.

70. The term "multi-enzyme complex" means:

a) a complex of enzyme proteins isolated from the cell by extraction and precipitation;

b) a complex of enzymes of the cell membrane;

c) a complex of enzymes that catalyze the synthesis of a primary or secondary metabolite;

d) a complex of exo- and endoproteases.

71. By polyketide synthesis, the following molecules shall be assembled:

(a) Tetracycline; b) penicillin; c) streptomycin; d) cyclosporine.

72. A complex component of the nutrient medium, which dramatically increased the productivity of fermentation in the case of penicillin:

a) soybean flour; b) pea flour; c) corn extract; d) cotton flour.

73. The precursor of penicillin, which sharply increased its yield when added to the medium:

(a) Beta-dimethylcysteine; b) valine;

c) phenylacetic acid; d) alpha-aminoadipic acid.

74. The precursor in the biosynthesis of penicillin shall be added:

a) at the beginning of fermentation; b) on the second or third day after the start of fermentation;

c) every day for a 5-day process.

75. Process air for biotechnological production shall be sterilized:

(a) Heating; b) filtration; c) irradiation.

76. The fight against phage infection in the fermentation shops of the antibiotic industry shall be most rational by:

(a) Tightening control over the sterilization of process air;

b) tightening control over the sterilization of the nutrient medium;

c) obtaining and using phage-resistant strains of a biological object;

d) tightening control over the sterilization of equipment.

77. The advantage of plant raw materials obtained from the cultivation of cell cultures over raw materials obtained from plantation or wild plants:

a) a large concentration of the target product; b) lower cost;

c) standardization; d) easier extraction of the target product.

78. Auxins - a term under which specific growth stimulants are combined:

a) plant tissues; b) actinomycetes;

c) animal tissues; d) eubacteria.

79. The conversion of digitoxin cardenolide to less toxic digoxin (12-hydroxylation) shall be carried out by cell culture:

(a) Acremonium chrysogenum; b) Saccharomyces cerevisiae;

c) Digitalis 1anata; d) Tolypocladium inflatum.

80. The reasons for the high efficacy of antibiotic drugs "unazin" and "augmentin" are:

a) in low toxicity (compared with ampicillin and amoxacillin); b) in low cost;

c) in action on beta-lactam-resistant strains of bacteria; d) in the prolongation of the effect.

81. What property of the new betalactam antibiotic is most valuable in the treatment of bacterial complications in patients with HIV infection?

(a) Resistance to betalactamases; b) low toxicity;

c) binding to PSB 2; d) prolonged circulation.

82. To check what quality of the serial injectable penicillin is used in the medical industry penicillinase (betalactamase)?

(a) Toxicity; b) transparency; c) sterility; d) pyrogenicity.

83. Antibiotic tolerance of the pathogen shall be due to:

a) destruction of the antibiotic; b) active release;

c) low content of autolysines; d) the absence of a target for an antibiotic.

84. Mycobacteria - the causative agents of modern tuberculosis infection are resistant to chemotherapy due to:

a) compensatory mutations; b) slow growth;

c) intracellular localization; d) weakening of the immunity of the host organism.

85. Monitoring (in relation to the drug):

a) introduction into the body; b) allocation;

c) detection in tissues; d) concentration monitoring.

86. Screening (of medicines):

(a) Improvement through chemical transformation; b) improvement through biotransformation;

c) search and selection ("sifting") of natural structures; d) complete chemical synthesis.

87. Target:

a) site on the surface of the cell; b) an intermediate target inside the cell;

c) the final intracellular target; d) the functional group of the macromolecule.

88. The purpose of genome sequencing shall be to establish:

a) genome size b) nucleotide sequences c) A-T content

d) the ratio of A-T/HZ of nucleotide pairs; e) changes in metabolism;

89. As the main method of proteomics, the following shall be used:

a) microscopy b) gas-liquid chromatography c) two-dimensional electrophoresis

d) radioisotope e) spectral

90. The ivi genes shall be expressed:

a) on an artificial poor nutrient medium b) on an artificial rich nutrient medium

c) under conditions of growth in vivo d) under conditions of growth in vitro e) always

91. The direction of genomics directly related to proteomics:

a) structural b) comparative c) functional d) formal e) all

92. Methicillin resistance (MRSA) is caused by:

a) the appearance of capsules b) the speed of reproduction c) the beta-lactamase complex

d) the appearance of PSB-2a with low affinity for penicillins and cephalosporins used in clinical treatment

e) active emission

93. In the treatment of AIDS patients or in other situations with the manifestation of reduced activity of the immune system, it is preferable to use:

a) PSB-1a b) PSB-1b c) PSB-2 d) PSB-3 e) increased doses of antibiotic

94. Specific localization of betalactamases in gram-positive bacteria:

a) outside the cell b) on ribosomes c) on the inner surface of the cytoplamatic membrane

d) at the poles of the cell; e) in the periplasmic space under the porin channels;

95. Specific localization of betalactamases in gram-negative bacteria:

a) outside the cell b) on the inner surface of the cytoplamatic membrane

c) in the cytoplasmic space evenly

e) in the periplasmic space under the porin channels (e) on the ribosomes;

96. The reason for the spread of betalactamases among pathogens in the clinic shall be the frequency of use:

a) betalactam antibiotics b) aminoglycosides c) tetracyclines

d) macrolides e) fluoroquinolones

97. The specific nature of the relationship between the amount of antibiotics used and the appearance of betalactamases:

a) direct b) indirect c) reverse d) irrelevant e) indirect

98. Antibiotics that can penetrate the outer membrane of gram-negative bacteria:

a) benzylpencilline b) erythromycin c) ampicillin d) fuzidine e) nystatin

99. A method for maintaining the productivity of microbial cultures necessary for a biotechnologist:

a) in the refrigerator b) under a layer of mineral oil c) in bulk materials

d) freeze-drying, e) cryostorage;

100. Antisense oligonucleotides are promising for the treatment of:

a) infectious bacterial diseases b) oncological diseases

c) antifungal diseases d) hereditary monogenic diseases

e) viral diseases

101. Biotechnology is...

a) study of the biological activity of medicinal plant raw materials;

b) the use of cultures of cells, bacteria, animals, plants, providing the synthesis of specific substances

c) development of new dosage forms of drugs with the help of living systems

d) the study of the "structure-effect" dependence in the action of drugs

e) synthesis of new medicinal products and study of their properties

102. The sequence of stages of the biotechnological process:

a) processing of the target product, processing of raw materials, fermentation and biotransformation

b) biotransformation, fermentation, processing of raw materials and target product

c) initial processing of raw materials, fermentation, biotransformation, final processing of the target product

103. In biotechnology, the concept of "biological object" corresponds to the following definition:

a) the organism on which new biologically active substances are tested

b) organisms that cause microbial contamination of technological equipment

c) an enzyme used for genetically engineered processes

d) an organism that produces biologically active substances

e) an enzyme used for medicinal purposes

104. Distinctive features of the prokaryotic cell:

a) small size b) the presence of a nucleus c) the presence of subcellular organelles

d) multilayered cell wall e) chromosomal DNA in the nucleus

105. Prokaryotes are ...

(a) Large multicellular structures that do not contain organelles

b) small cells with cytoplasmic DNA, characterized by the absence of organelles

c) small cells surrounded by a rigid cell wall, characterized by the absence of organelles and the presence of DNA in the cytoplasm

106. The optimal temperature regime for the development of mesophilic microorganisms shall be:

a) 45-90 °C b) 10-47 °C c) 37 °C d) from -5 to +35 °C e) over 90 °C

107. The ability to convert sugar into ethanol shall be possessed by:

a) Aspergillus oryzae b) Aspergillus terricola c) Escherichia coli

d) Bacillus subtitilis e) Saccharomyces cerevisiae

108. To obtain protoplasts from fungal cells, the following shall be used:

a) lysozyme b) trypsin c) "snail enzyme" d) pepsin

109. Chemical mutagens:

a) X-rays b) positrons c) temperature conditions d) analogues of nitrogenous bases

110. Genetic engineering is ...:

a) a method based on the isolation and cultivation of tissues and cells of higher organisms

b) a change in the primary structure of DNA in a specific part of it, which, ultimately, leads to a change in the phenotype of a biological object used in biotechnological processes

c) the method of creating recombinant or hybrid DNA;

111. A plasmid is ...:

(a) A specific strain of Escherichia coli used for biotechnological purposes

b) a ring-shaped DNA molecule - an extrachromosomal element of genetic information

c) a section of the RNA strand that carries information about the structure of the gene

d) a virus that multiplies in the cytoplasm of a microbial cell

e) a chromosome used as a vector for introducing DNA into bacterial cells

112. The selection of transformed cells containing recombinant DNA (hybrid plasmid) shall be carried out:

(a) Temperature resistance testing

b) testing for resistance to certain antibiotics

c) by the ability to stain with hematoxylin

d) by morphological characteristics

e) by the rate of growth and reproduction

113. Distinctive features of the eukaryotic cell:

a) large size b) no nucleus c) rigid cell wall

d) absence of subcellular organelles e) chromosomal DNA in the cytoplasm

114. Eukaryotes are ...

(a) Large-sized multicellular structures containing organelles and chromosomal DNA

b) small cells with chromosomal DNA, characterized by the absence of organelles

c) small cells surrounded by a rigid cell wall, characterized by the absence of organelles and the presence of chromosomal DNA

d) small cells surrounded by a membrane of phospholipid and protein layers, having a nucleus with a chromosomal

DNA and membrane-surrounded membranes

115. Thermophiles serve as a source of ...

a) genes encoding thermostable enzymes

b) genes encoding thermolabile enzymes

c) material used for biodegradation of toxic wastes

d) material for the production of biogas

116. Saccharomyces cerevisiae –

a) prokaryotic analogue of E. coli, which is a model for the study of human cells

b) eukaryotic analogue of E. coli, which is a model for the study of human cells

117. Mutations are ...:

a) a method based on the isolation and cultivation of tissues and cells of higher multicellular organisms

b) a change in the primary structure of DNA in a specific part of it, which, ultimately, leads to a change in the phenotype of a biological object used in biotechnological processes

c) the method of creating recombinant or hybrid DNA;

118. Cell engineering is...:

a) a method based on the isolation and cultivation of tissues and cells of higher multicellular organisms

b) a change in the primary structure of DNA in a specific part of it, which, ultimately, leads to a change in the phenotype of a biological object used in biotechnological processes

c) the method of creating recombinant or hybrid DNA;

119. The process of manufacturing genetically engineered drugs shall include:

a) copying the gene of the person responsible for the synthesis of the necessary product

b) modification of the patient's genetic apparatus to increase the biosynthesis of necessary products

c) the introduction of a microbial cell with recombinant DNA into the human body

d) cultivation and isolation of microbial cells with recombinant DNA

e) the introduction of a human gene into the plasmid of a microbial cell

120. Requirements for DNA vectors:

a) the absence of a restriction site in which the insert is made b) large size c) species specificity

d) the presence of selective genetic markers for the identification of recipient cells carrying recombinant

DNA

121. Methods for introducing cloned genes into somatic cells:

(a) Microinjections

b) with the help of chemical reagents that change the permeability of membranes

c) with the help of liposomes, "shadows" of erythrocytes

d) extracorporeal treatment of chromosomes of a bacterial cell

e) infection of the cell with recombinant viruses

122. Engineering Enzymology:

a) a method based on the isolation and cultivation of tissues and cells of higher organisms

b) a change in the primary structure of DNA in a specific part of it, which, ultimately, leads to a change in the phenotype of a biological object used in biotechnological processes

c) the method of creating recombinant or hybrid DNA;

d) biotechnological processes using the catalytic action of enzymes isolated from the composition

biological systems or cells that are artificially deprived of the ability to grow.

123. For the production of enzymes, the method of industrial cultivation is currently used

Microorganisms:

a) surface cultivation b) deep cultivation

124. Chemical method of immobilization of enzymes:

a) the formation of covalent bonds between the carrier and the enzyme

b) the incorporation of the enzyme into microcapsules

c) the inclusion of the enzyme in polymer gels

d) the inclusion of the enzyme in the polymer fibers

125. The immobilization of individual enzymes is limited to such a circumstance as:

a) high lability of the enzyme; b) the presence of a coenzyme in the enzyme;

c) the presence of subunits in the enzyme; d) belonging of the enzyme to hydrolases.

126. Immobilization of producer cells shall be appropriate if the target product:

a) soluble in water; b) insoluble in water;

c) localized inside the cell; d) it is the biomass of cells.

127. A technology based on the immobilization of a biological object shall reduce the presence of a medicinal product

of the following impurities:

(a) Traces of heavy metals; b) proteins;

c) mechanical particles; d) traces of organic solvents.

128. The biosynthesis of antibiotics used as medicinal substances is enhanced and occurs earlier on

Environments:

(a) Rich in nitrogen sources; b) rich in carbon sources;

c) rich sources of phosphorus; d) nutrient-poor.

129. Physical method of immobilization of enzymes:

a) by means of covalent bonding b) metallochelate method

c) incorporation into the gel d) microencapsulation e) adsorption on an insoluble carrier

130. The metal-chelate method of immobilization shall be based on:

a) the formation of a chemical bond between the molecules of the enzyme and the carrier

b) the action of electrostatic forces and surface tension forces.

c) the properties of transition metals to form complexes

d) retention of the solution surrounding the enzyme

131. The method of microencapsulation of immobilization shall be based on:

a) the formation of a chemical bond between the molecules of the enzyme and the carrier

b) the action of electrostatic forces and surface tension forces.

c) the property of transition metals to form complexes

d) retention of the solution surrounding the enzyme

132. Material for immobilization of enzymes by metallochelate method:

a) titanium chloride or hydroxides b) polyacrylamide c) bovine serum albumin d)

calcium alginate e) agar e) cefadex

133. Polymers used before microencapsulation to preserve the activity of the enzyme:

a) titanium chloride or hydroxides b) polyacrylamide

c) cellulose derivatives d) bovine serum albumin e) agar

134. Enzyme used to produce fructose from glucose:

a) glucose isomerase b) aminoacylase c) penicillinamide

d) β-galactosidase e) prostaglandin endoperoxide synthetase

135. Enzyme used to produce semi-synthetic penicillins:

a) glucose isomerase b) aminoacylase c) penicillinamide

d) β-galactosidase e) prostaglandin endoperoxide synthetase

136. Enzyme induction:

a) a decrease in the activity of the enzyme b) an increase in the rate of synthesis

c) decrease in the rate of synthesis

137. Retroinhibition by the final product in the biosynthesis of biologically active substances:

a) suppression of the last enzyme in the metabolic chain;

b) suppression of the initial enzyme in the metabolic chain;

c) suppression of all enzymes in the metabolic chain.

d) significant accumulation of biomass as opposed to the biosynthesis of target products

138. Catabolic repression

a) suppression of the last enzyme in the metabolic chain;

b) significant accumulation of biomass as opposed to the biosynthesis of target products

c) suppression of the initial enzyme in the metabolic chain;

d) suppression of all enzymes in the metabolic chain.

139. The way to overcome the phenomenon of "exclusion of the inductor":

(a) Application of the predecessors of the target product

b) selection of nutrient media with a limited glucose content

c) the use of intracellular sorbents

d) the use of immobilized analogues of the initial enzyme

e) restriction on the introduction of predecessors of the target product;

140. Characteristics of enzymes:

a) high activity b) low activity c) non-specificity

d) small molecular weight

141. Immobilized enzymes:

(a) Enzymes that retain significant activity over a wide range of pH

b) enzymes that retain their structure and activity for a long time

142. Activation of an insoluble carrier in case of immobilization of the enzyme shall be necessary:

a) to enhance the incorporation of the enzyme into the gel; b) to increase the sorption of the enzyme;

c) to increase the activity of the enzyme; d) for the formation of a covalent bond.

143. Immobilization of whole cells of drug producers shall be irrational in the case of:

a) high lability of the target product (medicinal substance);

b) use of the target product only in injectable form;

c) intracellular localization of the target product;

d) high hydrophilicity of the target product;

144.The objectives of immobilization of enzymes in biotechnological production are:

a) increase in specific activity; b) increasing stability;

c) expansion of the substrate spectrum; d) repeated use.

145. The economic advantage of biotechnological production based on immobilized

biological objects, before the traditional one is due to:

(a) Less labour; b) cheaper raw materials;

c) repeated use of a biological object; d) acceleration of the production process.

146. The term "multi-enzyme complex" means:

a) a complex of enzyme proteins isolated from the cell by extraction and precipitation;

b) a complex of enzymes of the cell membrane;

c) a complex of enzymes that catalyze the synthesis of a primary or secondary metabolite;

d) a complex of exo- and endoproteases.

147. The method of immobilization "adsorption on the carrier" shall be based on:

a) the formation of a chemical bond between the molecules of the enzyme and the carrier

b) the action of electrostatic forces and surface tension forces.

c) the properties of transition metals to form complexes

d) retention of the solution surrounding the enzyme

148. The method of immobilization "inclusion in the gel" shall be based on:

a) the formation of a chemical bond between the molecules of the enzyme and the carrier

b) the action of electrostatic forces and surface tension forces.

c) the properties of transition metals to form complexes

d) retention of the solution surrounding the enzyme

e) complete polymerization of the carrier

149. Carriers for immobilization of enzymes by the method of "inclusion in the gel":

a) titanium chloride or hydroxides b) polyacrylamide

c) cellulose derivatives d) bovine serum albumin

150. To prevent inactivation of the enzyme before microencapsulation:

a) remove oxygen from the solution; b) complete polymerization of the carrier is carried out;

c) mix the enzyme with polymers that contribute to the preservation of its activity

151. To immobilize plant cells, the following method may be used:

a) covalent bonding b) metallochelate method

c) inclusion of calcium alginate in the gel d) microencapsulation

e) adsorption on an insoluble carrier

152. Enzyme used to produce lactose-free milk:

a) glucose isomerase b) aminoacylase c) penicillinamide

d) β-galactosidase e) prostaglandin endoperoxide synthetase

153. Enzyme used to produce easily digestible essential amino acids:

a) glucose isomerase b) aminoacylase c) penicillinamide

d) β-galactosidase e) prostaglandin endoperoxide synthetase

154. What element of the operon must be displaced in order for repression to be replaced by induction:

a) RNA polymerase b) promoter c) operator d) repressor protein

155. Ways to overcome retro-inhibition:

a) the use of precursors of the target product; b) the use of intracellular sorbents;

c) the use of immobilized analogues of the initial enzyme

156. "Glucose effect":

a) suppression of excess glucose of the last enzyme in the metabolic chain;

b) significant accumulation of biomass due to excess glucose as opposed to the biosynthesis of target products

c) suppression of the initial enzyme in the metabolic chain by excess glucose;

157. "Suicidal effect" characteristic of superproducers:

a) suppression of activity synthesized in excess by the target product (often an antibiotic)

Biological object

b) suppression of the last enzyme in the metabolic chain by excess glucose;

b) significant accumulation of biomass due to excess glucose as opposed to the biosynthesis of target products

c) suppression of the initial enzyme in the metabolic chain by excess glucose;

158. Regulated fermentation in the process of biosynthesis shall be achieved by the method:

(a) Periodic; b) continuous;

c) weaning-topping; d) semi-periodic.

159. The fight against phage infection in the fermentation shops of the antibiotic industry shall be most rational by:

(a) Tightening control over the sterilization of process air;

b) tightening control over the sterilization of the nutrient medium;

c) obtaining and using phage-resistant strains of a biological object;

d) tightening control over the sterilization of equipment.

160. Advantages of biotechnological production of organic products over chemical methods

Synthesis:

a) synthesis of the target product in the form of a complex mixture b) non-specificity

c) insignificant yield of the target product d) the possibility of obtaining pure isomers

e) the use of large quantities of water (e) Lack of specificity

161. Natural serums shall be applied to nutrient media in order to:

a) maintaining osmotic pressure in the cell b) protecting cells from damage

c) strengthening of energy processes in the cell;

162. The purpose of sterilization of process air:

a) destruction of bacterial spores b) stabilization of the qualitative and quantitative composition

c) ensuring the respiration of microorganisms-biological objects

163. "Weak" zones during sterilization of equipment:

a) steam jackets b) agitators c) air filters

d) exhaust process air exhaust pipes

164. By the nature of the cultivation of the producer, the biosynthetic process shall be divided into:

a) periodic, semi-periodic, continuous, weaning-topping

b) superficial and deep

165. Surface fermentation (in a monolayer):

a) a suspension of cells is obtained by treating the crushed embryonic tissue with trypsin; Cells in such a suspension become flat and divide, settling on the surface of the vessel

b) producer cages due to agitation or turbine mixing and passing under pressure of air in

the entire volume of the nutrient medium

166. The following shall prevail:

a) deep cultivation method b) surface cultivation method

167. Continuous fermentation process:

a) at the end of the fermentation cycle, when draining the culture liquid in the apparatus, leave it for about

10%, followed by the introduction of 90% of the fresh nutrient medium

b) in the process of biosynthesis, small portions of the culture medium are continuously selected from the fermenter and at the same time the same volume of the nutrient medium is added to it

c) all components of the nutrient medium and seed are simultaneously loaded into the fermenter, a full fermentation cycle is performed and, upon completion of the process, the entire volume of spent culture liquid is collected

d) in the process of biosynthesis, large portions of the culture medium are continuously selected from the fermenter and at the same time

The same amount of nutrient medium is added to it

168. Multi-cyclic fermentation process:

a) all components of the nutrient medium and seed are simultaneously loaded into the fermenter, a full fermentation cycle is performed and, at the end of the process, the entire volume of spent culture liquid is collected

b) in the process of biosynthesis, small portions of the culture medium are continuously selected from the fermenter and at the same time the same volume of the nutrient medium is added to it

c) in the process of biosynthesis, large portions of the culture medium are continuously selected from the fermenter and at the same time

The same amount of nutrient medium is added to it

d) at the end of the fermentation cycle, when draining the culture liquid in the apparatus, leave it for about

10%, followed by the introduction of 90% of the fresh nutrient medium

169. Low molecular weight primary metabolite:

a) glucose isomerase b) penicillin c) ascorbic acid

170. The rate of reproduction of microorganisms-biological objects shall be more influenced by:

a) the temperature of the culture medium; b) the degree of aeration of the medium;

c) the concentration of the limiting substrate d) the pH of the medium

171. Secondary metabolites shall be synthesized (in larger quantities):

a) in the lag phase; b) in the phase of accelerated growth; c) in the logarithmic phase; d) in the phase of delayed

Growth; e) in the stationary phase;

172. The periodic addition of the substrate shall lead:

a) to the lengthening of the lag phase b) to the lengthening of the die off phase

c) to the shortening of the die off phase; d) to the lengthening of the exponential phase;

173. When obtaining protein products, the biotechnological process must be stopped before the transition:

a) in the lag phase b) in the exponential phase c) the phase of dying off

d) in the stationary phase, e) the deceleration phase;

174. The maximum quantity of the target product shall be obtained:

a) at a low final density of the culture of microorganisms-biological objects

b) at the maximum final density of the culture of microorganisms-biological objects

175. Advantages of a continuous fermentation process over a periodic one:

a) no need for equipment for the collection of cells, their destruction

b) inconsistency of biosynthetic processes

c) the duration of the process is more than 500 hours

d) inability to maintain sterile conditions for a long time

176. The main hardware element of the biotechnological process:

a) bioreactor-fermenter b) head filter for process air purification

c) homogenizers d) bubblers e) sterilizing air filters

177. Secreted target product:

a) removed from the cells, destroying them and removing cellular "fragments"

b) isolated directly from the culture liquid

178. In case of destruction of bacterial cell walls, the following shall be used:

a) lysozyme b) "snail enzyme" c) trypsin d) papain

179. Physical methods of cell disintegration:

a) repeated freezing-thawing b) alkali treatment

c) the use of lytic enzymes

180. Process air for biotechnological production shall be sterilized:

(a) Heating; b) filtration; c) irradiation

d) radiation in small doses; e) antibiotic substances;

181. The concept of "cultivation medium" includes:

a) a certain qualitative and quantitative composition of the components of the nutrient medium;

b) physicochemical and physiological parameters of the nutrient medium

c) a set of parameters reflecting the qualitative and quantitative composition of the components of the nutrient medium, and

its physicochemical and physiological properties

182. Natural Serums:

a) glucose in combination with aspartic acid; b) organo-mineral complexes;

c) embryonic blood serum

183. The purpose of sterilization of nutrient media:

(a) Destruction of bacterial spores

b) stabilization of the qualitative and quantitative composition

c) ensuring the respiration of microorganisms-biological objects

184. Methods of sterilization of filters used to purify process air:

a) heating b) hot steam treatment c) radiation in small doses

185. Nutrient media shall sterilize:

a) saturated steam b) irradiation c) radiation in small doses d) treatment with antiseptics

186. According to the principle of the organization of material flows, the biosynthetic process shall be divided into:

a) periodic, semi-periodic, continuous, weaning-topping, multicyclic

b) superficial and deep

187. Deep fermentation:

a) a suspension of cells is obtained by treating the crushed embryonic tissue with trypsin; Cells in such a suspension become flat and divide, settling on the surface of the vessel

b) producer cages due to agitation or turbine mixing and passing under pressure of air in

the entire volume of the nutrient medium

188. Batch fermentation process:

a) all components of the nutrient medium and seed are simultaneously loaded into the fermenter, a full fermentation cycle is performed and, at the end of the process, the entire volume of spent culture liquid is collected

b) in the process of biosynthesis, small portions of the culture medium are continuously selected from the fermenter and at the same time the same volume of the nutrient medium is added to it

c) in the process of biosynthesis, large portions of the culture medium are continuously selected from the fermenter and at the same time

The same amount of nutrient medium is added to it

d) at the end of the fermentation cycle, when draining the culture liquid in the apparatus, leave it for about

10%, followed by the introduction of 90% of the fresh nutrient medium

189. Weaning-topping fermentation process:

a) at the end of the fermentation cycle, when draining the culture liquid in the apparatus, leave it for about

10%, followed by the introduction of 90% of the fresh nutrient medium

b) in the process of biosynthesis, small portions of the culture medium are continuously selected from the fermenter and at the same time the same volume of the nutrient medium is added to it

c) all components of the nutrient medium and seed are simultaneously loaded into the fermenter, a full fermentation cycle is performed and, upon completion of the process, the entire volume of spent culture liquid is collected

d) in the process of biosynthesis, large portions of the culture medium are continuously selected from the fermenter and at the same time

The same amount of nutrient medium is added to it

190. Individual high molecular weight target product:

a) glucose isomerase b) penicillin c) ascorbic acid

191. Low molecular weight secondary metabolite

a) glucose isomerase b) penicillin c) ascorbic acid

192. The sequence of the main phases of growth of microorganisms:

a) stationary phase, lag phase, acceleration phase, exponential phase, die off phase

b) lag phase, stationary phase, acceleration phase, exponential phase, die off phase

c) lag phase, acceleration phase, exponential phase, deceleration phase, stationary phase, die off phase

193. Primary metabolites shall be synthesized (in larger quantities):

a) in the lag phase; b) in the phase of accelerated growth; c) in the exponential phase;

d) in the phase of slow growth; e) in the stationary phase;

194. The highest yield of the target biotechnological product shall be observed:

(a) Batch fermentation

b) with periodic fermentation with the addition of a substrate

195. In the production of protein products, the biotechnological process must be stopped before it passes into

stationary phase due to:

a) with a gradual decrease in the substrate b) with the synthesis of proteases in this phase

c) with an increase in the number of the predecessor of the target product;

196. Disadvantages of a continuous fermentation process compared to a periodic one:

a) no need for equipment for the collection of cells, their destruction

b) consistency of biosynthetic processes

c) the duration of the process is more than 500 hours

197. The maximum final density of the culture of microorganisms shall be achieved:

a) in batch fermentation with the addition of a substrate

b) with periodic fermentation c) with continuous fermentation

198. If the target product is localized inside the cells:

a) destroy cells, remove cellular "fragments"

b) removed from the culture liquid

199. To isolate cells from large volumes of the culture medium, the following shall be used:

a) membrane filtration b) low-speed centrifugation

c) incubation in a thermostat

200. When destroying the cell walls of yeast and mold fungi, apply:

a) lysozyme b) "snail enzyme" c) trypsin d) papain

## Assessment tools for intermediate control (exam)

**Questions for the exam in the discipline "Medical and Pharmaceutical Biotechnology"**

1. Modern biotechnology. The concept of a biological object. General information about biological objects.
2. General classification of biotechnological products. Classification of biotechnological pharmaceutical products.
3. Existing definitions of biotechnology as a science and sphere of production. Biotechnology is one of the foundations of modern pharmacy.
4. Biotechnology as a basic stage and as one of the intermediate stages of obtaining a medicinal substance. A biotechnological process that fully ensures the production of the target product
5. Biosynthesis and organic synthesis are complementary ways of creating drugs (for example, antibiotics and hormones).
6. The use of the properties of a biological object to improve it in order to create an effective and safe production of medicines.
7. Improvement of biological objects used in the production of medicines and diagnostic drugs. Methods of breeding.
8. Improvement of biological objects used in the production of medicines and diagnostic drugs. Methods of introduction of foreign genes: transformation, transduction, conjugation.
9. Methods of engineering enzymology in the production of medicines. Advantages of using immobilized biological objects in the isolation and purification of drugs.
10. Immobilization of enzymes and whole cells of biological objects in biotechnological production. Environmental and economic benefits.
11. Methods of immobilization of enzymes and whole cells. Examples of the use of immobilized biological objects in the medical industry.
12. Immobilization of enzymes and cells-producers of medicinal substances.
13. Conditions necessary for higher organisms and microorganisms in biotechnological systems in the production of drugs. Life support systems.
14. Components of biotechnological production. Preparatory and main stages of production.
15. Methods of sterilization of process air, equipment and culture media in biotechnological production.
16. Thermal sterilization of nutrient media. The Deindorfer-Humphrey criterion. Preservation of the biological usefulness of media during their sterilization.
17. Classification of industrial biosynthesis of medicinal substances by the organization of material flows, by methods of cultivation of producers, by the role of

the target product in the metabolism of the producer.

18. Influence of physical, chemical, and biological factors on fermentation processes.

19. Distinctive differences between deep and surface fermentation.

20. Criteria characterizing the process of biosynthesis.

21. Fermentation apparatus (fermenters). Process regulation systems.

22. General information about the structure of bioreactors of different types. What types of bioreactors are used to work with industrial biocatalysts.

23. Features of the isolation of target products from the culture liquid, distinguishing the process from the isolation of target products in organic synthesis.

24. Centrifugation and separation in biotechnological production. Types of centrifuges. Types of separators. Specificity of application when working with biological objects and products of biosynthesis.

25. Filtration methods in biotechnological production. Specificity related to biological objects and parameters of culture liquids. Pre-treatment of culture fluids. Filter presses. Leaf filters.

26. Membrane separation methods in biotechnological production. Microfiltration. Electrodialysis. Reverse osmosis. Ultrafiltration.

27. Drying methods in relation to biological objects and products of biosynthesis. Spray "dryers". Freeze-drying "dryers". Physical phenomena in the cell during freezing.

28. Plant cells. Application in the biotechnological process for the transformation of medicinal substances.

29. Methods of cultivation of plant cells. Callus and suspension cultures. Immobilization of plant cells.

30. Biotechnological production of drugs based on plant cell cultures. Totipotency. Benefits of using cell cultures.

31. Suspension cultivation of plant cells: parameters of a biological object that need to be taken into account; apparatus for cultivation.

32. GMP rules and their significance for the production of medicines. Features of GMP in the case of biotechnological production.

33. GMP rules in the production of biotechnological medicines. Reasons for the existence of international, regional and national GMP regulations.

34. GMP Rules and Pharmacopoeia Monographs. Their complementarity.

35. A list of the main sections in the GMP rulebook. The meaning of individual sections.

36. GLP and GCP rules for testing new drugs (for example, antibiotics).

37. Biotechnology of amino acids. Chemical-enzymotic method of production. Microbiological synthesis.

38. Intracellular regulation of amino acid biosynthesis and ways to intensify this process in production.

39. Construction of amino acid producing strains and ways to intensify the process by optimizing fermentation conditions.

40. Obtaining vitamins and coenzymes by biotechnology methods. Vitamin B production$_{12}$. Producers. Genetically engineered strain.

41. Vitamin B production$_{2}$. Producers. Genetically engineered strain.

42. Production of ascorbic acid. Combination of chemical synthesis and bioconversion steps. Microorganisms that carry out bioconversion in various schemes for the production of ascorbic acid. The stage of conversion of D-sorbitol to L-sorbose.

43. Obtaining vitamin PP. Producers of NAD. Ways to increase the yield of the target product.

44. Producers of ergosterol, β-carotene, ubiquinones. Biotechnological schemes of production.

45. Microbiological transformation of steroids in the creation of steroid drugs.

46. The main sources of raw materials for the production of steroid drugs.

47. Physiological expediency of biotransformations of steroid compounds.

48. Bioconversion of steroids. Bioobjects used for the processes of 11-hydroxylation, 1, 2-dehydrogenation, cleavage of the side chain.

49. Microbiological synthesis of hydrocortisone and the production of prednisolone from it by bioconversion.

50. Producers of antibiotics. Habitat. Selection methods.

51. The biological role of antibiotics. Reasons for their late accumulation in the fermentation medium in comparison with the accumulation of biomass producer

52. General data on the biosynthesis of antibiotics. Precursors of β-lactam antibiotics, aminoglycosides, erythromycin, tetracycline.

53. Multienzyme complexes in the cells of antibiotic producers.

54. Regulation of antibiotic biosynthesis. Carbon and nitrogen catabolite regulation. Inhibition by the type of feedback (retro-inhibition).

55. Mold fungi are producers of antibiotics. The main features of the structure of the cell and the development cycle during fermentation. Antibiotics formed by fungi.

56. Antibiotics and other biologically active substances formed by fungi. General data on their chemical structure and application. Properties of producers.

57. Actinomycetes are producers of antibiotics. Features of the structure and development cycle during fermentation. Antibiotics formed by actinomycetes.

58. Bacteria (eubacteria) are producers of antibiotics. The structure of the cell. Antibiotics produced by bacteria.

59. Semi-synthetic antibiotics. Biosynthesis and orgsynthesis in the creation of semi-synthetic antibiotics (examples).

60. Mechanisms of resistance to β-lactam antibiotics. New β-lactam antibiotics that are effective against resistant forms of bacteria. Purposeful transformation.

61. Mechanisms of development of resistance to aminoglycoside antibiotics.

New effective aminoglycosides. Purposeful transformation.

62. Liposomal dosage forms of antibiotics. Advantages over traditional forms. Methods of obtaining.

63. Natural sources of antibiotic resistance genes. Organizational measures as one of the ways to combat antibiotic resistance.

64. Preparations of normoflora: colibacterin, bifidumbacterin, lactobacterin, bificol. Properties. Purpose of application. Microorganisms that serve as the basis of drugs.

65. Lactic acid bacteria. Mechanisms of inhibitory action on pathogenic and putrefactive bacteria. Other functions favorable to the human body. Preparations based on lactic acid bacteria.

66. Preparations based on live cultures of symbiont microorganisms. Value in dysbiosis.

67. Recombinant proteins. Design and features of cultivation of microorganisms-producers of proteins alien to them.

68. Purification of recombinant proteins obtained by microbiological synthesis. Specific impurities in the final product: control and removal.

69. Insulin. Sources of raw materials. Recombinant human insulin. Reasons for obtaining by microbiological synthesis. Diagram of the production process.

70. Construction of human insulin producing strains. Benefits of E. coli as a producer.

71. Immunobiotechnology of drugs.

72. Monoclonal antibodies. Obtaining and applying.

73. ELISA principle. Homogeneous and heterogeneous ELISA. Applications. Advantages.

74. Vaccine. Classification. Characteristics of each individual type of vaccine: live, inactivated, subunit, DNA vaccines.

75. Features of the technology for obtaining vaccines. Control of specific activity. Storage.

# Indicative list of valuation tools (OS)

| № | Code | The name of the appraisal means | Brief description of the evaluation tool | Presentation appraisal funds in the fund |
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| **Oral questioning** | | | | |
| 1 | UO-1 | Interview | A means of control, organized as a special conversation between the teacher and the student on topics related to the discipline being studied, and calculated to clarify the amount of knowledge a student on a particular section, topic, problem, etc. | Questions on topics/sections of the discipline |
| 2 | UO-2 | Colloquium | A means of controlling the assimilation of educational material of a topic, section or sections of the discipline, organized as a training session in the form of an interview between the teacher and students | Questions on topics/sections of the discipline |
| 3 | UO-3 | Report, report | The product of the student's independent work, which is a public speech on the presentation of the results obtained, the solution of a certain educational, practical, educational, research or scientific topic | Topics of reports, reports |
| 4 | UO-4 | Round table, discussion, controversy, dispute, debate | Assessment tools that allow students to be included in the process of discussing a controversial issue, problem and assess their ability to argue their own point of view | List of discussion topics for a round table, discussion, controversy, dispute, debate |
| **Written works** | | | | |
| 1 | PP-1 | Test | A system of standardized tasks that allows you to automate the procedure for measuring the level of knowledge and skills Student | Test Task Fund |
| 2 | PP-2 | Examination | A tool for testing the ability to apply the knowledge gained to solve problems of a certain type on a topic or section | A set of control tasks By variants |

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| 3 | PR-3 | Essay | A tool that allows you to assess the student's ability to present in writing the essence of the problem posed, independently analyze this problem using concepts and analytical<br>tools of the relevant discipline, to draw conclusions summarizing the author's position on the problem posed | Essay topics |
| 4 | PP-4 | Abstract | The product of the student's independent work, representing<br>is a summary in writing of the results of the theoretical analysis of a certain scientific (educational and educational | Topics of essays |
| | | | research) topics, where the author reveals the essence of the study<br>problems, gives different points of view, as well as their own views on it | |
| 5 | PP-5 | Coursework, course project | The product of the student's independent work, which is a summary in writing of the results of the theoretical analysis of a certain scientific (educational and research) topic, where the author reveals the essence of the problem under study, gives various points of view, as well as his own<br>Views on it | Topics of term papers / projects, term paper plans works/projects, guidelines for writing CR and KP |
| 6 | PR-6 | Laboratory work | A tool for consolidating and practical mastering of the material<br>for a specific section | A set of tasks for Laboratory work |
| 7 | PP-7 | Abstract | The product of the student's independent work, reflecting<br>the main ideas of the lecture, message, etc. | Sections of the discipline |
| 8 | PP-8 | Portfolio | A targeted selection of the student's works, revealing his individual educational achievements in one or more<br>several academic disciplines | Portfolio structure |
| 9 | PP-9 | Project | The final product obtained as a result of planning and performing a set of educational and research tasks. It allows you to assess the ability of students to independently construct their knowledge in the process of solving practical problems and problems, navigate the information space and the level of formation of analytical, research skills, practical and creative thinking skills. Can be performed<br>individually or by a group of students | Topics of group and/or individual projects |

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| 10 | PP-10 | Business and/or role-playing game | Joint activity of a group of students under the guidance of a teacher in order to solve educational and professionally oriented problems through game modeling of a real problem situation. Allows you to evaluate the ability to analyze and solve typical professional problems | Theme (problem), concept, roles and expected result for each game |
| 11 | PP-11 | Case Study | A problem task in which the student is asked to comprehend the real professionally-oriented situation necessary to solve this problem | Tasks for solving case problems |
| 12 | PP-12 | Workbook | Didactic complex designed for independent the work of the student and allows him to assess the level of assimilation of educational material | Sample workbook |
| 13 | PP-13 | Multi-level tasks and tasks | There are tasks and tasks:<br>a) reproductive level, allowing to assess and diagnose knowledge of factual material (basic concepts, algorithms, facts) and the ability to correctly use special terms and concepts, recognition of objects of study within a certain section of the discipline;<br>6) reconstructive level, allowing to evaluate and diagnose the ability to synthesize, analyze, summarize factual and theoretical material with the formulation of specific conclusions, the establishment of cause-and-effect relationships;<br>c) a creative level that allows you to evaluate and diagnose skills, integrate knowledge of various fields, and argue your own point of view | A set of multi-level tasks and tasks |
| 14 | PP-14 | Cash-Graphic work | A tool for testing the ability to apply the acquired knowledge according to a predetermined methodology for solving tasks or tasks by module or the discipline as a whole | A set of tasks for performing the calculation graphic work |

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| 15 | PR-15 | Creative task | A partially regulated task that has a non-standard solution and allows you to diagnose skills, integrate knowledge of various fields, and argue your own point<br>View. It can be performed individually or by a group of students | Topics of group and/or individual creative tasks |
| Technical means | | | | |
| 1 | TC-1 | Simulator | Technical means that can be used<br>to control the professional skills and abilities acquired by the<br>student to manage a specific material object | A set of tasks for working on the simulator |