Assessment tools for certification
in the discipline "Biopharmacy"
for students entering in 2022
according to the educational program
33.05.01 Pharmacy,
specialty,
full-time education
2025-2026 academic year

The current assessment includes the following types of tasks: testing, solving situational problems, writing and defending an abstract, and an interview on test questions.

4.1.1. Examples of test tasks

Verifiable indicators of competence achievement: UK-2.1.1, UK-6.1.1, OPK-1.1.1, OPK-3.1.1, OPK-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.

1. In what year was the term biopharmaceutical formulated:
   - А. 1955Schwann and Leeuwenhoek
   - Б. 1838Wagner and Levi
   - В. 1961 Watson and Crick
   - Г. 1961Wagner and Levi
2. The directions of the national drug policy are:
   - А. Improving the list of vital and essential drugs in the direction of detailing the list.
   - Б. Improving the pricing system for medicines.
   - В. Achieving a high level of rationality in the prescription of drugs by doctors and their use by the population.
   - Г. Implementation of government measures to support research and development of new drugs.
   - Д. All of the above.
3. From the point of view of pharmacology, fundamental pharmacy and biopharmacy, the main task of the technology of dosage forms is to create a drug that is distinguished by:
   - А. maximum efficiency;
   - Б. security;
   - В. stability and ease of use
   - Г. all of the above.
4. The life cycle of a reproduced medicinal product does not include:
   - А. pharmaceutical development
   - Б. preclinical studies
   - В. state registration.
5. Pharmacodynamics studies:
   - А. pharmacological effects of drugs: localization, mechanism and types of action.
   - Б. quantitative and qualitative changes in drugs in the blood, other body fluids and organs, as well as the mechanisms that cause these changes.
6. To carry out the process of absorption of a substance, it is necessary that:
   - А. the active ingredient of the drug must be released from the dosage form;
   - Б. 2. the released substance must reach the absorption surface
   - В. 3. Both conditions must be met.
7. Absorption of medicinal substances is:
   - А. the entry of a medicinal substance from the systemic bloodstream into various organs and tissues.
   - Б. the process of movement of a drug from the injection site into the systemic bloodstream
8. The sum of chemical transformations that a medicinal substance undergoes in the body is called:

А. suction
Б. distribution
В. metabolism (biotransformation)
Г. withdrawal

9. Pharmacokinetics is what:
   А. what does medicine do to the body
   Б. what the body does with the medicine.
10. Permeation is
   А. transport of drug molecules from the absorption surface through the cell membrane
   Б. the entry of a medicinal substance from the systemic bloodstream into various organs and tissues.

4.1.2. Examples of situational tasks

The indicators of competency achievement being verified: UK-2.2.1, UK-2.3.1, UK-6.2.1, UK-6.3.1, OPK-1.2.1, OPK-1.3.1, OPK-3.2.1, OPK-3.3.1, OPK-6.2.1, OPK-6.3.1, PC-1.2.1, PC-1.3.1, PC-1.3.2, PC-1.3.3, PC-3.2.1, PC-3.3.1, PC-8.2.1, PC-8.3.1, PC-9.2.1, PC-9.3.1.

SITUATIONAL PROBLEM.

Distribute the drugs into original and generics. Name them by INN

A. Renitek, Ednit, Enap Enalapril;

B. Drotaverin, No-shpa, Spasmol;

V. Bisoprolol, Concor, Coronal, Cordinorm.

SITUATIONAL PROBLEM.

Arrange the following routes of administration in order of the slowest rate of onset of the therapeutic effect: rectal, intravenous, inhalation, oral. Explain the advantages and disadvantages of these routes of administration.

SITUATIONAL PROBLEM.

You work in an analytical laboratory and have analyzed the drug Afobazol. You have obtained the following results. The dissolution time of Afobazol tablets on the Rotating Basket device was 25 minutes: 75% of the drug was released. Does the studied series of tablets meet the requirements of the State Pharmacopoeia for the Dissolution test?

4.1.3. Examples of abstract topics

Verifiable indicators of competence achievement: UK-2.1.1, UK-6.1.1, OPK-1.1.1, OPK-3.1.1, OPK-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.

1. Combination drugs and principles of their use.
2. Transdermal patches with nitroglycerin: assortment, design, principle of action, indications for use.
3. Medicines and food products: the influence of components and combinations of food products on the pharmacodynamics and pharmacokinetics of drugs, reasons, unacceptable combinations.

4.1.4. Examples of interview control questions

Verifiable indicators of competence achievement: UK-2.1.1, UK-6.1.1, OPK-1.1.1, OPK-3.1.1, OPK-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.

1. Provide a definition of the concepts of original (reference) drug and generic drug.
2. Describe the stages of creation and launch of an original medicinal product.
3. List the main characteristics of the original drug.
4. Describe the stages of creation and launch of a generic drug.
5. List the main characteristics of a generic drug.
6. List the advantages of the original generic drug.
7. What methods are used to confirm the bioequivalence of a generic drug?

4.2. Assessment tools for conducting midterm assessment in the discipline

Interim certification is carried out in the form ofoffset.

The midterm assessment includes the following types of tasks: testing, interview, solving a situational problem.

4.2.1. Examples of test tasks

Verifiable indicators of competence achievement: UK-2.1.1, UK-6.1.1, OPK-1.1.1, OPK-3.1.1, OPK-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.

1. Bioavailability of a drug is a term that reflects:
   - A. the amount of unchanged active substance reaching the systemic circulation relative to its metabolites;
   - Б. the amount of active substance reaching the systemic circulation;
   - B. the amount of medicine that has entered the patient's body.
2. Bioavailability of injectable drugs is:
   - A. 100%;
   - Б. 80-90%;
   - B. 70-80%;
3. The bioavailability of injectable drugs is influenced by factors such as:
   - A. patient's age;
   - Б. history of liver and kidney failure;
   - B. presence of concomitant diseases in the anamnesis;
   - Г. none of the above.
4. Absolute bioavailability of drugs is a term that reflects:
   - A. the concentration of the drug in the patient's urine after oral administration;
   - Б. the concentration of a drug in the blood after taking the drug;
   - B. how much higher the concentration of the drug is after its administration by a route other than intravenous.
5. Relative bioavailability of drugs reflects:
   - A. what amount of the drug taken will theoretically reach the systemic circulation and have a therapeutic effect;
   - Б. how much of the drug taken reached the systemic circulation;
   - B. to what extent the concentration of the drug taken in the blood corresponds to the concentration of the drug used as a standard or administered by another route.
6. The processes of absorption, distribution, biotransformation and excretion of medicinal substances are studied by:
   - A. pharmacodynamics;
   - Б. pharmacokinetics;
   - B. pharmacogenetics;
   - Г. all of the above.
7. The action of drugs that begins with irritation of receptors in a certain area of the body:
   - A. electoral;
   - Б. local;
   - B. resorptive;
   - Г. reflex.
8. Accumulation of the drug in the body:
   - A. biotransformation;
   - Б. cumulation;
   - B. sensitization;
   - Г. excretion.
9. When administered intravenously, the drug arrives earlier:
   - A. into the subcutaneous tissue;
   - Б. into skeletal muscles;
   - B. in the kidneys;

Г. all of the above.

10. Suspensions are used in all the listed ways, except:
    А. inside;
    Б. intravenously;
    В. intramuscularly;
    Г. subcutaneously.
11. The elimination of drugs from the body is:
    А. biotransformation;
    Б. resorption;
    В. tolerance;
    Г. excretion.
12. The introduction of drugs with a violation of the integrity of the skin is carried out:
    А. intralumbar;
    Б. rectally;
    В. sublingually;
    Г. orally.

4.2.2. Example of situational tasks

The verified indicators of competence achievement: UK-2.2.1, UK-2.3.1, UK-2.3.2, UK-2.3.3, UK-6.2.1, UK-6.2.2, UK-6.3.1, OPK-1.2.1, OPK-1.3.1, OPK-3.2.1, OPK-3.3.1, OPK-6.2.1, OPK-6.3.1, PC-1.2.1, PC-1.3.1, PC-1.3.2, PC-1.3.3, PC-3.2.1, PC-3.3.1, PC-8.2.1, PC-8.3.1, PC-9.2.1, PC-9.3.1.

Situational task.

A woman with a child came to the pharmacy asking to recommend an antipyretic drug for a child of the first year of life. Tell us about the features of using drugs in this age period. Specify the dosage forms that are optimal for children of this age. Give examples of drugs and their dosage forms.

Situational task.

When studying the bioequivalence of Riboflavin dragees produced by different factories and having the same composition and dosage, it was found that the content of the medicinal substance in the blood of the subjects was different. Are the drugs equivalent and why? What forms of equivalence exist?

4.2.3. List of interview questions

No.	Questions for midterm assessment	Verifiable indicators of competency achievement
1.	Biopharmacy: history of origin, goals, tasks of the discipline. Basic terms in biopharmacy.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
2.	Modern achievements of biopharmaceuticals in the field of creating effective and safe drugs.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
3.	The concepts of pharmacodynamics and pharmacokinetics of a drug in pharmacology and biopharmaceuticals, main indicators and characteristics.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
4.	Concepts of bioavailability: absolute and relative bioavailability.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
5.	Bioequivalence of medicinal products: concept, types, main characteristics.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.

6.	Pharmaceutical factors, classification.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
7.	Pharmaceutical factor: simple chemical modification, its importance in biopharmaceuticals, examples of drugs created by simple chemical modification.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
8.	Pharmaceutical factor, technological process, its importance, examples of the influence of violations of the technological process at various stages of production of a drug on its bioavailability.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
9.	The influence of the degree of dispersion of medicinal substances on their bioavailability from dosage forms.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
10.	Pharmaceutical factor: physical state of the pharmaceutical substance, influence on the therapeutic efficacy of the drug: degree of grinding, as well as the phenomena of polymorphism and stereoisomerism.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
11.	The concept of drug solubility and its impact on bioavailability.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
12.	Pharmaceutical factor "excipients", its content. Requirements for modern excipients.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
13.	Pharmaceutical factor "excipients": Classification and nomenclature of excipients.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
14.	The mechanism of influence of excipients on the rate of release and absorption of medicinal substances from the dosage form.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
15.	The pharmaceutical factor “dosage form and route of administration”, its importance for the bioavailability and therapeutic efficacy of drugs.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
16.	The influence of the type of dosage form on the bioavailability of a drug, criteria for choosing a dosage form depending on the required therapeutic effect.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
17.	Routes of administration of drugs, their advantages and disadvantages, criteria for choosing the route of administration.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
18.	Administration regimen: features of drug use. The problem of drug interactions.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
19.	The concept of equivalence of medicinal products. Types of equivalence.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
20.	Original and generic drugs: definition, characteristics, stages of development and launch, examples.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.

21.	Original and generic drugs: definition, problem of bioequivalence of generic drugs.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
22.	Types of equivalence. The concept of therapeutic non-equivalence of drugs and the causes and occurrence.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
23.	The influence of the patient's physiological state on the pharmacodynamics and pharmacokinetics of drugs: features of use during pregnancy and lactation.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
24.	The influence of the patient's physiological state on the pharmacodynamics and pharmacokinetics of drugs: features of drug therapy in newborns and children of the first year of life.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
25.	Drug interactions: types, ways of elimination, examples.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
26.	Interaction of drugs with food components. Unfavorable combinations. Methods of eliminating undesirable interactions. Examples.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
27.	Combined medicinal products. Advantages, features of manufacturing technology, principles of rational use.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
28.	Pharmaceutical incompatibility, types of incompatibility, examples.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
29.	Transdermal therapeutic systems. Design, advantages, mechanism of action, examples of drugs.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.
30.	Application of nanotechnology to create effective and safe drugs. Types of nanoparticles. Mechanism of action of drugs based on nanocarriers.	UC-2.1.1, UC-6.1.1, GPC-1.1.1, GPC - 3.1.1, GPC-6.1.1, PC-1.1.1, PC-3.1.1, PC-8.1.1, PC-9.1.1.

The full fund of assessment tools for the discipline is available in the Volgograd State Medical University's EIS at the following link(s):

https://elearning.volgmed.ru/course/view.php?id=12407

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