

**FEDERAL STATE BUDGET EDUCATIONAL
HIGHER EDUCATION INSTITUTION
"ROSTOV STATE MEDICAL UNIVERSITY"
MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION**

FACULTY OF TREATMENT AND PREVENTION

Appraisal Fund
in the discipline "Clinical Pharmacology"

Specialty 05/31/01 General Medicine

1. Interim certification form.

- Pass

2. Type of intermediate certification.

- Interview

3. List of competencies formed by the discipline or in formation which discipline is involved

general professional (OPK)

Code	Name	Indicator(s)	achievements	general professional
GPC-8	Readiness for medical use of drugs and other substances and their combinations in solving professional problems.	Able to prescribe treatment and monitor its effectiveness and safety.		

4. Stages of developing competencies in the process of mastering the discipline

Sections of the discipline	Codes generated competencies
	OPK-8
Semester 11 (B)	
Section 1. General issues of clinical pharmacology.	+
Section 2. Particular issues of clinical pharmacology.	+

5. Types of assessment materials in accordance with the generated competencies

Name of the competency achievement indicator (ID)	Types of assessment materials	
	Current certification	Interim certification
OPK-8	• Questions for control	• Summary questions for interviews

6. Current control

Types and forms of control from the RPD of discipline	Number of example (standard) tasks for 1 competence
Oral survey, interview	test questions on the topics of the section

OPK - 8

Interview, oral questioning

1. Pharmacoepidemiology. Definition concepts, tasks And methods pharmacoepidemiological studies.
2. ADR, methods for assessing the effectiveness and safety of clinical use of drugs.
3. Clinical pharmacogenetics and its pediatric aspects. Genetic factors influencing the pharmacokinetics and pharmacodynamics of drugs. Reactions of the recipient's body to taking drugs in the most common enzymopathies.

4. Modern drug market. The role of clinical pharmacology in regulation medicinal market. Development, testing and registration of new drugs (GLP, GCP, GMP standards).
5. Interaction PM. Types of interaction PM (pharmaceutical, pharmacokinetic, pharmacodynamic). Clinical significance of drug interactions. Principles of rational combination of drugs.
6. Classification of NSAIDs according to the severity of the anti-inflammatory effect and selectivity for different types of cyclooxygenase. Pharmacodynamic effects and pharmacokinetic features, NDRs and measures for their prevention.
7. Mechanism of action of NSAIDs Indications for use and features of individual drugs from the NSAID group.
8. NLR, control of SCS therapy. Clinical manifestations and risk factors for development secondary adrenal insufficiency.
9. Inhaled corticosteroids: clinical pharmacology, place in the treatment of asthma and COPD
10. The concept of stepwise therapy for bronchial asthma. Flexible dosing of ICS ("SMART therapy").

7. Interim certification

Types of intermediate certification from the RPD disciplines	number of example (standard) tasks for 1 competency
Interview	All control questions for the discipline (or semester)

OPK – 8

Interview

I. General issues of clinical pharmacology

1. Subject and objectives of pharmacotherapy. Relationship between pharmacotherapy and theoretical and clinical disciplines." Clinical pharmacology: subject, structure, tasks, role in medicine.
2. Types of pharmacotherapy.
3. Relationship between pharmacodynamics and pharmacokinetics. Determination of the magnitude of the pharmacological effect. Therapeutic effect, therapeutic range and therapeutic breadth of a drug. Maintenance dose.
4. Terminology in clinical pharmacology and pharmacotherapy. Concepts: biologically active substance, pharmacological agent, drug, medicinal product, dosage form, active substance.
5. Terminology in clinical pharmacology and pharmacotherapy. Concepts: clinical pharmacology, pharmacotherapy, substance elimination, elimination quota, elimination constant.
6. Terminology in clinical pharmacology and pharmacotherapy. Concepts: half-life, volume of distribution, clearance, equilibrium concentration, minimum therapeutic level, therapeutic range, therapeutic latitude.
7. Pharmacokinetics. Definition. Role in the development of pharmacotherapy, challenges, opportunities.
8. Routes of administration of drugs.
9. Absorption of drugs. Mechanisms of drug transport through biomembranes.
10. Distribution of drugs in organs and tissues.
11. Binding of drugs to proteins.
12. Metabolism of drugs.

13. Removal of drugs.
14. Modeling of pharmacokinetic processes. Two-chamber pharmacokinetic model. Determination of clearance.
15. Bioavailability. Relative bioavailability. The practical significance of these indicators.
16. The concept of bioequivalence of medicinal substances. Peak concentration of drugs in the blood. Time to reach maximum concentration. The area under the curve of changes in drug concentration in the blood.
17. Therapeutic drug monitoring.
18. Pharmacodynamics. Definition. Role and significance in the development of pharmacotherapy. Types of action of medicinal substances.
19. Mechanisms of action of drugs.
20. Dosing of medications.
21. Repeated use of medications.
22. Drug interactions. Kinds. Pharmaceutical interaction.
23. Pharmacokinetic interaction of drugs.
24. Pharmacodynamic interaction of drugs.
25. The influence of a person's age on the effect of drugs. Features of pharmacotherapy in newborns.
26. Features of pharmacotherapy during pregnancy.
27. Features of pharmacotherapy in lactating women.
28. Features of pharmacotherapy in old age.
29. Interchangeability of medicines. Drugs of choice. Types of equivalence.
30. The influence of environmental factors on the effect of drugs.
31. The role of hereditary factors in pharmacotherapy, pharmacogenetics.
32. Side effects of drugs. Specific side effects associated with the pharmacological properties of drugs. Toxic effect of drugs. Stealing syndrome. Paramedicinal side effects.
33. Side effects of drugs. Allergic reactions to medications. Drug addiction. Withdrawal syndrome.
34. Adverse drug reactions. WHO classification.
35. Pharmacoeconomics. Definition, objectives, basic research methods and concepts.
36. Pharmacoepidemiology. Definition, objectives, basic research methods and concepts.
37. Form system. The importance of the formulary for the rational use of drugs.
38. Medicinal toxicology. Main clinical syndromes of acute drug poisoning. Specific antidotes.

II. Particular issues of clinical pharmacology

1. Nitrates: classification, mechanism of action, main pharmacodynamic effects, pharmacokinetic features, side effects, contraindications. Application for various forms of ischemic heart disease.
2. Beta-blockers: classification, mechanism of action, main pharmacodynamic effects, pharmacokinetic features, side effects, contraindications. Beta blocker withdrawal syndrome. Application for various forms of ischemic heart disease.
3. Calcium antagonists: classification, main pharmacodynamic effects, side effects, contraindications. Application for various forms of ischemic heart disease.
4. Thiazide diuretics: classification, main pharmacodynamic effects, side effects, contraindications. The place of diuretics in the treatment of arterial hypertension.

5. ACE inhibitors and AT1 receptor blockers: classification, mechanism of action, main pharmacodynamic effects, pharmacokinetic features, side effects, contraindications. The place of ACE inhibitors and AT1 receptor blockers in the treatment of arterial hypertension.
6. Alpha1-adrenergic receptor blockers and centrally acting drugs (central alpha2-sympathomimetics, I1-imidazoline receptor agonists): classification, main pharmacodynamic effects, side effects, indications and contraindications for use in hypertension.
7. Loop, thiazide, potassium-sparing diuretics and carbonic anhydrase inhibitors (classification, pharmacodynamic features). Prescription tactics for CHF. Spironolactone as a neurohumoral modulator.
8. ACE inhibitors and AT1 receptor blockers: classification, mechanism of action, main pharmacodynamic effects, pharmacokinetic features, side effects, contraindications. The place of ACE inhibitors and AT1 receptor blockers in the treatment of CHF.
9. Beta-blockers: classification, mechanism of action, main pharmacodynamic effects, pharmacokinetic features, side effects, contraindications. The place of beta blockers in the treatment of CHF.
10. Platelet hemostasis. Medicines that prevent the formation of platelet thrombus: classification, mechanism of action, indications and contraindications for use.
11. Coagulation hemostasis. Unfractionated and low molecular weight heparins: classification, mechanism of action, pharmacokinetic features, side effects, indications and contraindications for use. Control of heparin therapy.
12. Coagulation hemostasis. Indirect-acting anticoagulants: classification, mechanism of action, side effects, indications and contraindications for use. Therapy control.
13. Fibrinolysis system. Fibrinolytics: classification, mechanism of action, side effects, indications and contraindications for use.
14. NSAIDs: classification according to anti-inflammatory activity, mechanism of action, main pharmacodynamic effects. Indications for use.
15. NSAIDs: classification according to the degree of selectivity to various types of COX. Main side effects, risk factors for complications, monitoring the safety of long-term NSAID therapy.
16. Systemic glucocorticosteroids (SCS): mechanism of action, classification, main pharmacodynamic effects, contraindications.
17. SCS: side effects. Secondary adrenal insufficiency: risk factors, prevention measures. Types of pharmacotherapy for SCS. Chronotherapy, alternating therapy, pulse therapy.
18. Antacid drugs: classification, mechanism of action, main side effects, indications for use.
19. H2-histamine blockers: classification, mechanism of action, main side effects, indications for use.
20. Proton pump blockers: classification, mechanism of action, main side effects, indications for use.
21. Treatment of Helicobacter-associated diseases: general principles and schemes of eradication therapy.
22. Classification, clinical and pharmacological characteristics of penicillins. Indications for use.
23. Classification of cephalosporins. Clinical and pharmacological characteristics of cephalosporins. Indications for use.
24. Classification, clinical and pharmacological characteristics of aminoglycosides. Indications for use.
25. Classification, clinical and pharmacological characteristics of fluoroquinolones.

- Indications for use.
26. Classification, clinical and pharmacological characteristics of macrolides.
Indications for use.
 27. Basic principles of rational antibiotic therapy: goals, choice of drug, evaluation of effectiveness, duration of antibiotic therapy. The concept of “stepped” antibiotic therapy.
Approaches to the treatment of community-acquired pneumonia.
 28. Perioperative prevention in surgery. Indications, purpose, treatment regimens.
 29. Types of antimicrobial activity. Time-dependent, concentration-dependent antibiotics.
 30. Mechanisms of antibiotic resistance.
 31. Step-by-step therapy of bronchial asthma. Clinical and pharmacological characteristics of IGCs, indications for use, duration of prescription, evaluation of effectiveness.
 32. Step-by-step therapy of bronchial asthma Membrane stabilizing agents in the treatment of bronchial asthma: clinical and pharmacological characteristics of the main groups of drugs, indications for use.
 33. Step-by-step therapy of bronchial asthma. Antileukotriene drugs in the treatment of bronchial asthma: clinical and pharmacological characteristics of the main groups of drugs, indications for use.
 34. Classification of methylxanthines. Features of drug pharmacokinetics. Indications for use. Side and toxic effects. Major adverse drug interactions.
 35. Beta 2 – short-acting adrenergic agonists and anticholinergics in the treatment of bronchial asthma. Indications and contraindications for use, drugs of choice, principles of use, side effects.
 36. Step-by-step therapy of bronchial asthma. Beta 2 - long-acting adrenergic agonists in the treatment of bronchial asthma. Indications and contraindications for use, drugs of choice, principles of use, side effects.

8. Description of indicators and criteria for assessing competencies at their stages formation, description of rating scales

	Levels of competency development		
	<i>Threshold</i>	<i>Sufficient</i>	<i>High</i>
Criteria	Competence formed. Demonstrated threshold, satisfactory sustainable level practical skill	Competence formed. Demonstrated enough level independence, sustainable practical skill	Competence formed. Demonstrated high level independence, high adaptability practical skill

Competency assessment indicators and rating scales

Grade "unsatisfactory" (not accepted) or lack of maturity competencies	Grade "satisfactorily" (passed) or satisfactory (threshold) level of development competencies	Rated "good" (passed) or sufficient level development competencies	Excellent rating (passed) or high level development competencies
Inability of the learner to learn independently demonstrate knowledge when solving tasks, lack of independence in application of skills. The lack of confirmation of the development of competence indicates negative results in mastering the academic discipline.	student demonstrates independence in application of knowledge skills and abilities to solve educational tasks in full According to sample given teacher, by tasks, solution of which there were shown teacher, it should be considered that competence formed on satisfactory level.	student demonstrates independent application knowledge, skills and skills at solving tasks, similar samples that confirms Availability formed competencies for higher level. Availability such competence on sufficient level indicates sustainable fixed practical skill	student demonstrates ability to complete independence in choosing a method solutions non-standard assignments within disciplines with using knowledge, skills and skills acquired as in the course of mastering this discipline, and adjacent disciplines should consider competence formed on high level.

Criteria for evaluating forms of control:

Interviews:

Mark	Description
Great	The mark "EXCELLENT" is given to an answer that shows a solid knowledge of the basic processes of the subject area being studied and is distinguished by the depth and completeness of the topic; mastery of terminology; the ability to explain the essence of phenomena, processes, events, draw conclusions and generalizations, give reasoned answers, give examples; fluency in monologue speech, logic and consistency of response.
Fine	The mark "GOOD" evaluates an answer that reveals a solid knowledge of the basic processes of the subject area being studied, and is distinguished by the depth and completeness of the topic; mastery of terminology; the ability to explain the essence of phenomena, processes, events, draw conclusions and generalizations, give reasoned answers, give examples; fluency in monologue speech, logic and consistency of response. However, one or two inaccuracies in the answer are allowed.

satisfactorily	<p>Mark "SATISFACTORILY" is assessed answer, indicating mainly knowledge of the processes of the subject area being studied, characterized by insufficient depth and completeness of the topic; knowledge of the basic issues of theory; poorly developed skills in analyzing phenomena and processes, insufficient ability to give reasoned answers and give examples; insufficient fluency in monologue speech, logic and consistency of response. There may be several errors in the content of the answer.</p>
unsatisfactory	<p>Mark "UNSATISFACTORILY" is assessed answer, revealing ignorance of the processes of the subject area being studied, characterized by a shallow disclosure of the topic; ignorance of the basic issues of theory, unformed skills in analyzing phenomena and processes; inability to give reasoned answers, poor command of monologue speech, lack of logic and consistency. Serious errors in the content of the answer are allowed.</p>

Evaluation criteria for the test

Mark in the record book	Description
passed	The mark "PASSED" is used to evaluate an answer that reveals a solid knowledge of the basic processes of the subject area being studied and is distinguished by the depth and completeness of the topic; mastery of terminology; the ability to explain the essence of phenomena, processes, events, draw conclusions and generalizations, give reasoned answers, give examples; fluency in monologue speech, logic and consistency of response. However, one or two inaccuracies in the answer are allowed.
not accepted	Mark "NOT PASSED" is assessed answer, revealing ignorance of the processes of the subject area being studied, characterized by a shallow disclosure of the topic; ignorance of the basic issues of theory, unformed skills in analyzing phenomena and processes; inability to give reasoned answers, poor command of monologue speech, lack of logic and consistency. Serious errors in the content of the answer are allowed.