

**Evaluation tools for certification  
in the discipline  
"Methods of pharmaceutical analysis"  
for students of the educational program  
of the specialty / area of training 33.05.01 Pharmacy,  
profile Pharmacy  
(specialist's level),  
form of study full-time  
for the 2023-2024 academic year**

End-of-course assessment in the discipline “Methods of pharmacopoeial analysis” is carried out in the form of exam in the semester VI.

End-of-course assessment includes following types of assignments:

- solving a case study;
- interview on test questions from sections of the discipline.

**Examples of exam questions**

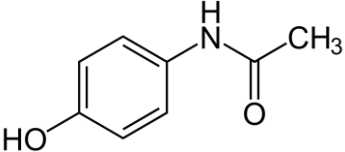
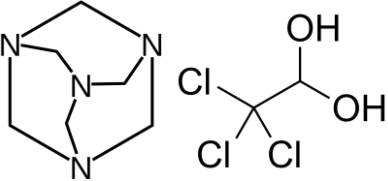
No	Assignment text	Competence indicators		
		GC	GPC	PC
1.	The Russian State Pharmacopoeia. The International Pharmacopoeia. National and regional pharmacopoeias. Pharmacopoeial monographs: types, structure and terms of use.	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
2.	Pharmacopoeial analysis. Criteria, basic terms and concepts of pharmacopoeial analysis.	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
3.	Determination of melting point. Methods, equipment.	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
4.	Boiling point. The physical meaning of boiling point. Methods for determining the boiling point. Determination of the temperature limits of distillation.	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
5.	Refractometry. Absolute and relative refractive index. Snell's Law. Calculations in refractometry. Measurement of refractive index. Equipment.	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
6.	Polarimetry – definition, concept. Natural and polarized rays of light. The degree of polarization. Optically active substances. Chirality. Optical system of polarimeters. Rotation angle. Specific rotation. Calculation formulas.	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
7.	Determination of ash. Total ash, sulphated ash. Ash insoluble in hydrochloric acid. Methods of determination. Calculation formulas.	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
8.	Determination of drug solubility. Types of concentration used in pharmaceutical analysis.	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12

				PC-18
9.	Determination of color intensity of liquids. Determination of transparency and degree of turbidity of drug solutions.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
10.	Chromatographic methods of analysis. Classification. Thin layer chromatography. Gas chromatography. Ion exchange chromatography. High performance liquid chromatography (HPLC).	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
11.	Acidity, alkalinity. The ionic product of water. Determination of pH. Acid-base indicators. Potentiometric method for determining the acidity of the medium. Colorimetric method for determining the acidity of the medium.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
12.	Pharmacopoeial analysis of compounds containing halogens. Alkali metal halides.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
13.	Pharmacopoeial analysis of compounds containing oxygen and sulfur. Sodium thiosulfate, hydrogen peroxide.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
14.	Pharmacopoeial analysis of compounds containing boron. Boric acid, sodium tetraborate.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
15.	Pharmacopoeial analysis of compounds containing magnesium, zinc and calcium. Magnesium sulfate, zinc sulfate, calcium chloride.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
16.	Pharmacopoeial analysis of bismuth subnitrate.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
17.	Pharmacopoeial analysis of compounds containing silver, copper and platinum. Silver nitrate, silver colloidal for external use. Copper sulfate. Ferrous sulfate. Cisplatin.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
18.	Halogenated hydrocarbons of the aliphatic series. Ethyl chloride (chloroethane), chloroform, fluothane (halothane).	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
19.	Alcohols and esters. Diethyl ether. Oxidation reactions of medical ether, storage conditions of the drug. Ethyl alcohol.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
20.	Alcohols and esters. Glycerol. Nitroglycerin. Explosion hazard, warning measures, storage conditions.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
21.	Aldehydes and their derivatives: formaldehyde, hexamethylenetetramine (methenamine).	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
22.	Carbohydrates: glucose.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
23.	Aliphatic carboxylic acids and their derivatives. Potassium acetate, calcium gluconate, sodium citrate.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
24.	Amino acids of the aliphatic series. Glutamic acid, cysteine, gamma-aminobutyric acid (GABA).	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
25.	Amino acids of the aliphatic series. Proline derivatives: captopril, enalapril. Aminocaproic acid.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
26.	Phenols. Phenol, thymol, resorcinol.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12

				PC-18
27.	Carboxylic acids of the aromatic series. Benzoic acid, salicylic acid, acetylsalicylic acid.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
28.	Aromatic amino acids – derivatives of para-aminobenzoic acid. Procaine, benzocaine, tetracaine.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
29.	Aromatic amines: paracetamol. Derivatives of phenylacetic and phenylpropionic acids: diclofenac, ibuprofen.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
30.	Benzenesulfochloramide derivatives: chloramine B, halazone.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
31.	Substituted sulfonylureas as antidiabetic agents: butamide, chlorpropamide.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
32.	Sulfonamides. Sulfanilamide, sulfacetamide sodium. Sulfaguanidine, sulfathiazole.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
33.	Diethylaminoacetanilides: trimecaine, lidocaine.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
34.	Terpenoids. Bicyclic terpenoids: Menthol, validolum. Bicyclic terpenoids: camphor, bromocamphor.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
35.	Derivatives of 5-nitrofuran. Nitrofurazone.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
36.	Pyrazole derivatives. Phenazone, metamizole sodium.	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18

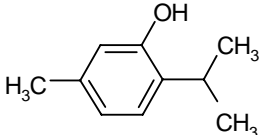
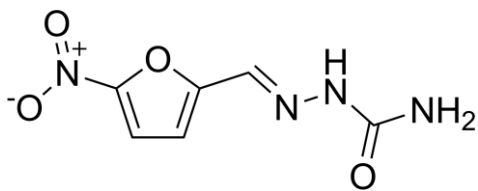
### **Examples of case studies for exam**

1.	<p>The trainee prepared a solution of caffeine-sodium benzoate using the mass-volume method and determined the refractive index of this solution.</p> <ul style="list-style-type: none"> <li>– Calculate the concentration of a solution of sodium caffeine benzoate if the refractive index of the solution is 1.3663, the refractive index of water is 1.333.</li> <li>– The refractive index factor of caffeine sodium benzoate is 0.00112.</li> <li>– Give a definition and brief description of this method. What law underlies this method?</li> </ul>	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
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2.	<p>The enterprise received a drug substance that was received for the production of drug tablets of several series of the following structure:</p> <div style="text-align: center;">  </div> <p>When this substance is boiled with diluted hydrochloric acid, a specific odor of acetic acid appears.</p> <ul style="list-style-type: none"> <li>- Make a conclusion about the authenticity of the drug substance.</li> <li>- According to the chemical properties, propose identification reactions and quantification methods. Write reaction equations.</li> <li>- Give the Russian, Latin and rational names of the drug. Describe its physicochemical characteristics.</li> </ul>	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
3.	<p>The trainee prepared a 40% glucose solution for injection and determined the rotation angle of this solution.</p> <ul style="list-style-type: none"> <li>- Calculate the concentration of the glucose solution if the values of the optical rotation angle <math>\alpha = 5.1^\circ; 4.9^\circ; 5.3^\circ</math>.</li> <li>- A cuvette length is 20 cm; 6.25 ml of the drug was diluted in a 50 ml flask.</li> <li>- Specific rotation <math>[\alpha]</math> of glucose is <math>52.8^\circ</math>.</li> <li>- Evaluate the compliance of the concentration of the prepared solution with the requirements of the normative documentation.</li> <li>- Give a definition and brief description of this method. What law underlies this method? Describe the operation principle of polarimeter.</li> </ul>	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
4.	<p>When assessing the quality of pharmaceutical substances of the following chemical structures:</p> <div style="text-align: center;">  </div> <p>Both powders are white, finely crystalline substances, the first is odorless and sublimes without melting, and the second has a characteristic pungent odor.</p>	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18

	<ul style="list-style-type: none"> <li>– Provide quality assesment for abovementioned substances on indicator "Description".</li> <li>– Name these substances and characterize their chemical structure and solubility.</li> <li>– What class of compounds do these substances belong to, and how are they produced industrially?</li> <li>– According to the chemical structure, suggest identification reactions and assay methods.</li> </ul>			
5	<p>The quality control department of a pharmaceutical enterprise received the pharmaceutical substance "Phthalazole" for quality assessment.</p> <ul style="list-style-type: none"> <li>– Write the structural formula of this substance, characterize the chemical structure, highlight the functional groups.</li> <li>– Which drug class does this compound belong to? What other drugs of this class do you know?</li> <li>– According to the chemical structure, suggest identification reactions and assay methods. Write the reaction equations.</li> </ul>	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
6	<p>The quality control department of a pharmaceutical enterprise received substances with the following structures:</p> <div style="text-align: center;"> </div> <ul style="list-style-type: none"> <li>– What group of compounds do these substances belong to? What medicinal substance do they form? Characterize it according to the indicators "Description" and "Solubility".</li> <li>– Give the Russian and Latin names of this medicinal substance.</li> <li>– Give reactions for identifying and quantifying the compound.</li> </ul>	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
7	<p>Assess the quality of the pharmaceutical substance "Metamizole".</p> <ul style="list-style-type: none"> <li>– Give the structural formula of this compound; characterize its structure and physical properties.</li> <li>– Explain the method of preparation and methods of pharmaceutical analysis of this substance.</li> <li>– For what diseases and in what dosage forms is this drug used?</li> </ul>	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18
8	<p>The quality control department of a pharmaceutical enterprise received an APC with the following structure:</p>	GC – 1 GC – 8	GPC–1 GPC–5	PC–1 PC–12 PC–18

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	 <ul style="list-style-type: none"> <li>- Name given substance and characterize the chemical structure, name the functional groups.</li> <li>- When assessing the quality of this medicinal product in samples of one series, the appearance did not meet the requirements of the "Description" section</li> <li>- the powder was wet and had dirty pink colour. Explain the reasons for changes in its quality for this indicator in accordance with the methods of production and properties.</li> <li>- Based on the chemical structure, suggest identification reactions.</li> <li>- Write the reactions used to identify phenolic hydroxyl group.</li> </ul>			
9	<p>A pharmaceutical substance with the following chemical structure was received by the pharmaceutical enterprise for analysis:</p>  <p>Name this substance and characterize the chemical structure, name the functional groups.</p> <ul style="list-style-type: none"> <li>- Suggest identification tests.</li> <li>- Explain iodometric assay method of a given substance based on its reducing properties.</li> </ul>	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18
10	<p>The drug quality control center received the pharmaceutical substance "Chloramine B".</p> <ul style="list-style-type: none"> <li>- Write the structural formula of this substance, characterize the chemical structure, indicate the functional groups.</li> <li>- Which drug class does this compound belong to? What other drugs of this class do you know?</li> <li>- According to the chemical structure, suggest identification reactions and assay methods. Write reaction equations.</li> </ul>	GC – 1 GC – 8	GPC-1 GPC-5	PC-1 PC-12 PC-18

Considered at the meeting of the department of Pharmaceutical and Toxicological Chemistry  
"27" may 2023, protocol No9

Head of the department



Ozerov A.A.