Evaluation tools for certification
in the internship in quality control of medicines
for students for students in 2021 admission
according to the educational program
specialist degree
in the specialty of training 33.05.01 Pharmacy
direction (profile) Pharmacy,
form of study full-time (face to face)
for the 2025-2026 academic year

Assessment tools for conducting intermediate practice assessment.

The intermediate certification in the discipline is carried out in the form of a credit with an assessment and includes the following types of tasks: performing practical tasks, checking and evaluating practice reports, checking and evaluating completed individual tasks.

1. List of questions for preparation for the Intermediate certification:

№	Questions for the Intermediate assessment	Verifiable indicators of competence achievement
1.	Intra-pharmacy quality control of medicines. Types of control.	PC-12.1.1., PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.3.1., PC-5.1.1., PC-5.2.1., PC-5.3.1.
2.	Pharmaceutical analysis. Types of pharmaceutical analysis.	PC-12.1.1., PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.3.1., PC-5.1.1., PC-5.2.1., PC-5.3.1.
3.	Organoleptic control of medicines.	PC-12.3.1., PC-4.1.1., PC-4.3.1.
4.	Determination of solubility of medicinal products in accordance with the State Pharmacopoeia of the Russian Federation.	PC-12.1.1., PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.3.1., PC-5.2.1.
5.	Determination of chloride impurities in medicinal products in accordance with the State Pharmacopoeia of the Russian Federation.	PC-12.1.1., PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.3.1., PC-5.1.1., PC-5.2.1., PC-5.3.1.
6.	Determination of sulfate impurities in medicines in accordance with the State Pharmacopoeia of the Russian Federation.	PC-12.1.1., PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.3.1., PC-5.1.1., PC-5.2.1., PC-5.3.1.
7.	Determination of ammonium salt impurities in medicines in accordance with the State Pharmacopoeia of the Russian Federation.	PC-12.1.1., PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.3.1., PC-5.1.1., PC-5.2.1., PC-5.3.1.
8.	Determination of calcium salt impurities in medicines in accordance with the State Pharmacopoeia of the Russian Federation.	PC-12.1.1., PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.3.1., PC-5.1.1., PC-5.2.1., PC-5.3.1.
9.	Determination of heavy metal impurities in	PC-12.1.1., PC-12.2.1., PC-12.3.1.,

	medicines in accordance with the State Pharmacopoeia of the Russian Federation.	PC-4.1.1., PC-4.3.1., PC-5.1.1., PC-5.2.1., PC-5.3.1.
10.	Determination of the quality of purified water in accordance with the State Pharmacopoeia of the Russian Federation.	PC-12.1.1., PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.3.1., PC-5.1.1., PC-5.2.1., PC-5.3.1.
11.	Physical quality control of medicines.	PC-12.1.1., PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.3.1., PC-5.2.1.
12.	Titration. Calculations for titration of medicines.	PC-12.2.1., PC-12.3.1., PC-4.1.1., PC-4.2.1., PC-4.3.1., PC-5.2.1.

2. Examples of tasks for assessing the Mastery of practical skills.

Verifiable indicators of competence achievement: PC-4.2.1, PC-4.3.1, PC-5.2.1, PC-5.3.1, PC-12.2.1, PC-12.3.1.

1. Evaluate the quality of the substance "Boric acid" according to the indicator "Description".

2. Evaluate the quality of the substance "Boric acid" according to the indicator "Solubility".

3. Determine the purity and limits of the impurity "Sulfates" in the substance "Boric acid" in accordance with the requirements of regulatory documentation.

4. Evaluate the quality of purified water based on the content of chloride impurities.

5. Evaluate the quality of the "Potassium Chloride" substance according to the "Description" indicator.

6. Evaluate the quality of the "Potassium Chloride" substance based on the "Solubility" indicator.

7. Determine the purity and limits of the "Heavy metals" impurity content in the "Potassium Chloride" substance in accordance with the requirements of the regulatory documentation.

8. Evaluate the quality of purified water based on the content of sulfate impurities.

9. Evaluate the quality of the substance "Magnesium sulfate" according to the "Description" indicator.

10. Evaluate the quality of the "Magnesium Sulfate" substance based on the "Solubility" indicator.

11. Determine the purity and limits of the "Chlorides" impurity in the "Magnesium Sulfate" substance in accordance with the requirements of the regulatory documentation.

12. To evaluate the quality of purified water based on the content of impurities of ammonium salts.

13. Evaluate the quality of the "Sodium Bicarbonate" substance according to the "Description" indicator.

14. Evaluate the quality of the "Sodium bicarbonate" substance based on the "Solubility" indicator.

15. Determine the purity and limits of the impurity content of "Calcium Salt" in the substance "Sodium bicarbonate" in accordance with the requirements of regulatory documentation.

16. Evaluate the quality of purified water based on the content of sulfate impurities.

17. Issue the documentation of the established sample for the acceptance control of the medicinal substance "Boric acid" (substance).

18. Issue the documentation of the established sample for the acceptance control of the medicinal substance "Potassium chloride" (substance).

19. Issue the documentation of the established sample for the acceptance control of the medicinal substance "Magnesium sulfate" (substance).

20. Issue the documentation of the established sample for the acceptance control of the medicinal substance "Sodium bicarbonate" (substance).

21. Perform physical control of a custom-made medicinal product (checking the mass of individual doses of powder – at least three doses).

3. Examples of tasks for assessing the development of practical skills
Verifiable indicators of competence achievement: PC-12.3.1., PC-4.3.1., PC-5.2.1.

1. Calculate the boric acid content based on the results of quantitative titrimetric determination: To 0.8968 g of the substance, 100 ml of a 20% mannitol solution was added, previously neutralized by phenolphthalein with 0.1 M sodium hydroxide solution, heated to complete dissolution, cooled and titrated with 1 M sodium hydroxide solution with the same indicator until a non-vanishing pink staining appeared. A sample of the substance was titrated with 13.9 ml of 1 M NaOH solution.
   1 ml of 1 M sodium hydroxide solution corresponds to 61.83 mg of boric acid.

2. Calculate the content of "Potassium chloride" based on the results of quantitative titrimetric determination: 0.05013 g of the substance was dissolved in 20 ml of water and titrated with 0.1 M silver nitrate solution until orange-yellow (indicator – 5% potassium chromate solution). 6.7 ml of 0.1 M AgNO3 solution was used to titrate the sample of the substance.
   1 ml of 0.1 M silver nitrate solution corresponds to 7,455 mg of potassium chloride KCl.

3. Calculate the content of "Magnesium sulfate" based on the results of quantitative titrimetric determination: 0.14686 g of the substance was dissolved in 50 ml of water, 5 ml of ammonia buffer solution was added and titrated with vigorous stirring with 0.05 M sodium edetate solution until blue staining appeared (the indicator is acid chromium black special). 11.7 ml of 0.05 M sodium edetate solution was used to titrate the sample of the substance.
   1 ml of 0.05 M sodium edetate solution corresponds to 12.32 mg of magnesium sulfate.

4. Calculate the content of "Sodium bicarbonate" based on the results of quantitative titrimetric determination: 0.1688 g of the substance was dissolved in 20 ml of carbon dioxide–free water and titrated with 0.1 M hydrochloric acid solution (indicator - 0.1 ml of 0.1% methyl orange alcohol solution). A sample of the substance was titrated with 19.4 ml of 0.1 M HCl solution.
   1 ml of 0.1 M hydrochloric acid solution corresponds to 8.401 mg of sodium bicarbonate.

4. Examples of report topics (individual tasks).
Verifiable indicators of competence achievement: PC-4.1.1, PC-12.1.1, PC-5.1.1.

1. To study the complex of equipment available at the production base for determining the solubility of the substance of drugs.
2. To study the complex of equipment available at the production base for determining the disintegration of tablets and capsules of medicinal products.
3. To study the complex of equipment available at the production base for determining the abrasion resistance of medicinal product tablets.

4. To study the complex of equipment available at the production base for determining the refractive index and the concentration of the liquid form of drugs on it.
5. To study the complex of equipment available at the production base for the photocolorimetric determination of drugs.
6. To study the complex of equipment available at the production base for determining the pH of aqueous solutions of medicinal products.
7. To study the complex of equipment available at the production base for the determination of impurities of inorganic ions in substances and tablets of medicinal products.
8. To study and implement a set of measures and equipment at the production base for the analysis of purified and injectable water.
9. To study the complex of equipment available at the production base for the quantitative assessment of drugs by the titrimetric method (acid-base titration).
10. To study the complex of equipment available at the production base for the quantitative assessment of drugs by the titrimetric method (oxidimetry).
11. To study the complex of equipment available at the production base for the quantitative assessment of drugs by the titrimetric method (complexometry).

5. Example of an exam card

Federal State Budgetary Educational Institution of Higher Education
"Volgograd State Medical University"
Ministry of Health of the Russian Federation

Department: **Pharmaceutical, toxicological chemistry, pharmacognosy and botany.**
Discipline: **Internship In Quality Control Of Medicines**
Speciality at the speciality **33.05.01 Pharmacy**
Academic year: **2025 – 2026**

EXAMINATION CARD № 1

1 Evaluate the quality of the substance ‘Boric acid’ by the indicator ‘Description’.

2. Evaluate the quality of purified water by the content of impurity of chlorides.

3. Determine the purity and limits of the impurity content of ‘Calcium salts’ in the substance ‘Sodium hydrogen carbonate’ in accordance with the requirement of regulatory documentation.

4. Calculate the content of boric acid according to the results of quantitative determination by titrimetric method:

To 0.8968 g of substance was added 100 ml of 20% solution of mannitol, previously neutralised by phenolphthalein 0.1 M sodium hydroxide solution, heated until complete dissolution, cooled and titrated with 1 M sodium hydroxide solution with the same indicator until the appearance of non-vanishing pink staining. 13.9 ml of 1 M NaOH solution was used for titration of the substance.

1 ml of 1 M sodium hydroxide solution corresponds to 61.83 mg of boric acid.

Seal place Head of department Ozerov A.A.

The full fund of evaluation funds for the internship in quality control of medicines is available in the EIOS of VolgSMU at the link:
https://elearning.volgmed.ru/course/view.php?id=11215

Considered at the meeting of the department of Pharmaceutical and Toxicological Chemistry, pharmacognosy and botany "30" May 2025, protocol No10

Head of the Department  Ozerov A.A.