Evaluation tools for certification
in the internship in quality control of medicines
for students for students in 2020 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 2024-2025 academic year

Current certification includes the following types of assignments: interview on control questions, assessment of mastering of practical skills (abilities).

Intermediate certification on practice includes the following types of tasks: interview on control questions, assessment of mastering of practical skills (abilities), preparation of a report (is a defence of the report on the results of individual tasks) and solving situational tasks.

1. List of control questions for the interview

№	Questions for the certification	Verifiable indicators of competence achievement
1.	Using the State Pharmacopoeia (online), find the pharmacopoeial monograph of the substance of mineral origin 'Boric acid'	UC-1.2.2.; GPC-6.2.1. GPC -6.3.2.
2.	Using the State Pharmacopoeia (on-line), find the pharmacopoeial monograph of the substance of mineral origin 'Potassium chloride'	UC-1.2.2.; GPC-6.2.1. GPC -6.3.2.
3.	Using the State Pharmacopoeia (on-line), find the pharmacopoeial monograph of the substance of mineral origin 'Magnesium sulphate'	UC-1.2.2.; GPC-6.2.1. GPC -6.3.2.
4.	Using the State Pharmacopoeia (on-line), find the pharmacopoeial monograph of the substance of mineral origin 'Sodium hydrogen carbonate'	UC-1.2.2.; GPC-6.2.1. GPC -6.3.2.
5.	Using the State Pharmacopoeia (on-line), find the pharmacopoeial monograph substance 'Purified water'	UC -1.2.2.; GPC -6.2.1. GPC -6.3.2.
6.	Quality control of medicines. Intra-pharmacy control	UC -1.2.3.; GPC -3.1.1. PC-4.1.1.
7.	Quality control of medicines. Obligatory full chemical control of medicines.	UC -1.2.3.; GPC -3.1.1. PC-4.1.1.
8.	Quality control of medicinal products. Written control. Oral	UC -1.2.3.; GPC -3.1.1.

	control.	PC-4.1.1.

2. Examples of tasks to assess the mastery of practical skills

Verifiable indicators of achievement of competences: UC-1.2.2; UC-1.3.1; UC-4.1.5; UC-8.1.2; GPC-1.2.1; GPC-1.2.2; GPC-1.3.1; GPC-3.3.1; GPC-6.2.1; GPC-4.1.1; GPC -4.3.2.

1. Assess the quality of the substance 'Boric acid' according to the indicator 'Description'.
2. Evaluate the quality of the substance 'Boric acid' by the indicator 'Solubility'.
3. Determine the purity and limits of the impurity 'Sulphates' in the substance 'Boric acid' in accordance with the requirement of regulatory documentation.
4. Evaluate the quality of purified water by the content of impurity of chlorides.
5. Assess the quality of the substance 'Potassium chloride' according to the indicator 'Description'.
6. Assess the quality of the substance 'Potassium chloride' by the indicator 'Solubility'.
7. Determine the purity and limits of the impurity 'Heavy metals' in the substance 'Potassium chloride' in accordance with the requirement of regulatory documentation.
8. Evaluate the quality of treated water by the content of sulphate impurity.
9. Assess the quality of the substance 'Magnesium sulfate' according to the indicator 'Description'.
10. Evaluate the quality of the substance 'Magnesium sulphate' by the indicator 'Solubility'.
11. Determine the purity and limits of the impurity 'Chlorides' in the substance 'Magnesium sulfate' in accordance with the requirement of regulatory documentation.
12. Evaluate the quality of treated water by the content of impurity of ammonium salts.
13. Assess the quality of the substance 'Sodium hydrogen carbonate' according to the indicator 'Description'.
14. Evaluate the quality of the substance 'Sodium hydrogen carbonate' by the indicator 'Solubility'.
15. Determine the purity and limits of impurity 'Calcium salts' in the substance 'Sodium hydrogen carbonate' in accordance with the requirement of regulatory documentation.
16. Evaluate the quality of treated water by the content of sulfate impurity.

17. To draw up the documentation of the established sample for acceptance control of the medicinal substance ‘Boric acid’ (substance).
18. Draw up standardised documentation for acceptance control of the medicinal substance ‘Potassium chloride’ (substance).
19. Draw up standardised documentation for acceptance control of the medicinal substance Magnesium sulphate (substance).
20. Draw up standardised documentation for acceptance control of the medicinal substance ‘Sodium hydrogen carbonate’ (substance).
21. Perform physical control of the medicinal product of individual manufacturing (check the weight of individual doses of powder - at least three doses).

3. Examples of situational tasks

Verifiable indicators of competences achievement: UC-1.2.3; UC-1.3.1; GPC-1.3.1; PC-4.3.2.

1. Calculate the content of boric acid from the results of quantitative determination by the titrimetric method:

To 0.8968 g of substance was added 100 ml of 20% mannitol solution, previously neutralised 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 the appearance of a 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.

2. Calculate the content of ‘Potassium chloride’ from the results of quantitative determination by the titrimetric method:

0.05013 g of the substance was dissolved in 20 ml of water and titrated with 0.1 M silver nitrate solution to orange-yellow colouring (indicator - 5% potassium chromate solution). 6.7 ml of 0.1 M AgNO3 solution was used for titration of the substance.

1 ml of 0.1 M silver nitrate solution corresponds to 7.455 mg of potassium choride KCl.

3. Calculate the content of ‘Magnesium Sulphate’ from the results of quantitative determination by titrimetric method:

0.14686 g of the substance was dissolved in 50 ml of water, added 5 ml of ammonia buffer solution and titrated under vigorous stirring with 0.05 M sodium edetate solution until blue colouring appeared (indicator - acid chromium black special). 11.7 ml of 0.05 M sodium edetate solution was used for titration of the substance.

1 ml of 0.05 M sodium edetate solution corresponds to 12.32 mg of magnesium sulphate

4. Calculate the content of 'Sodium hydrogen carbonate' from the results of quantitative determination by the titrimetric method:

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% alcoholic methyl orange solution). 19.4 ml of 0.1 M HCl solution was used for titration of the substance.

1 ml of 0.1 M hydrochloric acid solution corresponds to 8.401 mg of sodium bicarbonate

4. Examples of individual assignment topics

Verifiable indicators of achievement of competences: UC-1.2.1; UC-1.2.2; UC - 1.2.3; UC-4.2.1; GPC-1.1.1; GPC-3.1.1; PC-4.1.1.

1. Examine the complex of equipment available at the production base to determine the solubility of drug substance.
2. To study the complex of the equipment available at the production base to determine the disintegrability of tablets and capsules of drugs.
3. To study the complex of the equipment available at the production base to determine the abrasion of tablets of drugs.
4. To study the complex of the equipment available at the production base to determine the refractive index and according to it the concentration of the liquid form of drugs.
5. To study the complex of equipment available at the production base for photocolorimetric determination of drugs.
6. To study the complex of the equipment available at the production base for determination of pH of aqueous solutions of drugs.
7. Examine the complex of equipment available at the production base for the determination of impurities of inorganic ions in the substance and tablets of drugs.
8. To study the complex of measures and equipment at the production base for analysis of purified water and water for injections and implement it.
9. To study the complex of equipment available at the production base for quantitative assessment of drugs by titrimetric method (acid-base titration).
10. To study the complex of the equipment available at the production base for quantitative estimation of drugs by titrimetric method (oxidimetry).
11. Study the set of equipment available at the production base for quantitative assessment of drugs by titrimetric method (complexometry).

The full fund of assessment tools for internship is available in the EIES of VolgSMU at the link:

https://elearning.volgmed.ru/course/view.php?id=10075

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