МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ
БЕЛОРУССКИЙ ГОСУДАРСТВЕННЫЙ МЕДИЦИНСКИЙ УНИВЕРСИТЕТ
КАФЕДРА ФАРМАЦЕВТИЧЕСКОЙ ХИМИИ С КУРСОМ ПОВЫШЕНИЯ КВАЛИФИКАЦИИ
И ПЕРЕПОДГОТОВКИ

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ФАРМАЦЕВТИЧЕСКАЯ ХИМИЯ

PHARMACEUTICAL CHEMISTRY

Сборник задач
для студентов 3-го курса медицинского факультета иностранных учащихся,
обучающихся по специальности «Фармация»

В двух частях

Часть 2

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Включает примеры решения типовых задач по фармацевтической химии, условия задач и место для их решения. Содержатся задачи на химические и инструментальные методы анализа. Студенты приобретают навык расчета по результатам контроля качества лекарственных средств.

Предназначен для студентов 3-го курса медицинского факультета иностранных учащихся, обучающихся по специальности «Фармация» на английском языке.

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EDUCATIONAL CARD

Student _____ group _____

(FULL NAME)

No.	Laboratory lesson topic	Teacher's signature
1	Pharmacopoeial analysis of pharmaceutical substances of inorganic nature: p-elements: solutions of hydrogen peroxide, iodine, povidone-iodine, sodium and potassium chlorides, sodium and potassium bromides, sodium and potassium iodides	
2	Pharmacopoeial analysis of pharmaceutical substances of inorganic nature: p-elements: basic heavy bismuth nitrate, sodium bicarbonate, sodium thiosulfate, boric acid, sodium tetraborate, hydrated aluminum oxide, hydrated aluminum phosphate, aluminum chloride, sulfur for external use	
3	Pharmacopoeial analysis of pharmaceutical substances of inorganic nature: d-elements	
4	Pharmacopoeial quality control of pharmaceutical substances of aliphatic nature: alkanes, alcohols, ethers, aldehydes, sulfoxides	
5	Pharmacopoeial quality control of pharmaceutical substances of aliphatic nature: carbohydrates, terpenoids	
6	Pharmacopoeial quality control of pharmaceutical substances of aliphatic nature: carboxylic acids, amino acids	
7	Final lesson «Pharmacopoeial analysis of pharmaceutical substances of inorganic and aliphatic nature»	
8	Pharmacopoeial quality control of pharmaceutical substances of aromatic nature: phenols, aromatic acids	
9	Pharmacopoeial quality control of pharmaceutical substances of aromatic nature: phenylalkylamines, sulfanilic acid	
10	Pharmacopoeial quality control of pharmaceutical substances of heterocyclic nature: furan, nitrofuran and nitroimidazole derivatives	
11	Pharmacopoeial quality control of pharmaceutical substances of heterocyclic nature: derivatives of benzopyran, pyrazole, benzimidazole, pyridine, corrine	
12	Pharmacopoeial quality control of pharmaceutical substances of heterocyclic nature: derivatives of isoquinoline, purine, pteridine, isoalloxazine, pyrimidothiazole	
13	Pharmacopoeial quality control and pharmaceutical chemistry of terpenoids derivatives, chromone, seco derivatives of ergosterol and naphthoquinone, related to fat-soluble vitamins and their derivatives	
14	Pharmacopoeial quality control and pharmaceutical chemistry of aromatic amino acid derivatives related to medicinal products for local anesthesia	
15	Final lesson «Pharmacopoeial analysis of pharmaceutical substances of aromatic and heterocyclic nature, vitamins, drugs for local anesthesia»	
16	Quality control of pharmaceutically prepared drugs (extemporaneous drugs). Quality control of industrially manufactured medicines	
17	Practical skills test	

PHARMACOPOEIAL ANALYSIS OF PHARMACEUTICAL SUBSTANCES OF INORGANIC NATURE: P-ELEMENTS: SOLUTIONS OF HYDROGEN PEROXIDE, IODINE, POVIDONE-IODINE, SODIUM AND POTASSIUM CHLORIDES, SODIUM AND POTASSIUM BROMIDES, SODIUM AND POTASSIUM IODIDES

1. Pharmacist-analyst carried out quality control of the PhS hydrogen peroxide 30 % solution (M = 34.01 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 1.010 g of the test sample was diluted with water R to a volume of 100.0 ml. To 10.0 ml of the resulting solution 20 ml of diluted sulfuric acid R was added and titrated with 0.02 M potassium permanganate solution (k = 0.9920) until a pink color appeared. As a result of the analysis it was found that the mass fraction of hydrogen peroxide is 30.1 %. Write the equation for the reaction that take place. Calculate volume of titrant spent.

2. Pharmacist-analyst carried out quality control of sodium chloride PhS (M = 58.44 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 50.0 mg of the test sample was dissolved in water R, diluted up to a volume of 50 ml with the same solvent and titrated with 0.1 M silver nitrate solution (k = 0.9910) potentiometrically. 8.40 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of sodium chloride in the test sample (weight loss on drying is 0.70 %) relative to dry substance with a preliminary calculation of titer.

3. Pharmacist-analyst carried out quality control of potassium bromide PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 100.3 mg of the test sample was dissolved in water R, 5 ml of diluted nitric acid solution R was added and diluted with water R to a volume of 50 ml. Titrated with a 0.1 M solution of silver nitrate (k = 0.9985)

potentiometrically. 8.50 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of potassium bromide in the test sample taking into account that 1 ml of 0.1 M silver nitrate solution corresponds to 11.90 mg KBr, and content of chloride impurities in the test sample is 0.3 %.

4. Pharmacist-analyst carried out quality control of potassium iodide PhS (M = 166.0 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 1.500 g of the test sample was dissolved in water R and diluted up to a volume of 100.0 ml with the same solvent. To 20.0 ml of the resulting solution, 40 ml of hydrochloric acid R was added and titrated with 0.05 M potassium iodate solution (k = 1.0230) until color changed from red to yellow. Add 5 ml of chloroform R and continue titration, vigorously shaking, until chloroform layer becomes discolored. 17.5 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of potassium iodide in the test sample (mass loss on drying is 0.35 %) relative to dry substance with a preliminary calculation of titer.

5. Pharmacist-analyst carried out quality control of sodium bicarbonate PhS (M = 84.0 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 1.500 g of the test sample was dissolved in 50 ml of carbon dioxide-free water R and titrated with 1 M hydrochloric acid solution (k = 1.020), using 0.2 ml of methyl orange R solution as an indicator. 17.4 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of sodium bicarbonate in the test sample with a preliminary calculation of titer. According to the requirements of the Pharmacopeia sodium bicarbonate content must be no less than 99.0 % and no more than 101.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

PHARMACOPOEIAL ANALYSIS OF PHARMACEUTICAL SUBSTANCES OF INORGANIC NATURE: p-ELEMENTS: BASIC HEAVY BISMUTH NITRATE, SODIUM BICARBONATE, SODIUM THIOSULFATE, BORIC ACID, SODIUM TETRABORATE, HYDRATED ALUMINUM OXIDE, HYDRATED ALUMINUM PHOSPHATE, ALUMINUM CHLORIDE, SULFUR FOR EXTERNAL USE

1. Pharmacist-analyst carried out quality control of the PhS basic, heavy bismuth nitrate ($4[BiNO_3(OH)_2]$, BiO(OH)) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 250.0 mg of the test sample was dissolved by heating in 10 ml of a mixture of 2 volumes of perchloric acid and 5 volumes of water. 200 ml of water R and 50 mg of xylenol orange indicator mixture R were added to the hot solution and titrated with 0.1000 M sodium edetate solution until a yellow color appeared. 8.70 ml of titrant was used for titration. Write the equations for the reactions that take place. Calculate the mass fraction of Bi (M = 209.0 g/mol) in the sample relative to dry substance (mass loss on drying is 1.50 %) with a preliminary calculation of titer. According to the requirements of the Pharmacopeia bismuth content must be no less than 71.0 % and no more than 74.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

2. Pharmacist-analyst carried out quality control of the PhS aluminum hydroxide polyhydrate (M = 78.00 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 2,000 g of the substance was dissolved by heating in 15 ml of concentrated hydrochloric acid. After cooling volume of the solution was brought to 500.0 ml with water. To 20.0 ml of the resulting solution 25.0 ml of 0.05000 M sodium edetate solution and 20.0 ml of acetate buffer solution pH 4.5 were added. Heated to a boil and held for 5 minutes. After cooling, 50 ml of 95 % alcohol and 2 ml of 0.05 % dithizone solution were added. Titrate with a 0.05000 M solution of zinc sulfate until it turns bright pink. At the same time a control experiment was carried out. For titration in the experiment with the test sample 6.70 ml of titrant was consumed, in the control experiment – 24.9 ml. Write the equations for the reactions that take place. Calculate the mass fraction of aluminum hydroxide in the sample with a preliminary calculation of titer. According to the requirements of the Pharmacopeia sample contains at least 76.5 % aluminum hydroxide. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

3. Pharmacist-analyst carried out quality control of the PhS hydrated aluminum phosphate (M = 122.0 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 400.0 mg of the test sample was dissolved in 10 ml of diluted hydrochloric acid and diluted with water to a volume of 100.0 ml. To 10.0 ml of the resulting solution was added 10.0 ml of 0.1 M sodium edetate solution (k = 0.9800), 30 ml of a mixture of equal volumes of ammonium acetate solution and diluted acetic acid, boiled for 3 minutes and cooled. To the resulting solution was added 25 ml of 96 % alcohol and 1 ml of a freshly prepared solution of 0.25 g/l dithizone in 96 % alcohol. What volume of 0.1 M $ZnSO_4$ (k = 1.0103) will be required to titrate excess of sodium edetate? The mass fraction of aluminum phosphate in the test sample is 99.5 % in terms of calcined substance. Weight loss on calcination is 17.0 %. Write equations for reactions take place.

4. Pharmacist-analyst carried out quality control of the potassium permanganate PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 0.302 g of the test sample was dissolved in water R and made up to a volume of 100.0 ml with the same solvent. To 20.0 ml of the resulting solution were added 20 ml of water R, 1 g of potassium iodide R and 10 ml of diluted hydrochloric acid R. Released iodine was titrated with 0.1000 M sodium thiosulfate solution using 1 ml of starch solution R as an indicator. 18.4 ml of titrant was used. Write the equations for the reactions that take place. Calculate the mass fraction of potassium permanganate in the sample taking into account that 1 ml of 0.1 M sodium thiosulfate solution corresponds to 3.160 mg of potassium permanganate. According to the requirements of the Pharmacopeia content of potassium permanganate must be no less than 99.0 % and no more than 100.5 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of boric acid PhS (M = 61.83 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 1.0000 g of the test sample was dissolved by heating in 100 ml of water R containing 15 g of mannitol R and titrated with 1 M sodium hydroxide solution (k = 1.0210) until a pink color appeared using 0.5 ml of phenolphthalein solution R as an indicator. 15.6 ml of titrant was used for titration. Write the equations for the reactions that take place. Calculate the mass fraction of boric acid in the sample with a preliminary calculation of titer. According to the requirements of the Pharmacopeia boric acid content must be no less than 99.0 % and no more than 100.5 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

PHARMACOPOEIAL ANALYSIS OF PHARMACEUTICAL SUBSTANCES OF INORGANIC NATURE: d-ELEMENTS

1. Pharmacist-analyst carried out quality control of the PhS of zinc oxide (M = 81.4 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 150.0 mg of the test sample was dissolved in 10 ml of diluted acetic acid. Resulting solution was diluted with water to 200 ml, 50 mg of an indicator mixture of xylenol orange R was added, and then hexamethylenetetramine R was added until a violet-pink color of the solution appeared. After this an additional 2 g of hexamethylenetetramine R was added and titrated with 0.1 M sodium edetate solution (k = 1.0150) until purple-pink color changed to yellow. 17.9 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of zinc oxide in the sample relative to calcined substance with a preliminary calculation of titer if the weight loss on calcination for the test sample is 0.90 %.

2. Pharmacist-analyst carried out quality control of the PhS zinc sulfate heptahydrate (M = 287.5 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 0.300 g of the test sample was dissolved in 5 ml of diluted acetic acid, 50 mg of an indicator mixture of xylenol orange R and then hexamethylenetetramine R were added until a violet-pink color of the solution appeared. After this an additional 2 g

of hexamethylenetetramine R was added and titrated with 0.1 M sodium edetate solution (k = 0.9820) until violet-pink color changed to yellow. Write the equation for the reaction that take place. Calculate volume of titrant consumed by pharmacist for titration with a preliminary calculation of titer if the mass fraction of zinc sulfate heptahydrate in the sample is 99.8 %.

3. Pharmacist-analyst carried out quality control of the PhS iron sulfate heptahydrate (M = 278.0 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 2.5 g of sodium bicarbonate R was dissolved in a mixture of 150 ml of water R and 10 ml of sulfuric acid R. After the rapid emission of bubbles 500.0 mg of the test sample was added to the solution and dissolved stirring gently. 0.1 ml of ferroin was added to the resulting solution and titrated with a 0.1 M solution of ammonium cerium nitrate (k = 1.0370) until red color disappeared. 17.2 ml of titrant was used for titration. Write the equations for the reactions that take place. Calculate the mass fraction of iron sulfate heptahydrate in the sample with a preliminary calculation of titer. According to the requirements of the Pharmacopeia content of iron sulfate heptahydrate must be no less than 98.0 % and no more than 105.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

4. Pharmacist-analyst carried out quality control of the PhS iron chloride hexahydrate (M = 270.3 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 200.0 mg of the test

sample was placed in a conical flask with a ground glass stopper, dissolved in 20 ml of water R, 10 ml of diluted hydrochloric acid R, 2 g of potassium iodide R were added, capped and kept in a place protected from light for 1 hour, and then titrated with 0.1 M sodium thiosulfate solution (k = 0.9600), using starch solution as an indicator, which was added at the end of the titration. 7.60 ml of titrant was used for titration. Write the equations for the reactions that take place. Calculate the mass fraction of iron chloride hexahydrate in the sample taking into account that 1 ml of 0.1 M sodium thiosulfate solution corresponds to 27.03 mg of iron chloride hexahydrate. According to the requirements of the Pharmacopeia content of iron chloride hexahydrate must be no less than 98.0 % and no more than 102.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of the PhS copper sulfate pentahydrate (249.7 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 200 mg of the test sample was dissolved in 50 ml of water R, added 2 ml of sulfuric acid R, 3 g of potassium iodide R and titrated with 0.1 M sodium thiosulfate solution (k = 1.0470), using as an indicator a solution of starch, which was added to end of titration. Write the equations for the reactions that take place. Calculate the volume of titrant consumed by the pharmacist for titration with a preliminary calculation of titer if the mass fraction of copper sulfate pentahydrate in the sample is 99.3 %.

PHARMACOPOEIAL QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCES OF ALIPHATIC NATURE: ALKANES, ALCOHOLS, ETHERS, ALDEHYDES, SULFOXIDES

1. Pharmacist-analyst carried out quality control of glycerol PhS 85 % (M = 92.1 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 75.0 mg of the test sample was thoroughly mixed with 45 ml of water R. To the resulting solution was added 25.0 ml of a mixture of 1 volume of 0.1 M sulfuric acid solution and 20 volumes of 0.1 M sodium periodate solution. Kept in a place protected from light for 15 minutes. Add 5.0 ml of a solution of 500 g/l ethylene glycol R and keep in a place protected from light for 20 minutes. Resulting solution was titrated with 0.1 M sodium hydroxide solution (k = 1.027) using 0.5 ml of phenolphthalein R solution as an indicator. A control experiment was carried out in parallel. 7.00 ml of titrant was used for titration in the experiment with the test sample, and 0.30 ml in the control experiment. Write the equations for the reactions that take place. Calculate the mass fraction of glycerol in the test sample with a preliminary calculation of titer. According to the requirements of the Pharmacopeia content of glycerin must be no less than 83.5 % and no more than 88.5 % (m/m). Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

2. Pharmacist-analyst carried out quality control of the PhS formaldehyde 35 % solution (M = 30.03 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. Place 1,000 g of the test sample in a 100.0 ml volumetric flask containing 2.5 ml of water R and 1 ml of diluted sodium hydroxide solution R, shake and dilute with water to a volume of 100.0 ml. To 10.0 ml of the resulting solution, 30.0 ml of 0.05 M iodine solution (k = 1.0140) was added, mixed and 10 ml of diluted sodium hydroxide solution R was added. Mixture was kept for 15 minutes, then 25 ml of diluted sulfuric acid was added R, 2 ml of starch solution R and titrated with 0.1 M sodium thiosulfate solution (k = 0.9000). Write the equations for the reactions that take place. Calculate the mass fraction of formaldehyde in the test sample with a preliminary calculation of titer if 6.20 ml of titrant was used for titration. According to the

requirements of the Pharmacopeia content of formaldehyde must be no less than 34.5 % and no more than 38.0 % (m/m). Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

3. Pharmacist-analyst carried out quality control of the PhS chloral hydrate (M = 165.4 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 4,000 g of the test sample was dissolved in 10 ml of water R and 40.0 ml of 1,000 M sodium hydroxide solution was added. Solution was kept for 2 minutes and titrated with a 0.5000 M solution of sulfuric acid, using 0.1 ml of a solution of phenolphthalein R as an indicator. The neutralized solution was titrated with a 0.1000 M solution of silver nitrate, using 0.2 ml of a solution of potassium chromate R as an indicator. 15.9 ml of sulfuric acid solution and 1.20 ml of silver nitrate solution were used for titration. Write the equations for the reactions that take place. Calculate the mass fraction of chloral hydrate in the sample with a preliminary calculation of titer. According to the requirements of the Pharmacopeia content of chloral hydrate must be no less than 98.5 % and no more than 101.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

4. Pharmacist-analyst carried out quality control of the macrogol-300 PhS according to the «Test» indicator. When determining the hydroxyl number, 1,500 g of the test sample was placed in a dry conical flask equipped with a reflux condenser. Add 25.0 ml of phthalic anhydride solution R, stir until dissolved and reflux for 60 minutes on a hot plate. Cool, rinse the refrigerator first with 25 ml of pyridine R, then with 25 ml of water R, add 1.5 ml of phenolphthalein solution R and titrate with 1 M potassium hydroxide solution until a pale pink color appears. At the same time, a control experiment was carried out. Difference in titrant volumes in two

titrations turned out to be 9.36 ml. Calculate the hydroxyl number for the test sample. According to the requirements of the Pharmacopeia hydroxyl number for macrogol-300 should be in the range from 340 to 394. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of the macrogol-1500 PhS according to the «Test» indicator. It was experimentally established that the dynamic viscosity of the solution is 40 mPa × s. Calculate the kinematic viscosity of macrogol-1500 taking into account the density of 1.080 g/ml. According to the requirements of the Pharmacopeia kinematic viscosity for macrogol-1500 should be in the range from 31 to 46. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

PHARMACOPOEIAL QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCES OF ALIPHATIC NATURE: CARBOHYDRATES, TERPENOIDS

1. Pharmacist-analyst carried out quality control of the pharmaceutical substance lactulose according to the «Test» indicator. 1.25 g of the test sample containing 2.00 % water was dissolved in water R, 0.2 ml of concentrated ammonia solution R was added and diluted with water R to a volume of 25.0 ml. Optical rotation angle measured with a polarimetric tube length of 10.0 cm turned out to be –2.35°. Calculate value of the specific optical rotation of the test sample relative to dry substance. According to the requirements of the Pharmacopeia specific optical rotation can be in the range from –46.0 to –50.0. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

2. Pharmacist-analyst carried out quality control of the sodium saccharin PhS (M = 205.2 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 0.151 g of the test sample containing 10.0 % water was dissolved in 50 ml of anhydrous acetic acid R, slightly heated, and titrated with 0.1000 M perchloric acid solution potentiometrically. At the same time, a control experiment was carried out. For titration in the experiment with the test sample, 6.79 ml of titrant was consumed, in the control experiment — 0.20 ml. Write the equation for the reaction that take place. Calculate the mass fraction of sodium saccharin in the test sample relative to anhydrous substance with a preliminary calculation of titer. According to the requirements of the Pharmacopeia content of saccharin sodium must be no less than 99.0 % and no more than 101.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

3. Angle of optical rotation for an alcohol solution of levomenthol is –4.40° with a polarimetric tube length of 10.0 cm. Calculate mass of levomenthol (g) in 50.0 ml of such a solution. Specific optical rotation of levomenthol is – 50.0.

4. Pharmacist-analyst carried out quality control of the turpentine oil PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 102.0 mg of the test sample was diluted with 96 % alcohol R to a volume of 100.0 ml. 1.00 ml of the resulting solution was diluted with 96 % alcohol R to a volume of 50.0 ml. Optical density of the resulting solution at a wavelength of 210 nm and the thickness of the absorbing layer 1.00 cm turned out to be equal to 0.431. Calculate amount of terpenoids relative to α-pinene as a percentage. Specific absorption rate of α-pinene at a wavelength of 210 nm it is 237.5. According to the requirements of the Pharmacopeia content of the total terpenoids in terms of α-pinene must be at least 85 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of the anhydrous glucose PhS according to the indicator «Identification» in accordance with the methodology from the Pharmacopeia. 10.002 g of the test sample was dissolved in 80 ml of water R, 0.2 ml of diluted ammonia solution R1 was added, kept for 30 minutes and diluted with water R to a volume of 100.0 ml. Optical rotation angle measured with a polarimetric tube length of 10.0 cm turned out to be +5.30°. Calculate value of the specific optical rotation of the test sample relative to anhydrous substance. According to the requirements of the Pharmacopeia specific optical rotation can be in the range from +52.5 to +53.3. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

PHARMACOPOEIAL QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCES OF ALIPHATIC NATURE: CARBOXYLIC ACIDS, AMINO ACIDS

1. Pharmacist-analyst carried out quality control of the PhS manganese gluconate according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 0.4050 g of the test sample was dissolved in 50 ml of water R, 10 mg of ascorbic acid R, 20 ml of ammonium chloride buffer solution pH 10.0 R and 0.2 ml of a solution of 2 g/l black mordant 11 R in triethanolamine R were added. Titrated 0.1000 M sodium edetate solution R until the color of the solution changes from violet to pure blue. 9.19 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of manganese gluconate in the test sample relative to anhydrous substance taking into account that 1 ml of 0.1 M sodium edetate solution corresponds to 44.52 mg of manganese gluconate. According to the requirements of the Pharmacopeia content of manganese gluconate must be no less than 98.0 % and no more than 102.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

2. Pharmacist-analyst carried out quality control of the lactic acid PhS (M = 90.1 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 1.030 g of the test sample was placed in a ground stopper flask and 10 ml of water R and 20.0 ml of 1 M sodium hydroxide solution were added. Flask was stoppered and kept for 30 minutes. Titrated with a 1 M solution of hydrochloric acid until the pink color disappeared, using 0.5 ml of phenolphthalein R solution as an indicator. 9.80 ml of titrant was used for titration. Write the equations for the reactions that take place. Calculate the mass fraction of lactic acid in the test sample with a preliminary calculation of titer. According to the requirements of the Pharmacopeia content of lactic acid must be no less than 88.0 % and no more than 92.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

3. Pharmacist-analyst carried out quality control of glutamic acid PhS according to the «Test» indicator. When determining the specific optical rotation, 5.02 g of the test sample was dissolved in a 1 M solution of hydrochloric acid with careful heating and brought to a volume of 50.0 ml with the same solvent. Optical rotation angle measured with a polarimetric tube length of 100.0 mm turned out to be +3.07°. Calculate the specific optical rotation of the test sample (weight loss on drying is 0.10 %) relative to dry substance. According to the requirements of the Pharmacopeia specific optical rotation can be in the range from +30.5 to +32.5. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

4. Pharmacist-analyst carried out quality control of the glycine PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 70.0 mg of the test sample was dissolved in 5 ml of anhydrous formic acid R, added 50 ml of anhydrous acetic acid R and immediately after dissolution, titrated with 0.1000 M perchloric acid solution potentiometrically. 9.10 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of glycine in the sample relative to dry substance (mass loss on drying is 0.20 %), taking into account that 1 ml of 0.1 M perchloric acid solution corresponds to 7.51 mg of glycine. According to the requirements of the Pharmacopeia sample contains no less than 98.5 % and no more than 101.0 % glycine. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of the PhS DL-methionine (M = 149.2 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 140.0 mg of the test sample was dissolved in 3 ml of anhydrous formic acid R and added 30 ml of anhydrous acetic acid R. After dissolution, it was immediately titrated with 0.1 M perchloric acid solution (k = 1.0140) potentiometrically. 9.10 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of methionine in the sample relative to dry substance (mass loss on drying is 0.15 %) with a preliminary calculation of titer. According to the requirements of the Pharmacopeia sample contains no less than 99.0 % and no more than 101.0 % methionine. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

PHARMACOPOEIAL QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCES OF AROMATIC NATURE: PHENOLS, AROMATIC ACIDS

1. Pharmacist-analyst carried out quality control of paracetamol PhS (M = 151.2 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 300.0 mg of the test sample was dissolved in a mixture of 10 ml of water R and 30 ml of diluted sulfuric acid R, refluxed for 1 hour, then cooled and diluted with water to a volume of 100.0 ml. To 20.0 ml of the resulting solution, 40 ml of water, 40 g of ice, 15 ml of diluted hydrochloric acid R, 0.1 ml of ferroin R were added and titrated with a 0.1000 M solution of cerium sulfate until a greenish-yellow color appeared. At the same time, a control experiment was carried out.8.10 ml of titrant was used for titration in the experiment with the test sample, and 0.20 ml in the control experiment. Write the equations for the reactions that take place. Calculate the mass fraction of paracetamol in the test sample relative to dry substance (mass loss on drying is

0.30 %) with a preliminary calculation of titer. According to the requirements of the Pharmacopeia content of paracetamol must be no less than 99.0 % and no more than 101.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

2. Pharmacist-analyst carried out quality control of the phenol PhS (M = 94.1 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 2.000 g of the test sample was dissolved in water R and made up to a volume of 1000.0 ml with the same solvent. 25.0 ml of the resulting solution was placed in a flask with a ground glass stopper, 50.0 ml of a 0.0167 M solution of bromide bromate and 5 ml of hydrochloric acid R were added. Flask was closed with a stopper, kept for 30 minutes with periodic stirring and another 15 minutes without stirring. Add 5 ml of a 200 g/l solution of potassium iodide R, shake and titrate the solution with 0.1000 M sodium thiosulfate solution until it turns pale yellow. Add 0.5 ml of starch solution R, 10 ml of chloroform R and continue titrating with vigorous shaking. At the same time a control experiment was carried out. 18.2 ml of titrant was consumed for titration in the experiment with the test sample, and 49.7 ml in the control experiment. Write the equations for the reactions that take place. Calculate the mass fraction of phenol in the test sample with a preliminary calculation of titer. According to the requirements of the Pharmacopeia content of phenol must be no less than 99.0 % and no more than 100.5 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

3. Pharmacist-analyst carried out quality control of the resorcinol PhS (M = 110.1 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 500.0 mg of the test sample

was dissolved in water R and made up to a volume of 250.0 ml with the same solvent. 25.0 ml of the resulting solution was placed in a ground flask, 1.0 g of potassium bromide R, 50.0 ml of 0.0167 M potassium bromate solution, 15 ml of chloroform R, 15.0 ml of hydrochloric acid R1 were added, capped and kept in a place protected from light for 15 minutes with occasional shaking. Add 10 ml of a solution of 100 g/l potassium iodide R, shake thoroughly, hold for 5 minutes, then titrate with 0.1 M sodium thiosulfate solution (k = 0.9840), using 1 ml of starch solution R as an indicator. titration consumed 23.5 ml of titrant. Write the equations for the reactions that take place. Calculate the mass fraction of resorcinol in the test sample relative to dry substance (mass loss on drying is 0.90 %) with a preliminary calculation of titer. According to the requirements of the Pharmacopeia content of resorcinol must be no less than 98.5 % and no more than 101.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

4. Pharmacist-analyst carried out quality control of the sodium benzoate PhS (M = 144.1 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 250.0 mg of the test sample (weight loss on drying is 1.30 %) was dissolved in 20 ml of anhydrous acetic acid R and titrated with 0.1 M perchloric acid solution to a green color using 0.05 ml of naphtholbenzein solution R as an indicator. As a result of the analysis, it was found that the mass fraction of sodium benzoate in the sample is 99.2 %. Write the equation for the reaction that take place. Calculate the volume of titrant used by the pharmacist for titration with a preliminary calculation of titer.

5. Pharmacist-analyst carried out quality control of the salicylic acid PhS (M = 138.1 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 120.0 mg of the test sample (weight loss on drying is 0.40 %) was dissolved in 96 % alcohol R, added 20 ml of water R and titrated with 0.1 M sodium hydroxide solution (k = 1.0152), using as an indicator 0.1 ml of phenol red solution R. As a result of the analysis, it was found that the mass fraction of salicylic acid is 99.7 %. Write the equation for the reaction that take place. Calculate volume of titrant used by the pharmacist for titration.

PHARMACOPOEIAL QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCES OF AROMATIC NATURE: PHENYLALKYLAMINES, SULFANILIC ACID

1. Pharmacist-analyst carried out quality control of the chloramphenicol PhS according to the «Test» indicator. 1.51 g of the test sample was dissolved in ethanol R and made up to a volume of 25.0 ml with the same solvent. Optical rotation angle measured with a polarimetric tube length of 10.0 cm turned out to be +1.26°. Calculate value of the specific optical rotation of the test sample relative to dry substance (mass loss on drying is 0.40 %). According to the requirements of the Pharmacopeia specific optical rotation can be in the range from +18.5 to +20.5. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

2. Pharmacist-analyst carried out quality control of the sulfamethoxazole PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 205.0 mg of the test sample was dissolved in 50 ml of diluted hydrochloric acid R and 3 g of potassium bromide R was added. Cooled in ice water and then slowly titrated with constant stirring with 0.1 M sodium nitrite solution (k = 1.011) maintaining the temperature of the solution about 15 °C with potentiometric detection of the end point of the titration.8.00 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass of sulfamethoxazole in the sample taking into account the fact that 1 ml of 0.1 M sodium nitrite solution corresponds to 25.33 mg of sulfamethoxazole.

3. Pharmacist-analyst carried out quality control of the pharmaceutical substance of chloramphenicol palmitate according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 90.0 mg of the test sample was dissolved in 96 % alcohol R and made up to a volume of 100.0 ml with the same solvent. 10.0 ml of the resulting solution was brought to a volume of 250.0 ml with 96 % alcohol R. Optical density of the final solution at wavelength 271 nm and thickness of the absorbing layer 1.00 cm turned out to be equal to 0.622. Calculate mass fraction of chloramphenicol palmitate in the test substance relative to dry substance (mass loss upon drying is 0.30 %). The specific absorption index at a wavelength of 271 nm is 178. According to the requirements of the Pharmacopeia sample must contain not less than 98.0 % and not more than 102.0 % chloramphenicol palmitate. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

4. Pharmacist-analyst carried out quality control of the silver sulfadiazine PhS (M silver = 107.9 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. When determining the silver content, 251.0 mg of the test sample was added to 75 ml of water and 25 ml of concentrated nitric acid, stirred for 15 minutes and titrated with 0.1000 M ammonium thiocyanate solution potentiometrically. At the same time, a control experiment was carried out. For titration in the experiment with the test sample, 6.94 ml of titrant was consumed, in the control experiment — 0.10 ml. Write the equation for the reaction that take place. Calculate the mass fraction of aluminum hydroxide in the sample with a preliminary calculation of titer. According to the requirements of the Pharmacopeia sample contains no less than 29.3 % and no more than 30.5 % silver. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of the sulfonamide PhS (M = 172.2 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 139.0 mg of the test sample was dissolved in 50 ml of dilute hydrochloric acid R and 3 g of potassium bromide R was added. Cooled in ice water and then slowly titrated with constant stirring with 0.1 M sodium nitrite solution (k = 0.9981), maintaining solution temperature of about 15 °C, with potentiometric detection of the end point of the titration. As a result of the analysis, it was found that the mass fraction of sulfonamide is 99.5 %, and the loss in mass upon drying is 0.20 %. Write the equation for the reaction that take place. Calculate volume of titrant used by the pharmacist for titration with a preliminary calculation of titer.

PHARMACOPOEIAL QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCES OF HETEROCYCLIC NATURE: FURAN, NITROFURAN AND NITROIMIDAZOLE DERIVATIVES

1. Pharmacist-analyst carried out quality control of the nifuroxazide PhS (M = 275.2 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 0.200 g of the test sample was dissolved with heating in 30 ml of dimethylformamide R, 20 ml of water R was added and titrated with 0.1 M sodium hydroxide solution (k = 0.9957) potentiometrically.8.00 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass of nifuroxazide in the sample with a preliminary calculation of titer.

2. Pharmacist-analyst carried out quality control of the PhS ornidazole (M = 219.6 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. Dissolve 0.3005 g of the test sample in 50 ml of anhydrous acetic acid and add two drops of 0.1 % naphtholbenzein solution as an indicator. Resulting solution was titrated with a 0.1 M solution of perchloric acid (k = 0.9966) until the color of the solution turned green. At the same time, a control experiment was carried out.13.2 ml of titrant was used for titration, in the control experiment — 0.15 ml. Write the equation for the reaction that take place. Calculate the mass fraction of ornidazole in the sample relative to dry substance (mass loss on drying is 0.30 %) with a preliminary calculation of titer. According to the requirements of the Pharmacopeia sample contains no less than 98.0 % and no more than 101.0 % ornidazole. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

3. Pharmacist-analyst carried out quality control of the PhS metronidazole benzoate (M = 275.3 g/mol) according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 252.3 mg of the test sample was dissolved in 50 ml of anhydrous acetic acid R and titrated with 0.1 M perchloric acid solution (k = 0.9954) potentiometrically. 9.16 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of metronidazole benzoate in the test sample relative to dry substance (mass loss on drying is 0.50 %) with a preliminary calculation of titer. According to the requirements of the Pharmacopeia content of metronidazole benzoate must be no less than 98.5 % and no more than 101.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

4. Pharmacist-analyst carried out quality control of the nitrofurantoin PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 403.2 mg of the test sample was dissolved in 20 ml of dimethylformamide neutralized immediately before titration with thymol blue and titrated with 0.1000 M sodium methoxide solution to a dark green color. At the same time, a control experiment was carried out.16.3 ml of titrant was used for titration, in the control experiment — 0.10 ml. Write the equation for the reaction that take place. Calculate the mass fraction of nitrofurantoin in the sample in terms of dry matter (mass loss on drying is 5.20 %) taking into account the fact that 1 ml of 0.1 M sodium methylate solution corresponds to 23.82 mg of nitrofurantoin. According to the requirements of the Pharmacopeia sample contains not less than 98.0 % and not more than 102.0 % nitrofurantoin. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of the nitrofural PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 61.4 mg of the test sample was dissolved in 20 ml of dimethylformamide R and diluted with water R to a volume of 500.0 ml. 5.0 ml of the resulting solution was diluted with water R to a volume of 100.0 ml. A reference solution was prepared similarly using 60.0 mg of PhRS nitrofural. Optical density of the final test sample solution at wavelength 375 nm and the thickness of the absorbing layer of 1.00 cm turned out to be equal to 0.480, and the final PhRS solution — 0.471. Calculate mass fraction of nitrofural in the test substance in terms of dry matter (mass loss upon drying is 0.50 %). According to the requirements of the Pharmacopeia sample contains no less than 97.0 % and no more than 103.0 % nitrofural. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

6. Pharmacist-analyst carried out quality control of the PhS ascorbic acid according to the «Authenticity» indicator in accordance with the methodology from the Pharmacopeia. When determining pH of a solution 1,000 g of the test sample was dissolved in carbon dioxide-free water R and diluted to a volume of 20 ml with the same solvent. Calculate theoretical pH value of the solution that a pharmacist-analyst can obtain.

PHARMACOPOEIAL QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCES OF HETEROCYCLIC NATURE: DERIVATIVES OF BENZOPYRAN, PYRAZOLE, BENZIMIDAZOLE, PYRIDINE, CORRIN

1. Pharmacist-analyst carried out quality control of the pharmaceutical substance xanthinol nicotinate (M = 434.4 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 100.4 mg of the test sample was dissolved in 2 ml of glacial acetic acid, 18 ml of acetic anhydride was added and titrated with 0.1000 M perchloric acid solution potentiometrically. As a result of the analysis it was found that the mass fraction of xanthinol nicotinate in the sample (mass loss on drying is 0.20 %) is 99.2 %. Write the equation for the reaction that take place. Calculate volume of titrant consumed by the pharmacist for titration with a preliminary calculation of titer.

2. Pharmacist-analyst carried out quality control of the troxerutin PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 200.4 mg of the test sample was dissolved in 100.0 ml of water R. 10.0 ml of the resulting solution was diluted with water R to a volume of 100.0 ml. 10.0 ml of the resulting solution was diluted with water R to a volume of 100.0 ml. Optical density of the final solution at a wavelength of 350 nm and an absorbing layer thickness of 1.00 cm was found to be 0.467. Calculate the mass fraction of troxerutin in the test sample (weight loss on drying is 4.00 %) relative to dry substance, if the specific absorption index at a wavelength of 350 nm is 250. According to the requirements of the Pharmacopeia sample contains at least 95.0 % and no more than 105.0 % troxerutin. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

3. Pharmacist-analyst carried out quality control of the nicotinamide PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 0.100 g of the test sample was dissolved in 50 ml of anhydrous acetic acid R and titrated with 0.1000 M perchloric acid solution potentiometrically. 8.10 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of nicotinamide in the test sample in terms of dry matter (mass loss on drying is 0.40 %) taking into account that 1 ml of 0.1 M perchloric acid solution corresponds to 12.21 mg of nicotinamide. According to the requirements of the Pharmacopeia sample contains no less than 99.0 % and no more than 101.0 % nicotinamide. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

4. Pharmacist-analyst carried out quality control of the PhS rutoside trihydrate (M anhydrous substance = 610.6 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 200.0 mg of the test sample was dissolved in 20 ml of dimethylformamide R and titrated with 0.1000 M tetrabutylammonium hydroxide solution potentiometrically. 5.80 ml of titrant was used for titration. Water content of 100.0 mg of the test sample was preliminarily determined. This test used 2.20 ml of K. Fisher's reagent with a water titer of 4,000 mg/ml. Write the equations for the reactions that take place. Calculate the mass fraction of rutoside in the sample relative to anhydrous substance. According to the requirements of the Pharmacopeia sample contains no less than 95.0 % and no more than 101.0 % rutoside. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of the cyanocobalamin PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 103.1 mg of the test sample was dissolved in water R and made up to a volume of 500.0 ml with the same solvent. 25.0 ml of the resulting solution was diluted with water R to a volume of 200.0 ml. Optical density of the resulting solution at a wavelength of 361 nm and the thickness of the absorbing layer 1.00 cm turned out to be equal to 0.481. Calculate the mass fraction of cyanocobalamin in the sample relative to dry substance (mass loss on drying is 8.00 %). Specific absorption rate of cyanocobalamin at a wavelength of 361 nm is 207. According to the requirements of the Pharmacopeia cyanocobalamin content must be no less than 96.0 % and no more than 102.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

PHARMACOPOEIAL QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCES OF HETEROCYCLIC NATURE: DERIVATIVES OF ISOQUINOLINE, PURINE, PTERIDINE, ISOALLOXAZINE, PYRIMIDOTHIAZOLE

1. Pharmacist-analyst carried out quality control of the theophylline-ethylenediamine PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. When determining the ethylenediamine content (M = 60.1 g/mol), 0.252 g of the test sample was dissolved in 30 ml of water R, 0.1 ml of bromocresol green solution R was added and titrated with 0.1000 M hydrochloric acid solution until a green color appeared. 11.7 ml of titrant was used for titration. When determining the theophylline content (M = 180.2 g/mol), 201.0 mg of the test sample was dried at a temperature of 135 °C to constant weight. Residue was dissolved when heated in 100 ml of water R, cooled, 20 ml of 0.1 M silver nitrate solution was added, shaken, 1 ml of bromothymol blue solution R1 was added and titrated with 0.1 M sodium hydroxide solution. 9.39 ml of titrant was used for titration. Write the equations for the reactions that take place. Calculate the mass fraction of theophylline and ethylenediamine in a sample containing 1.00 % water relative to anhydrous substance with a preliminary calculation of titers. According to the requirements of the Pharmacopeia sample contains no less than 84.0 % and no more than 87.4 % theophylline, as well as

no less than 13.5 % and no more than 15.0 % ethylenediamine. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

2. Pharmacist-analyst carried out quality control of the PhS cocarboxylase hydrochloride (M = 460.8 g/mol) according to the indicator «Quantitative determination» in accordance with the methodology from the Pharmacopeia. 202.5 mg of the test sample was placed in a flask and dissolved in 10.0 ml of water. Resulting solution was titrated with a 0.1000 M sodium hydroxide solution with a 0.1 % thymolphthalein solution as an indicator until a blue color appeared. At the same time, a control experiment was carried out. 13.2 ml of titrant was used for titration in the experiment with the test sample, and 0.20 ml in the control experiment. Write the equation for the reaction that take place. Calculate the mass fraction of cocarboxylase hydrochloride in the sample relative to dry substance (weight loss on drying is 0.70 %) with a preliminary calculation of the titer taking into account that the sample contains 0.50 % phosphates, and 1 ml of a 0.1 M solution sodium hydroxide corresponds to 4.750 mg/ml phosphate ions. According to the requirements of the Pharmacopeia sample contains no less than 98.5 % and no more than 101.0 % cocarboxylase hydrochloride. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

3. Pharmacist-analyst carried out quality control of the pentoxifylline PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 205.0 mg of the test sample was dissolved in 5 ml of anhydrous acetic acid R, 20 ml of acetic anhydride R was added and titrated with 0.1000 M perchloric acid solution potentiometrically. 7.20 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of pentoxifylline in the sample relative to dry substance (mass loss on drying is 0.30 %), taking into account that 1 ml of 0.1 M perchloric acid solution corresponds to 27.83 mg of pentoxifylline. According to the requirements of the Pharmacopeia content of pentoxifylline must be no less than 99.0 % and no more than 101.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

4. Pharmacist-analyst carried out quality control of the riboflavin PhS according to the «Test» indicator in accordance with the methodology from the Pharmacopeia. 49.3 mg of the test sample was dissolved in 0.05 M sodium hydroxide solution free of carbonates, and made up to a volume of 10.0 ml with the same solvent. Optical rotation angle measured with a polarimetric tube length of 10.0 cm turned out to be –0.59°. Calculate specific optical rotation of the test sample relative to dry substance (mass loss on drying is 1.00 %). According to the requirements of the Pharmacopeia specific optical rotation of riboflavin should be in the range from– 115 to –135. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

PHARMACOPOEIAL QUALITY CONTROL AND PHARMACEUTICAL CHEMISTRY OF TERPENOIDS DERIVATIVES, CHROMONE, SECO DERIVATIVES OF ERGOSTEROL AND NAPHTHOQUINONE, RELATED TO FAT-SOLUBLE VITAMINS AND THEIR DERIVATIVES

1. Pharmacist-analyst carried out quality control of synthetic retinol oil concentrate according to the «Quantitative Determination» indicator. 25.0 mg of the test sample was dissolved in 5 ml of pentane, the resulting solution was diluted to 1000.0 ml with 2-propanol. Optical density of the solution at a wavelength of 326 nm and an absorbing layer thickness of 1.00 cm was found to be 0.699. Calculate the vitamin A content of 1 g of the test sample in IU. Conversion factor for the specific absorption rate of retinol esters in IU/g is 1900. Specific absorption rate of retinol is 1820.

2. Pharmacist-analyst carried out quality control of the ergocalciferol PhS according to the «Quantitative Determination» indicator in accordance with the methodology from the Pharmacopeia. 10.1 mg of the test sample was dissolved without heating in 10 ml of toluene R and diluted with the mobile phase to a volume of 100 ml. Solution of PhRS ergocalciferol 10.0 mg was prepared in a similar manner. Ratio of the peak areas of ergocalciferol in the chromatograms of the test and reference solutions turned out to be 0.990. Calculate the mass fraction of ergocalciferol in the sample, as well as its content in IU. 1 mg of ergocalciferol corresponds to 40,000 IU.

3. Pharmacist-analyst carried out quality control of the pharmaceutical substance menadione sodium bisulfite according to the «Test» indicator in accordance with the methodology from the Pharmacopeia. When determining the content of sodium hydrosulfite impurity (M = 104.06 g/mol) in a sample, 1.000 g of sample was dissolved in 30 ml of water R, 20 ml of 0.1 M sulfuric acid solution and

30.0 ml of 0.1 M iodine solution were added (k = 0.9658). Excess of iodine was titrated with 0.1 M sodium thiosulfate solution (k = 0.9859) using 1 ml of starch solution R as an indicator. 26.8 ml of titrant was used for titration. Write the equations for the reactions that take place. Calculate the mass fraction of sodium hydrosulfite in the sample relative to anhydrous substance (water content is 12.0 %) with a preliminary calculation of titer. According to the requirements of the Pharmacopeia sample contains no more than 2.00 % sodium hydrosulfite. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

4. Pharmacist-analyst carried out quality control of the isotretinoin pharmaceutical substance according to the indicator «Quantitative determination» in accordance with the Pharmacopeia. 200.3 mg of the test sample was dissolved in 70 ml of acetone and titrated with a 0.1000 M solution of tetrabutylammonium hydroxide in 2-propanol potentiometrically. At the same time, a control experiment was carried out. 6.80 ml of titrant was used for titration, in the control experiment — 0.20 ml. Write the equation for the reaction that take place. Calculate the mass fraction of isotretinoin in the sample relative to dry substance (mass loss on drying is 0.400 %) taking into account that 1 ml of 0.1 M solution of tetrabutylammonium hydroxide in 2-propanol corresponds to 30.04 mg of isotretinoin. According to the requirements of the Pharmacopeia sample contains not less than 98.0 % and not more than 102.0 % isotretinoin. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of the ergocalciferol PhS according to the «Test» indicator in accordance with the methodology from the Pharmacopeia. 201.2 mg of the test sample was quickly dissolved in 96 % aldehyde-free alcohol R and added to a volume of 25.0 ml with the same solvent. Optical rotation

angle measured with a polarimetric tube length of 10.0 cm turned out to be +0.85°. Calculate value of the specific optical rotation of the test sample. According to the requirements of the Pharmacopeia specific optical rotation of ergocalciferol should be in the range from +103 to +107. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

PHARMACOPOEIAL QUALITY CONTROL AND PHARMACEUTICAL CHEMISTRY OF AROMATIC AMINO ACID DERIVATIVES RELATED TO MEDICINAL PRODUCTS FOR LOCAL ANESTHESIA

1. Pharmacist-analyst carried out quality control of the pharmaceutical substance of articaine hydrochloride according to the indicator «Quantitative determination» in accordance with the Pharmacopeia. 250.0 mg of the test sample was dissolved in a mixture of 5.0 ml of 0.01 M hydrochloric acid solution and 50 ml of 96 % alcohol R and titrated with 0.1 M sodium hydroxide solution (k = 0.9910) potentiometrically. Titrant volume between two inflection points on the titration curve turned out to be 7.77 ml. Write the equation for the reaction that take place. Calculate the mass fraction of articaine hydrochloride in the sample relative to dry substance (weight loss on drying is 0.20 %) taking into account that 1 ml of 0.1 M sodium hydroxide solution corresponds to 32.08 mg of articaine hydrochloride. According to the requirements of the Pharmacopeia sample contains not less than 98.5 % and not more than 101.0 % articaine hydrochloride. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

2. Pharmacist-analyst carried out quality control of the PhS procaine hydrochloride (M = 272.8 g/mol) according to the indicator «Quantitative determination» in accordance with the Pharmacopeia. 400.0 mg of the test sample was dissolved in 50 ml of diluted hydrochloric acid R and 3 g of potassium bromide R were added. Cooled in ice water an indicator solution of tropeolin 00 R mixed with methylene blue R was added, and then slowly titrated with constant stirring 0. 1 M sodium nitrite solution (k = 0.9833), maintaining the solution temperature at about 15 °C until the color changes from red-violet to blue. 14.8 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass fraction of procaine hydrochloride in the sample (mass loss on drying is 0.40 %) with a preliminary calculation of titer. According to the requirements of the Pharmacopeia sample contains no less than 99.0 % and no more than 101.0 % procaine hydrochloride. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

3. Pharmacist-analyst carried out quality control of the PhS oxybuprocaine hydrochloride (M = 344.9 g/mol) according to the indicator «Quantitative determination» in accordance with the Pharmacopeia. 301.6 mg of the test sample was placed in a 100 ml conical flask, dissolved in a mixture of 20.0 ml anhydrous acetic acid and 20 ml acetic anhydride. Resulting solution was titrated with 0.1 M perchloric acid solution (k = 0.9965) potentiometrically. 8.75 ml of titrant was used for titration. Write the equation for the reaction that take place. Calculate the mass of oxybuprocaine hydrochloride in the test sample with a preliminary calculation of titer.

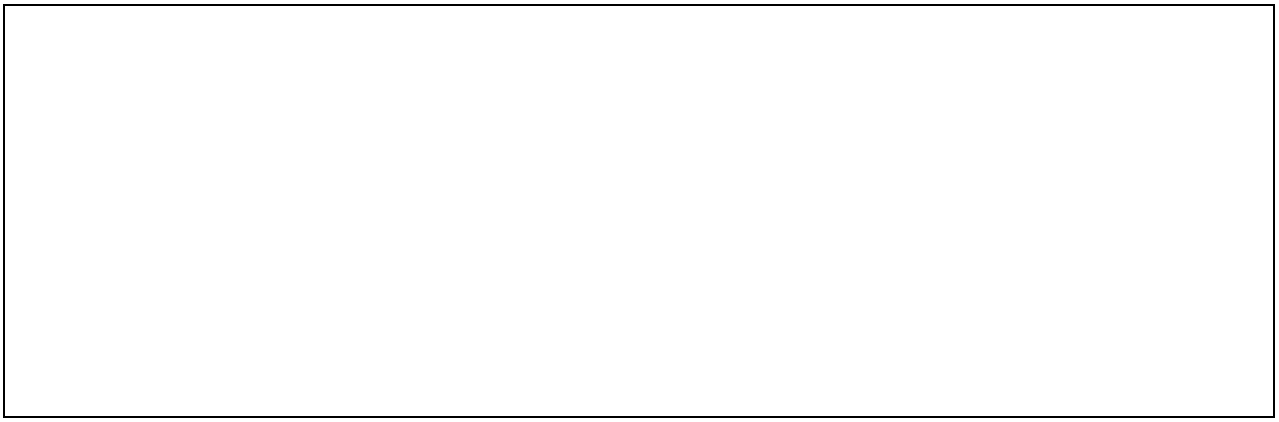
4. Pharmacist-analyst carried out quality control of the PhS lidocaine hydrochloride according to the «Test» indicator in accordance with the methodology from the Pharmacopeia. When determining water content by the Karl Fischer method, a sample weighing 250.0 mg was used. 3.33 ml of Karl Fischer reagent (iodinsulfur reagent) was used for titration, titer of which in water is 4.500 mg/ml. Write the equations for the reactions that take place. Calculate the mass fraction of water in the test sample. According to the requirements of the Pharmacopeia water content must be no less than 5.5 % and no more than 7.0 %. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.

5. Pharmacist-analyst carried out quality control of the PhS tetracaine hydrochloride (M = 300.8 g/mol) according to the «Quantitative determination» indicator with the technique from the Pharmacopeia. 250.3 mg of the test sample was dissolved in 50 ml of 96 % alcohol R, 5.0 ml of 0.01 M hydrochloric acid solution was added and titrated with 0.1 M sodium hydroxide solution (k = 1.0125) potentiometrically. As a result of the analysis, it was established that the mass fraction of tetracaine hydrochloride in the sample (mass loss on drying is 0.90 %) is 99.5 %. Calculate volume of titrant between two inflection points on the titration curve.

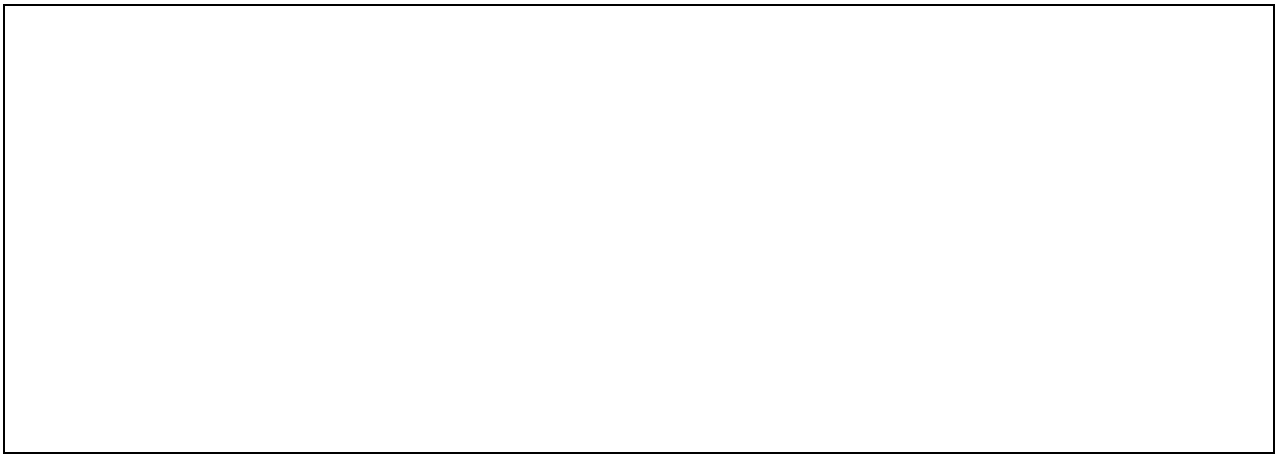
QUALITY CONTROL OF PHARMACEUTICALLY PREPARED DRUGS (EXTEMPORANEOUS DRUGS). QUALITY CONTROL OF INDUSTRIALLY MANUFACTURED MEDICINES

1. Pharmacist-analyst carried out quality control of pharmaceutically manufactured ascorbic acid powder according to the indicator «Quantitative determination». In the recipe content of ascorbic acid is 0.05 g and glucose monohydrate is 0.1 g. The average weight of one powder is 0.15 g. When determining the content of ascorbic acid 50.2 mg of the test sample was dissolved in 5 ml of water R, 2 drops of phenolphthalein R1 solution were added and titrated with 0.1 M sodium hydroxide solution (k = 0.9856) until a pink color appears. 1 ml of 0.1 M sodium hydroxide solution corresponds to 17.61 mg of ascorbic acid. 1.00 ml of titrant was used for titration. Calculate deviation in the mass of ascorbic acid in the analyzed powder. Make a judgment about whether the dosage form has been prepared satisfactorily if the permissible deviation in the mass of ascorbic acid in a given dosage form is ±15 %.

2. Pharmacist-analyst carried out quality control of tolperisone hydrochloride capsules according to indicator «Quantitative determination». 95.03 mg of capsule contents was placed in a 100.0 ml volumetric flask, 70 ml of water was added, after shaking for 30 minutes volume of the solution was brought to the mark with water and filtered. 1.0 ml of the resulting filtrate was placed in a 50.0 ml volumetric flask and volume of the solution was adjusted to the mark with water. Then 10.05 mg of a standard sample of tolperisone hydrochloride was placed in a 100.0 ml volumetric flask, dissolved in water and volume of the solution was adjusted to the mark with water. Place 5.00 ml of the resulting solution into a 50.0 ml volumetric flask and adjust the volume of the solution to the mark with water. Ratio of the test and standard solutions optical densities, measured on a spectrophotometer at the absorption maximum at a wavelength of 260 nm in a cuvette with a layer thickness of 1,000 cm, turned out to be 1.01. Calculate content of t tolperisone hydrochloride in the medicinal product as a percentage of the declared amount (150 mg) taking into account that the average weight of the contents of one capsule is 285.0 mg. According to the requirements of regulatory documentation the content of tolperisone hydrochloride must be no less than 92.5 % and no more than 107.5 % of the declared amount. Make a conclusion about the compliance of the test sample with the requirements of regulatory documentation.



3. Pharmacist-analyst carried out quality control of pharmaceutically manufactured dibazole powder according to the «Quantitative Determination» indicator. In the recipe content of dibazole is 0.005 g, and sucrose — 0.2 g. The average weight of one powder is 0.205 g. 203.0 mg of the test sample was dissolved in 2 ml of water R, 3 drops of bromophenol blue solution R were added, dropwise diluted acetic acid P until a greenish-yellow color appears and titrated with a 0.02 M solution of silver nitrate (k = 0.9568) until a violet color appears. 1.04 ml of titrant was used for titration. Calculate deviation in the mass of bendazole hydrochloride in the analyzed powder. 1 ml of 0.02 M silver nitrate solution corresponds to 4.89 mg of bendazole hydrochloride. Judge whether the dosage form has been satisfactorily prepared if the permissible deviation in the weight of bendazole hydrochloride in the dosage form is ±20 %.



4. Pharmacist-analyst carried out quality control of glucose in a 10 % solution with potassium chloride from a pharmaceutical manufacturer according to the «Quantitative determination» indicator. Content of potassium chloride was determined by argentometric titration. 1.0 ml of the solution was titrated with a 0.1 M solution of silver nitrate (k = 0.9955) until a yellowish-brown color appeared using potassium chromate solution R as an indicator. 1.62 ml of titrant was used for titration. 1 ml of 0.1 M silver nitrate solution corresponds to 7.456 mg of potassium chloride. Glucose content was determined refractometrically. Refractive index of the test sample is 1.3487. Calculate deviation in the mass of glucose in 100 ml of

the test solution. Increase in the refractive index with an increase in the concentration of potassium chloride by 1 % is 0.00127. Increase in the refractive index with an increase in the concentration of anhydrous glucose by 1 % is 0.00142. Judge whether a dosage form has been satisfactorily prepared if the permissible deviation in the mass of glucose in a given dosage form is ±3 %.

5. Pharmacist-analyst carried out quality control of glutamic acid 1 % solution for injection of pharmaceutical manufacture according to the indicator «Quantitative determination». 2.0 ml of the test sample was titrated with 0.1 M sodium hydroxide solution (k = 0.9999) until color of the solution changed from yellow to bluish-green, using bromothymol blue P1 solution as an indicator. 1.35 ml of titrant was used for titration. Calculate deviation in mass of glutamic acid (M = 147.1 g/mol) in 1000 ml of the test solution. 1 ml of 0.1 M sodium hydroxide solution corresponds to 14.71 mg of glutamic acid. Judge whether a dosage form has been satisfactorily prepared if the permissible deviation for the mass of glutamic acid in a given dosage form is ±6 %.

ANSWERS TO PROBLEMS

Pharmacopoeial analysis of pharmaceutical substances of inorganic nature: p-elements: solutions of hydrogen peroxide, iodine, povidone-iodine, sodium and potassium chlorides, sodium and potassium bromides, sodium and potassium iodides

1. 18.0 ml.
2. 98.0 %.
3. 99.7 %.
4. 99.4 %.
5. 99.4 %.

Pharmacopoeial analysis of pharmaceutical substances of inorganic nature: p-elements: basic heavy bismuth nitrate, sodium bicarbonate, sodium thiosulfate, boric acid, sodium tetraborate, hydrated aluminum oxide, hydrated aluminum phosphate, aluminum chloride, sulfur for external use

1. 73.8 %.
2. 88.7 %.
3. 7.02 ml
4. 96.5 %.
5. 98.5 %.

Pharmacopoeial analysis of pharmaceutical substances of inorganic nature: d-elements

1. 99.5 %.
2. 10.6 ml.
3. 99.2 %.
4. 98.6 %.
5. 7.60 ml.

Pharmacopoeial quality control of pharmaceutical substances of aliphatic nature: alkanes, alcohols, ethers, aldehydes, sulfoxides

1. 84.5 %.
2. 37.3 %.
3. 99.0 %
4. 350.
5. 37 mm2/s.

Pharmacopoeial quality control of pharmaceutical substances of aliphatic nature: carbohydrates, terpenoids

1. –48.0.
2. 99.5 %.
3. 9.6 g.
4. 89.0 %.
5. +53.0.

Pharmacopoeial quality control of pharmaceutical substances of aliphatic nature: carboxylic acids, amino acids.

1. 101.0 %.
2. 89.2 %.
3. +30.6.
4. 97.8 %.
5. 98.5 %.

Pharmacopoeial quality control of pharmaceutical substances of aromatic nature: phenols, aromatic acids

1.99.8 %.
2. 98.8 %.
3. 99.9 %.
4. 17.0 %.
5. 8.50 ml.

Pharmacopoeial quality control of pharmaceutical substances of aromatic nature: phenylalkylamines, sulfanilic acid

1. +20.9.
2. 204.9 mg.
3. 97.4 %.
4. 29.4 %.
5. 8.03 ml.

Pharmacopoeial quality control of pharmaceutical substances of heterocyclic nature: furan, nitrofuran and nitroimidazole derivatives

1. 197.3 mg.
2. 95.3 %.
3. 100.5 %.
4. 101.0 %
5. 100.1 %.
6. 2.32.

Pharmacopoeial quality control of pharmaceutical substances of heterocyclic nature: derivatives of benzopyran, pyrazole, benzimidazole, pyridine, corrin

1. 6.86 ml.
2. 97.1 %.
3. 99.3 %.
4. 97.1 %.
5. 98.0 %.

Pharmacopoeial quality control of pharmaceutical substances of heterocyclic nature: derivatives of isoquinoline, purine, pteridine, isoalloxazine, pyrimidothiazole

1. 85.0 %; 14.1 %.
2. 97.7 %.
3. 98.0 %.
4. –121.

Pharmacopoeial quality control and pharmaceutical chemistry of terpenoids derivatives, chromone, seco derivatives of ergosterol and naphthoquinone, related to fat-soluble vitamins and their derivatives

1. 99.0 %.
2. 99.6 %.
3. 300.7 mg.
4. 5.99 %.
5. 8.10 ml.

Pharmacopoeial quality control and pharmaceutical chemistry of aromatic amino acid derivatives related to medicinal products for local anesthesia

1. 5.31 × 105 IU.
2. 98.0 %, 396000 IU.
3. 1.51 %.
4. 99.4 %.
5. +106.

Quality control of pharmaceutically prepared drugs (extemporaneous drugs). Quality control of industrially manufactured medicines

1. 4.0 %.
2. 101.5 %.
3. 2.0 %.
4. 0.20 %.
5. 0.70 %.

CONTENTS

Учебное издание

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Хаминец Сергей Георгиевич
Мандрик Наталья Ивановна

ФАРМАЦЕВТИЧЕСКАЯ ХИМИЯ

PHARMACEUTICAL CHEMISTRY

Сборник задач
для студентов 3-го курса медицинского факультета иностранных учащихся, обучающихся по специальности «Фармация»

На английском языке

В двух частях

Часть 2

Ответственный за выпуск Р. И. Лукашов
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