MINISTRY OF HEALTH OF UKRAINE
ODESSA NATIONAL MEDICAL UNIVERSITY
Faculty of Pharmacy
Department of Pharmaceutical Chemistry and Drug Technology

APPROVED by

Vice-rector for scientific and pedagogical work

_____Eduard BURYACHKIVSKY

_____, 202_

METHODOLOGICAL DEVELOPMENT
TO THE INDEPENDENT WORK OF THE STUDENT
FROM EDUCATIONAL DISCIPLINE

Faculty, course Pharmaceutical, V course

Educational discipline Industrial practice in Pharmaceutical chemistry

(the name of the educational discipline)

Approved:

The meeting of the department Pharmaceutical chemistry

Odesa National Medical University

Minutes № _ dated _____

Head of Department (_____) Volodymyr GELMBOLDT
(signature) *(Name, last name)*

Developers:

prof. Gelmboldt V.O., as. Lytvynchuk I.V., Senior Lecturer Nikitin O.V., docent Lozhichevska, T. V.

Independent work No. 1

Topic: Modern methods of pharmaceutical analysis. Classification and characteristics. Peculiarities of pharmaceutical analysis are related to the intended use of drugs and the professional responsibility of the pharmacist. State principles and provisions regulating the quality of medicinal products.

Goal: Familiarize yourself with modern methods of pharmaceutical analysis and state principles and provisions regulating the quality of medicinal products.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Standardization, its purpose and tasks.
2) Name the types of standardization and describe them.
3) Name the main principles of standardization.
4) Tell us about the designation of regulatory documents.
5) List the structural elements of the standard.
6) State the construction rules and requirements for marking technical conditions.

Questions for self-control:

1) Name the types of regulatory documents and describe them.
2) Name the types and categories of standards.
3) Specify the main principles of state policy in the field of standardization.
4) Subjects and objects of standardization.
5) State the structural elements of quality control methods for medicinal products.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Calculate pBr and pAg when titrating 100 cm^3 0.1 N of KBr solution 0.1 N $AgNO_3$ solution if: a) 99 cm^3, b) 100 cm^3, c) 110 cm^3 of titrant are added. $PR(AgBr) = 7.7 \cdot 10^{-13}$.

Task 2. Preparation and establishment of the normality of the working solution of potassium rhodanide. Determine the normal concentration of the potassium

rhodanide solution and its titer against silver, if 20.00 cm^3 of 0.1014 N is used for the titration of 25.00 cm^3. $AgNO_3$ solution.

Task 3. How many percent of silver does the alloy contain, if after dissolving a weight of 0.3000 g of this alloy, 23.80 cm^3 of 0.1000 N was spent on the titration of the resulting solution. of NH_4SCN solution?

3. Test tasks for self-control:

1. Instrumental (physical and physico-chemical) methods of analysis include:
   A. Spectroscopic;
   B. Electrochemical;
   C. Gravimetric;
   D. True options A and B;
   E. There is no correct answer.
2. Physico-chemical methods of analysis include:
   A. Gravimetric;
   B. Titrimetric;
   C. Conductometric;
   D. All options are correct;
   E. There is no correct answer.
3. The methods of calculating the concentration of substances include:
   A. Method of one standard;
   B. Method of two standards;
   C. Method of three standards;
   D. True options A and B;
   E. There is no correct answer.
4. Electromagnetic radiation with a wavelength of 450 nm corresponds to the region:
   A. UV radiation;
   B. IR radiation;
   C. Visible radiation;
   D. γ-radiation;

E. There is no correct answer.

5. Groups causing the appearance of absorption bands in molecular spectra are called:
   A. Chromophores;
   B. Auxochromes;
   C. Functional;
   D. Coordinated;
   E. All options are correct.
6. The method of direct conductometry is based on measurement:
   A. voltage in the circuit;
   B. current strength;
   C. specific electrical conductivity of electrolyte solutions;
   D. electrode potential;
   E. all options are correct.
7. In coulometric titration, the titrant:
   A. is added from a burette;
   B. obtained in the process of electrolysis of an auxiliary reagent;
   C. measure with a pipette;
   D. there is no correct answer;
   E. is added in a twofold excess.
8. During the amperometric titration of sodium sulfate with lead salts (electroactive titrant) after the equivalence point, the strength of the diffusion current:
   A. increases;
   B. decreases;
   C. remains constant;
   D. first decreases, then increases;
   E. first increases, then decreases.
9. During the conductometric titration of acetic acid with an ammonia solution after the equivalence point, the specific electrical conductivity:

A. decreases;

B. increases;

C. increases slightly;

D. there is no correct answer;

E. decreases significantly.

10. The classification of chromatographic methods is based on the following features:

A. The nature of the sorbent;

B. Aggregate state of phases;

C. Sample volume;

D. Concentration of analyzed substances;

E. All the listed answers are correct.

4. Individual tasks for students of higher education on the topic:

1) Development and design of organization standards.

2) Development, construction rules and requirements for marking technical conditions.

3) Development, approval of national standards (classifiers) and introduction of changes.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.

3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.

4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.

5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.

8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.
2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.
4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.
5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 2

Topic: General pharmacopoeial methods of analysis. General provisions on chemical methods of drug analysis. State principles and provisions regulating the quality of medicinal products. Organization of quality control of medicinal products in Ukraine. State Pharmacopoeia of Ukraine. Modern strategies for creating innovative medicines. Pharmacopoeial analysis.

Goal: Familiarize yourself with general pharmacopoeial methods of analysis; organization of quality control of medicinal products in Ukraine.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Basic rules and stages of registration of medicinal products operating in Ukraine.

2) Documentary support of the process of registration of medicinal products in Ukraine.

3) Which reagent is used to determine the impurity of fluorides, according to the requirements of the SPhU, in medicinal products?

4) What is the reagent recommended by the SPh of Ukraine, which was added by the pharmacist analyst to detect chloride impurity when determining the benignity of calcium lactate?

5) How, in accordance with the requirements of the SPhU, is the degree of coloration of true solutions determined.

6) What requirements should be made to qualitative reactions used in tests for permissible limits of impurities?

Questions for self-control:

1) The need to harmonize the registration system with EU countries.
2) Licensing of medicines in the European Union.
3) Define the concept of "Specific impurities ".
4) During the interaction of the investigated solution with a solution of barium chloride, a white precipitate was formed, soluble in a solution of hydrochloric acid, with the release of colorless and odorless gas. A conclusion can be drawn about the presence of which ion?
5) Suggest reagents for detecting nitrite ions contained in the analyzed pharmaceutical.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. During the action of mineral acid on the analyzed solution, the release of gas bubbles is observed, which cause clouding of lime water. What does the analytical effect indicate?

Task 2. Give a selective reagent that can be used to identify chloride ion, bromide ion and iodide ion.

Task 3. When identifying the substance sodium iodide, the pharmacist-analyst of the control and analytical laboratory confirmed the reducing properties of the iodide ion. What reagent can be offered?

3. Test tasks for self-control:

1. The laboratory for quality control of medicinal products received a mucolytic drug containing ambroxol hydrochloride. To identify chloride ions, a solution must be used for its identification:

   A. silver nitrate;

   B. barium sulfate;

   C. glyoxalhydroxyanil;

D. potassium ferrocyanide;

E. diphenylamine.

2. Dexamethasone is a hormonal agent, the structure of which contains covalently bound fluorine. This allows, after mineralization of the substance, to identify fluoride ions using a solution:

   A. Calcium chloride;

   B. Sodium chloride;

   C. Ammonium oxalate;

   D. Silver nitrate;

   E. Sodium acetate.

3. The pharmacist-analyst identifies the antimicrobial agent "Ciprofloxacin hydrochloride". To detect the chloride ion, he conducts a reaction in the presence of concentrated sulfuric acid with such a reagent:

   A. Potassium dichromate;

   B. Sodium hydroxide;

   C. Magnesium sulfate;

   D. Potassium chloride;

   E. Zinc oxide.

4. The quality control of 0.1% injection solution of atropine sulfate is carried out in the central analytical laboratory of the pharmaceutical enterprise. Due to sulfate ions, the active substance can be identified when interacting with such a reagent:

   A. Barium chloride;

   B. Copper (II) sulfate;

   C. Potassium iodide;

   D. Sodium bicarbonate;

   E. Ammonium chloride.

5. During the pharmaceutical analysis, the drug substance was reacted with antipyrine (phenazone) in the presence of dilute hydrochloric acid. The appearance of green color allows identification:
    A. Nitrites;
    B. Sulfates;
    C. Fluorides;
    D. Bromides;
    E. Iodides.
6. Under the action of acetic acid diluted as a medicinal substance, a violent release of gas bubbles is observed, which causes cloudiness of the barium hydroxide solution. This test allows identification:
    A. Carbonates;
    B. Fluorides;
    C. Nitrites;
    D. Sulfates;
    E. Chlorides.
7. An anti-ulcer drug containing bismuth subcitrate has arrived at the drug quality control laboratory. During the reaction on the bismuth cation, the formation of a yellowish-orange color was observed. What reagent was used in this test??
    A. Thiourea;
    B. Glyoxalhydroxyanil;
    C. Hydrochloric acid;
    D. Sodium hydroxide;
    E. Potassium acetate.
8. As a result of the reaction of the analgesic "Metamisole sodium monohydrate" with a solution of potassium pyroantimonate, a white precipitate was formed. This confirms the presence of a medicinal substance in the structure:
    A. Sodium ions;

B. Covalently bound sulfur;

C. Methyl groups;

D. Phenyl radical;

E. Keto groups.

9. When conducting a pharmaceutical analysis, a sample of a medicinal substance moistened with dilute hydrochloric acid was introduced into a colorless flame. The appearance of an orange-red color makes it possible to identify such a cation:

A. Calcium;

B. Sodium;

C. Potassium;

D. Ammonia;

E. Barium.

10. A laboratory specialist of the pharmaceutical product certification center prepares reagents. A solution is used to identify medicinal products containing potassium ions:

A. Sodium cobalt nitrite;

B. Ammonium oxalate;

C. Barium chloride;

D. Sodium hydroxide;

E. Magnesium sulfate.

4. Individual tasks for students of higher education on the topic:

1) Office of Licensing and Certification of Production.

2) Department of the organization of state quality control of medicinal products.

3) Office of the organization of state control of the quality of medical products.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.
3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.
4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.
5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.
6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.
7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.
8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.
2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.
4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.
5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 3

Topic: Testing for the limit content of impurities. Pharmacopoeial reactions for the detection of impurities in medicinal products.

Goal: Get acquainted with the analysis of medicinal substances for the maximum content of impurities.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Classification of impurities.

2) Causes of impurities in the medicinal product.

3) Methods of determining impurities.

4) Normative and legal documents regulating the maximum content of impurities in the medicinal product.

5) Inadmissible impurities in "Purified water in containers" and methods of their determination.

6) Admissible impurities in "Purified water in containers" and methods of their determination.

Questions for self-control:

1) Name the term that characterizes the impurity for which the structure has not been established and which is determined only by qualitative analytical properties.

2) Which of the methods refers to the section of the State Pharmacopoeia of Ukraine "Testing for the limit content of impurities?

3) Water for injections is sterile according to the requirements of the Federal State Administration of Ukraine and should not contain oxidizing substances. What reagent can be used to detect this impurity?

4) What reagents can be used to determine the admixture of ammonium salts in water purified according to the requirements of the DFU?

5) What reagent can be used to identify the active substance in the drug "Salicylic acid alcohol solution" and to determine salicylic acid as an impurity by TLC method?

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. What color should the solution be when testing for the maximum content of iron impurities in the medicinal product.

Task 2. What color should the solution be when testing for the maximum content of ammonium salt impurities in the medicinal product.

Task 3. To determine a possible impurity in the substance of potassium iodide, the pharmacist-analyst added a solution of hydrochloric acid and a solution of barium chloride to the solution of the substance under investigation. What impurity did the pharmacist plan to detect?

3. Test tasks for self-control:

1. Levothyroxine sodium is a drug used for hypofunction of the thyroid gland. To detect chloride impurities when testing this agent, a solution must be used:
    A. Silver nitrate;
    B. Barium chloride;
    C. Magnesium sulfate;
    D. Copper (II) sulfate;
    E. Iron (III) chloride.
2. Furosemide is a drug from the group of loop diuretics. When testing this tool, a reaction was carried out with silver nitrate in the medium of dilute nitric acid. The appearance of white opalescence indicates the presence of an impurity:
    A. Chlorides;
    B. Calcium;
    C. Magnesium;
    D. Heavy metals;
    E. Ammonium salts.
3. A pharmacist-analyst conducts research on the substance of anhydrous glucose. To determine the calcium admixture, he conducts a reaction with the solution:
    A. Ammonium oxalate;
    B. Potassium pyroantimonate;
    C. Barium chloride;
    D. Sodium hydroxide;
    E. Sodium nitrite.
4. When testing the analgesic agent "Goalmizol sodium monohydrate", a reaction was carried out with a solution of barium chloride in the medium of diluted acetic acid. The appearance of white opalescence indicates the presence of an impurity:
    A. Sulfates;

B. Chlorides;
C. Calcium;
D. Heavy metals;
E. Ammonium salts.

5. Testing the calcium lactate substance involves a reaction with a solution of thioglycolic acid in the presence of citric acid and an ammonia solution. This reaction is used to determine such an impurity:
   A. Iron;
   B. Potassium;
   C. Chlorides;
   D. Sulfates;
   E. Ammonium salts.
6. A pharmacist-analyst conducts an analysis of the substance sodium benzoate. The presence of which impurity in the substance is indicated by the formation of white opalescence after the addition of diluted acetic acid and barium chloride solution?
   A. Sulfates;
   B. Zinc;
   C. Phosphates;
   D. Ammonia;
   E. Magnesium.
7. The pharmacist-analyst of the laboratory of the State Inspection for Quality Control of Medicinal Products conducts tests on the purity of the substance "Procaine hydrochloride" with the thioacetamide reagent. The formation of a brown color indicates the presence of an impurity?
   A. Heavy metals;
   B. Potassium;
   C. Aluminum
   D. Magnesium;

E. Calcium.

8. The pharmacist-analyst performs the analysis of the substance of ascorbic acid in accordance with the requirements of the SPhU. To determine the impurity of oxalic acid, he uses a solution:
   A. Calcium chloride;
   B. Sodium sulfate;
   C. Sodium chloride;
   D. Sodium bicarbonate;
   E. Sodium thiosulfate.
9. To determine fluoride admixture in medicinal compounds, the provisional analyst conducts steam distillation and then determines the presence of sodium fluoride by reacting with the reagent:
   A. Aminomethylalizaric acid;
   B. Methoxyphenylacetic acid;
   C. Thioacetamide;
   D. Rhodanbromide;
   E. Sulfuric iodine.
10. The pharmacist-analyst determines the iron impurity in the medicinal product in accordance with the requirements of the SPhU. The presence of this impurity is indicated by the appearance of such a color:
   A. Pink;
   B. Green;
   C. Blue;
   D. Storm;
   E. Black.

4. Individual tasks for students of higher education on the topic:

1) 1) Permissible and prohibited impurities in the medicinal product: procaine hydrochloride.

2) 2) Permissible and prohibited impurities in the medicinal product: acetylsalicylic acid.

3) 3) Permissible and prohibited impurities in the medicinal product: atropine sulfate.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.
2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.
3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.
4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.
5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.
6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.
7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.
8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.
2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.
4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.
5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 4

Topic: Analysis of physico-chemical properties of medicinal products as one of the elements of quality assessment of medicinal products. Analysis of purified water. Physical and chemical properties of water.

Goal: Get acquainted with the peculiarities of the analysis of the physical and chemical properties of medicinal products.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Determination of substances that reduce potassium permanganate.
2) Definition of carbon dioxide.
3) Determination of nitrates and nitrites.
4) Determination of ammonia and ammonium salts.
5) Standards for determining water turbidity.
6) Determination of water transparency and its relationship with turbidity.

Questions for self-control:

1) What physical and physico-chemical methods are used to identify medicinal products?
2) Water turbidity.
3) Methods of determining water turbidity.
4) Optical methods for determining turbidity.
5) Advantages of PIA over classical physico-chemical methods of analysis.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. To conduct a study of the quality of the proposed sample of distilled water.

Task 2. Draw a conclusion about the suitability of using distilled water for the manufacture of non-injectable sterile medicinal products.

Task 3. Draw a conclusion about the suitability of using distilled water for the manufacture of non-injectable non-sterile medicinal products.

3. Test tasks for self-control:

1. Water for injections is sterile according to the SPhU and should not contain oxidizing substances. What reagent (solution) does the pharmacist-analyst use to detect this impurity:
    A. Potassium permanganate;
    B. Ammonium oxalate;
    C. Iron (III) chloride;
    D. Barium chloride;
    E. Dilute sodium hydroxide
2. A pharmacist-analyst conducts an analysis of purified water. He uses a reagent to determine the admixture of ammonium salts in water purified according to the requirements of the SPhU:
    A. Nessler's reagent;
    B. Thioacetamide;
    C. Fehling;
    D. Sulfomolybdenum;
    E. Fisher.
3. The pharmacist-analyst determines impurities of ammonium salts (method A) in sodium tetraborate according to SPhU using a solution:
    A. Potassium tetraiodomercurate;
    B. Potassium ferrocyanide;
    C. Sodium tetraborate;
    D. Barium chloride;
    E. Silver nitrate.
4. As the main reagent when testing for the limit content of zinc impurities, the analytical chemist uses a solution:
    A. Potassium ferrocyanide;
    B. Ammonium thiocyanate;
    C. Sodium sulfide;
    D. Silver nitrate;

E. Barium chloride.

5. To determine the impurity of potassium in medicinal compounds, the pharmacist-analyst conducts a reaction with:
   A. Sodium tetraphenylborate;
   B. Sodium nitrate;
   C. Sodium tetraborate;
   D. Sodium sulfate;
   E. Sodium salicylate.
6. The chemist of the PTC of the pharmaceutical enterprise determines the quality of purified water. What reagent should he used to detect impurities of nitrates and nitrites?
   A. diphenylamine solution;
   B. ammonium oxalate solution;
   C. solution of sulfosalicylic acid;
   D. silver nitrate solution;
   E. barium chloride solution.
7. Determination of impurities of aluminum salts in medicinal products is carried out with a solution:
   A. 8-hydroxyquinoline;
   B. Pyridine;
   C. β-naphthol;
   D. ethanol;
   E. hydroxylamine.
8. To determine the admixture of fluorides in medicinal compounds, the provisional analyst conducts distillation with steam and then determines the presence of sodium fluoride by reacting with the reagent:
   A. Aminomethylalizaric acid;
   B. Methoxyphenylacetic acid;
   C. Thioacetamide;

D. Rhodanbromide;

E. Sulfuric iodine.

9. The pharmacist-analyst determines the iron impurity in the medicinal product in accordance with the requirements of the Federal Drug Administration. The presence of this impurity is indicated by the appearance of such a color:

A. Pink;

B. Green;

C. Blue;

D. Storm;

E. Black.

4. Individual tasks for students of higher education on the topic:

1) What physical and chemical methods can be used to quantitatively determine phenols?

2) What physicochemical methods can be used to quantitatively determine aromatic amines?

3) What physicochemical methods can be used to quantitatively determine aromatic nitro compounds?

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.

3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.

4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.

5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.

8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне

підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.

3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.

5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 5

Topic: General principles of identification of medicinal substances. Identification of medicinal substances of inorganic nature. Identification of medicinal substances of organic nature by functional groups (functional analysis).

Goal: Familiarize yourself with the features of identification of cations and anions and analysis by functional groups.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Qualitative reactions to the aldehyde group.
2) Reactions of the formation of auric dyes.
3) Qualitative reactions to the primary nitro group.
4) Qualitative reactions to the ester group.
5) Azo coupling reactions.
6) Schiff base formation reactions.

Questions for self-control:

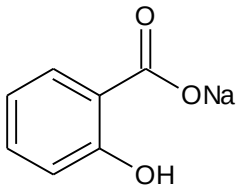
1) Qualitative reactions to sulfate ion.
2) Qualitative reactions to chlorine anion.
3) Qualitative reactions to the aluminum cation.
4) Qualitative reactions to calcium cation.
5) Qualitative reactions to the lead cation.

Indicative tasks for processing theoretical material:

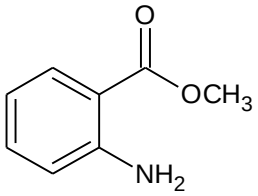
- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

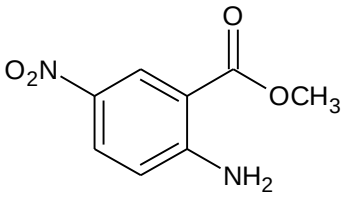
Task 1. Propose a functional analysis for the following compound:



Task 2. Propose a functional analysis for the following compound:



Task 3. Propose a functional analysis for the following compound:



3. Test tasks for self-control:

1. According to the requirements of SPhU, a reaction with potassium permanganate in a diluted sulfuric acid environment is used to identify ethanol. What is the oxidation product of ethanol?
   A. Acetaldehyde;
   B. Acetone;
   C. Acetylene;
   D. Diethyl ether;
   E. Acetate-ethyl ether.
2. For the purpose of identification, the pharmacist-analyst heated the ethanol substance with acetic acid diluted in the presence of concentrated sulfuric acid; a pleasant fruity smell appears. This indicates the formation of which substance?

A. Ethyl acetate;

B. Acetone;

C. Acetylene;

D. Ethylene;

E. Acetaldehyde.

3. The presence of phenolic hydroxyl in the paracetamol molecule can be confirmed by the complexation reaction with:

A. $FeCl_3$;

B. HCl;

C. $K_2Cr_2O_7$;

D. $K[BiI_4]$;

E. NH_2OH.

4. In order to identify the phenol substance in accordance with the requirements of the SPhU, a specialist of the State Inspection for Quality Control of Medicinal Products conducts an oxidation reaction in an ammonia environment. Name the compound formed:

A. Indophenol dye;

B. Azo dye;

C. Azomethyl dye;

D. Aurine dye;

E. Complex salt.

5. The drug thymol has a phenolic hydroxyl in its structure and is therefore easily oxidized. An indophenol test can be used to identify thymol. Select the reagents for this reaction:

A. Chloramine solution and ammonia solution;

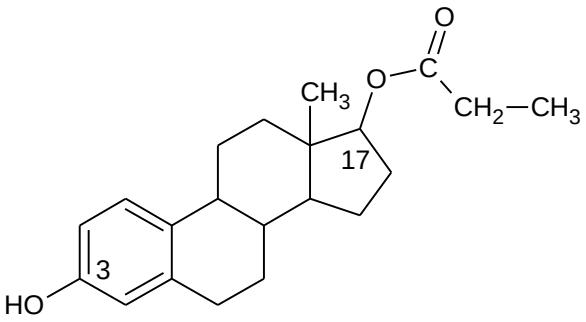
B. Hydrochloric acid solution;

C. A solution of sulfuric acid and formaldehyde;

D. Iodine solution and sodium hydroxide solution;

E. Sulfuric acid solution and bromine solution.

6. Medicinal products that have a phenolic hydroxyl in their structure undergo an electrophilic substitution reaction. Name a reaction that can be used to both identify resorcinol and quantify it:
    A. Bromination;
    B. Sulfation;
    C. Nitration;
    D. Alkylation;
    E. Hydroxymethylation.
7. The identification of pyridoxine hydrochloride (SPhU) is carried out by a specialist of the State Inspection for Quality Control of Medicinal Products using thin-layer chromatography. To develop a chromatogram, he uses the reactions of the formation of an indophenol dye. Name the required reagent:
    A. Dichloroquinone chloramide;
    B. Potassium iodobismuthate;
    C. Potassium nitrate;
    D. Dinitrobenzaldehyde;
    E. Sodium cobaltinitrite.
8. Name the functional groups in the estradiol propionate molecule:



    A. Phenolic hydroxyl, ester group;
    B. Alcohol hydroxyl, keto group;
    C. Enol hydroxyl, carboxyl group;
    D. Phenolic hydroxyl, ethoxy group;
    E. Alcoholic hydroxyl, ester group.

9. The structure of the drug molecule contains an ester group. To confirm its presence in the medicinal product, the pharmacist-analyst uses:
   A. Hydroxam sample;
   B. Le Rosen test;
   C. Murexide sample;
   D. Beilstein's test;
   E. Indophenol test.
10. The pharmacist-analyst conducts tests on the purity of the ether substance for anesthesia. One of the unacceptable impurities in the substance are aldehydes. To detect the content of aldehyde impurities in accordance with the requirements of the SPhU, he conducts a reaction with reagents:
   A. Potassium tetraiodomercurate alkaline solution;
   B. Ammonium oxalate, ammonium chloride;
   C. Hydrochloric acid, chloroform;
   D. Sodium hydrogen phosphate, hydrochloric acid;
   E. Sodium hydroxide, sodium carbonate.

4. Individual tasks for students of higher education on the topic:

1) To propose a functional analysis of a compound containing a phenolic hydroxyl and a primary aromatic amino group.
2) Offer a qualitative analysis of the compound: Sodium hydrotartrate.
3) Offer a qualitative analysis of the compound: Potassium acetate.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.
2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.
3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.
4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.
5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.
6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.
8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.
2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.
4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.
5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 6

Topic: Peculiarities of the use of pharmaceutical analysis in the quality control of medicines manufactured in a pharmacy. Analysis of concentration of solutions.

Goal: Familiarize yourself with the peculiarities of pharmaceutical analysis of drugs manufactured in a pharmacy. Methods of expressing the concentration of solutions.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Mass fraction.
2) Molar concentration of the solution.
3) Equivalent (normal) concentration of the solution.
4) Title.
5) Molar concentration of the solution.

6) Solubility.

Questions for self-control:

1) What solutions are called saturated, unsaturated, supersaturated? Can saturated solutions of AgCl and $BaSO_4$ be considered concentrated?

2) How does the Gibbs energy change during dissolution? Explain the role of enthalpy and entropy factors in the dissolution process.

3) What factors affect the solubility of gases? Formulate the laws of Henry-Dalton, I.M. Sechenov.

4) What factors determine the unlimited and limited solubility of two liquids?

5) For which substances do the values of molar and normal (molar equivalent concentration) concentrations coincide? Give examples.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Find the molar and normal concentration of a 49% solution of orthophosphoric acid (ρ = 1.88 g/cm3).

Task 2. How many milliliters of 36% (ρ = 1.18 g/cm^3) and 20% (ρ = 1.80 g/cm^3) solutions of hydrochloric acid are needed to prepare 100 ml of a 26% solution (ρ = 1.13 g/cm3).

Task 3. Calculate the mass of water and pentahydrate of copper (II) sulfate $CuSO_4 \cdot 5H_2O$, which are required to prepare 500 ml of a solution with a mass fraction of $CuSO_4$ anhydrous salt of 8% (ρ=1.084 g/ml).

3. Test tasks for self-control:

1. Levothyroxine sodium is a drug used for hypofunction of the thyroid gland.

   To detect chloride impurities when testing this agent, a solution must be used:

   A. Silver nitrate;

   B. Barium chloride;

   C. Magnesium sulfate;

   D. Copper (II) sulfate;

   E. Iron (III) chloride.

2. Furosemide is a drug from the group of loop diuretics. When testing this tool, a reaction was carried out with silver nitrate in the medium of dilute nitric

acid. The appearance of white opalescence indicates the presence of an impurity:

A. Chlorides;
B. Calcium;
C. Magnesium;
D. Heavy metals;
E. Ammonium salts.

3. The substance diltiazem hydrochloride has arrived at the laboratory of the pharmaceutical company. When testing it for the presence of an admixture of heavy metals, it is necessary to use such a reagent:

A. thioacetamide;
B. copper-tartrate;
C. molybdenum-vanadium;
D. sulfomolybdenum;
E. cyanobromide.

4. The pharmacist-analyst conducts an express analysis of a 2% boric acid solution. Quantitative determination of the active substance is carried out by the method:

A. alkalimetry;
B. argentometry;
C. complexonometry;
D. nitritometry;
E. acidimetry.

5. The pharmacist-analyst conducts an express analysis of the sedative mixture with sodium bromide. Quantitative determination of sodium bromide is carried out by the method:

A. argentometry;
B. complexonometry;
C. alkalimetry;

D. acidimetry;

E. nitritometry.

6. Dosage forms containing potassium bromide are used to treat insomnia. Potassium cation can be identified by reaction with the solution:

   A. sodium cobaltinitrite;

   B. potassium pyroantimonate;

   C. silver nitrate;

   D. barium chloride;

   E. potassium ferrocyanide.

7. The pharmacist-analyst conducts a quantitative determination of calcium chloride in the composition of the extemporaneous mixture. What titrated solution does he use?

   A. sodium edetate;

   B. potassium bromate;

   C. hydrochloric acid;

   D. potassium permanganate;

   E. sodium hydroxide.

8. An infusional 0.9% sodium chloride solution is used as a physiological solution. What method can be used to quantitatively determine the active substance?

   A. argentometry;

   B. nitritometry;

   C. complexonometry;

   D. acidimetry;

   E. alkalimetry.

9. The expectorant mixture includes sodium bicarbonate, potassium iodide and ammonium chloride. During the rapid analysis of this dosage form, the quantitative determination of sodium bicarbonate can be determined by the following method:

A. acidimetry;

B. alkalimetry;

C. argentometry;

D. complexonometry;

E. nitritometry.

10. Paracetamol is a drug that has an analgesic, antipyretic and anti-inflammatory effect. In the quantitative determination of the active substance by the cerimetric method, it is used as an indicator:

A. feroin;

B. sodium eosinate;

C. phenolphthalein;

D. starch;

E. potassium chromate.

4. Individual tasks for students of higher education on the topic:

1) Peculiarities of pharmaceutical analysis of injectable drugs manufactured in a pharmacy.

2) Peculiarities of pharmaceutical analysis of soft drugs manufactured in a pharmacy.

3) Peculiarities of pharmaceutical analysis of powders produced in a pharmacy.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.

3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.

4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.

5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.

8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.
2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.
4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.
5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 7

Topic: Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Analysis of unstable medicinal products.

Goal: Familiarize yourself with the peculiarities of pharmaceutical analysis of unstable medicinal products manufactured in a pharmacy.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) What types of control must semi-finished products be subject to?

2) Chemical control refers to intrapharmacy control of extemporaneous medicinal products. What is this type of control?

3) Physical control refers to in-pharmacy control of extemporaneous medicines. What is this type of control?

4) All extemporaneous medicinal products must be subject to written control. What is this type of internal pharmacy control?

5) All extemporaneous medicinal products must be subject to organoleptic control. What is this type of intrapharmacy control?

6) All extemporaneous medicinal products must be subject to written control. When the written control passport is filled out?

Questions for self-control:

1) The in-hospital pharmacy manufactures medicines according to doctors' prescriptions and dispenses medicines to hospital departments. What licenses should this pharmacy have?

2) Which extemporaneous medicinal products, made according to a doctor's prescription for a specific patient, are necessarily subject to all types of in-pharmacy control?

3) Two terms "Satisfactory" or "Not satisfactory" are used to assess the quality of an extemporaneous medicinal product. In what cases is the dissatisfaction of an extemporaneous medicinal product established?

4) Incompatibility of medicinal substances.

5) How to prevent incompatibility of substances when they are used together?

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Determine the volume of 0.1 N perchloric acid solution (Cf=1.0023), which will be spent on the titration of 0.1487 g of ftivazid (M.m. 271.28), if the mass fraction of ftivazid in the medicinal product is 99 ,15%.

Task 2. Determine the mass fraction of atropine sulfate (M.m. 676.8) in the medicinal product, if the mass of the test piece is 0.4983 g, the volume of 0.1 N perchloric acid solution (Cf=0.9892), spent on titration - 7.42 ml.

Task 3. Determine the mass fraction (%) of magnesium sulfate heptahydrate (refractometric method), if the refractive index of purified water is 0.3330, the refractive index of magnesium sulfate heptahydrate solution is 0.3394, the refractive index factor is 0.00093.

3. Test tasks for self-control:

1. Basic ways of expressing the concentration of a substance in a solution:

   A. molar concentration of the substance equivalent in the solution;

   B. solution titer;

   C. standard concentration;

D. all Answers are correct;

E. options A and B are correct.

2. The titer of the solution is:

A. number of grams of dissolved substance per 1 ml of solution;

B. number of grams of dissolved substance in 1 liter of solution;

C. number of moles of solute per 1 ml of solution;

D. number of moles of solute in 1 liter of solution;

E. Number of moles of solute in 1 g of solution.

3. Dilution factor:

A. the ratio of the volume of the flask to the volume of the pipette;

B. ratio of mass concentration to molar concentration;

C. the ratio of the volume of the titrant to the volume of the analyzed solution;

D. all options are correct;

E. there is no correct answers.

4. The main techniques (methods) of titration include:

A. direct titration;

B. repeated titration;

C. Fisher titration;

D. titration according to Howard;

E. Scheibler titration.

5. During titration, a substitute is used:

A. an auxiliary reagent that interacts with the specified substance;

B. two titrants;

C. a reagent that interacts with the titrant and the specified substance;

D. one titrant;

E. all Answers are correct.

6. The following methods are distinguished according to the type of the main reaction occurring during titration:

A. methods of acid-base interaction;

B. direct methods;

C. indirect methods;

D. reverse methods;

E. directed methods.

7. Titration curves depict graphical dependence:

A. all the specified options;

B. the concentration of the substance to be determined from the titrant volume;

C. the concentration of the determined substance from the degree of titration;

D. optical density of the solution from the volume of added titrant;

E. there is no correct Answers.

8. Titration is carried out:

A. by means of separate measurements;

B. by way of Bouguer;

C. by the pipetting method;

D. in a measuring cup;

E. by way of Burr.

9. Determinations are made by the reverse titration method:

A. nitrites;

B. nitrates;

C. chlorides;

D. carbonates;

E. phosphates.

10. Titrimetric methods use indicators:

A. acid-base;

B. potassium bromide;

C. acetic acid;

D. potassium acetate;

E. metamizol.

4. Individual tasks for students of higher education on the topic:

1) Legislative acts regulating in-pharmacy quality control of medicinal products.

2) The main types of in-pharmacy quality control of medicinal products manufactured in a pharmacy.

3) Registration of results of quality control of extemporaneous medicinal products.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.

3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.

4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.

5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.

8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.

3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.

5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття.

Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 8

Topic: Analysis of unstable medicinal products, as well as perishable medicinal products.

Goal: Familiarize yourself with the peculiarities of pharmaceutical analysis of unstable, perishable drugs.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) A characteristic feature of purine alkaloids is their instability when heated in an alkaline environment, which leads to the destruction of the heterocycle. In this case, what does caffeine turn into?

2) Adrenaline contains two phenolic hydroxyls in its structure, which determines the chemical instability of the compound. What chemical process occurs when a substance is stored improperly?

3) What processes can be manifested in case of unsatisfactory storage of an alcoholic solution of iodine?

4) What processes can be manifested in case of unsatisfactory storage of ammonia-anise drops?

5) What processes can occur when the phenol solution is not stored satisfactorily?

6) What processes can be manifested in case of unsatisfactory storage of terpin hydrate?

Questions for self-control:

1) What is the standardization of medicinal products and their technological forms?

2) Forms of quality control of medicines used in pharmacies.

3) Forms of internal pharmacy control in accordance with the requirements of the order of the Ministry of Health No. 626.

4) Physicochemical methods of analysis (potentiometry, chromatography, photocolorimetry).

5) Physical methods of analysis (refractometry, polarimetry, spectrophotometry).

Indicative tasks for processing theoretical material:

− Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Determine the mass fraction (%) of sodium hydrogen carbonate (M.m. 84.01) in the medicinal product, if 20.34 ml of 0.5 N hydrochloric acid solution was spent on the titration of a weight of 0.8590 g (Cf = 1.0000).

Task 2. Calculate the mass fraction of magnesium sulfate heptahydrate in a solution of medicine magnesium sulfate heptahydrate, if its refractive index is 1.3555, the refractive index factor is 0.00089.

Task 3. Determine the mass of sodium benzoate (M.m. 144.11), if 21.05 ml of 0.5 N hydrochloric acid solution (Cf = 1.2114) will be spent on its titration, and its percentage content in the medicinal product is 99.40%.

3. Test tasks for self-control:

1. The pharmacist-analyst determines the quantitative determination of the expectorant "Sodium benzoate" by the method of acidimetry. In order to eliminate the effect of benzoic acid on the indicator, the titration should be carried out in the presence of benzoic acid:
   A. diethyl ether;
   B. mannitol;
   C. mercury (II) acetate;
   D. hydrochloric acid;
   E. sodium hydroxide.
2. The pharmacist-analyst conducts quantitative determination of the antihistamine "Diphenhydramine hydrochloride" by the method of acidimetry in a non-aqueous environment. For what purpose does he add a solution of mercury (II) acetate?
   A. to bind chloride ions into a slightly dissociated compound;
   B. to enhance the hydrolysis of diphenhydramine hydrochloride;
   C. to change the density of the solution;
   D. to create the optimal pH value of the solution;
   E. to accelerate precipitation of diphenhydramine base.
3. The pharmacist-analyst determines the quantitative content of the substance "Ascorbic acid" by the iodometric method. He uses a solution as an indicator:

A. starch;

B. methyl orange;

C. bromophenol blue;

D. phenolphthalein;

E. murexide.

4. The pharmacist-analyst conducts quantitative determination of the antibacterial agent "Sulfatiazole" by the nitritometry method. The presence of which functional group determines the choice of method?

A. primary aromatic amino group;

B. aldehyde group;

C. carboxyl group;

D. sulfogroups;

E. hydroxyl group.

5. A pharmacist-analyst analyzes phenol in the composition of an antiseptic medicinal product. Phenolic hydroxyl is identified by reaction with the solution:

A. iron (III) chloride;

B. ninhydrin;

C. barium chloride;

D. potassium permanganate;

E. silver nitrate.

6. The antihistamine "Diphenhydramine hydrochloride" is an ether. The pharmacist-analyst identifies the compound by the reaction of the formation of an oxonium salt when added:

A. concentrated sulfuric acid;

B. solution of hydroxylamine hydrochloride;

C. iron (III) chloride solution;

D. dilute nitric acid;

E. potassium pyroantimonate solution.

7. The pharmacist-analyst identifies the antihistamine "Diphenhydramine hydrochloride" by the reaction of the formation of an oxonium salt with concentrated sulfuric acid. What functional group determines the possibility of carrying out this reaction?
    A. ethereal;
    B. aldehyde;
    C. sulfamide;
    D. amide;
    E. carboxylic.
8. A pharmacist-analyst analyzes the antianginal agent glycerin trinitrate (nitroglycerin). To identify the nitrate ions formed after hydrolysis, he uses a solution:
    A. diphenylamine;
    B. lanthanum (III) nitrate;
    C. thiourea;
    D. chloramine;
    E. glyoxalhydroxyanil.
9. Ethanol is formed as a result of alkaline hydrolysis of the local anesthetic "Benzocaine" (anesthesin). The pharmacist-analyst confirms the breakdown reaction product:
    A. iodoform;
    B. murexidna;
    C. thiochrome;
    D. ninhydrin;
    E. hydroxamomic.
10. The pharmacist-analyst identifies the aromatic nitro group in the structure of the antibacterial agent "Nitrofural" (furacilin). What reagent does he use in this case?
    A. sodium hydroxide;

B. magnesium sulfate;

C. ammonium oxalate;

D. calcium chloride;

E. iron(III) chloride.

4. Individual tasks for students of higher education on the topic:

1) Suggest a method of complete chemical control of the dosage form. Give reaction equations and calculation formulas.

Rp: Sol. Glucosi 5 % - 200 ml

D. S. For injections.

2) Propose a method of complete chemical control of the dosage form. Give reaction equations and calculation formulas.

Rp: Ung. Zinci 10% - 30,0

D. S. Apply a thin layer on the affected surface before going to bed.

3) Propose a method of complete chemical control of the dosage form. Give reaction equations and calculation formulas.

Rp: Sol. Natrii chloridi 10 % - 200 ml

D. S. For injections.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.
2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.
3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.
4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.
5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.
6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.
7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.
8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.

3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.

5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 9

Topic: Processing of auxiliary material, personal hygiene of aseptic block workers.

Goal: Familiarize yourself with the hygiene features of aseptic block workers.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Determination of chlorine in indoor air.
2) Determination of the concentration of iodine vapors in the air.
3) Express method for determination of carbon dioxide in the air.
4) Determination of dust concentration in the air.
5) Name the most common way of harmful substances entering the human body in a production facility.
6) Which method of assessing air pollution with industrial dust, including pharmaceuticals, is the most common?

Questions for self-control:

1) Personal hygiene of pharmacy workers.
2) Influence of the microbial factor on work in pharmacies.
3) Hygienic microbiological substantiation of the requirements for personal hygiene of the pharmacist.
4) Determination of dust dispersion.
5) Bringing the volume of air samples to normal conditions.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Determine the mass fraction (%) of zinc sulfate heptahydrate (M.m. 287.54) in eye drops, if 0.34 ml of 0.05 N trilon B solution (Cf = 1.0308).

Task 2. Determine the mass fraction (%) of sodium hydrocitrate for injections (M.m. 263.11) in the medicinal product, if 40.14 ml of 0.1 N of sodium hydroxide solution (Cf = 1.0785).

Task 3. Determine the mass fraction of chloramphenicol (M.m. 323.13) in the medicinal product, if 16.40 ml of 0.1 N sodium nitrite solution was spent on the titration of a weight of 0.5234 g of chloramphenicol (Cf = 0.9928).

3. Test tasks for self-control:

1. Adrenaline contains two phenolic hydroxyls in its structure, which determines the chemical instability of the compound. What chemical process occurs when a substance is stored improperly?
   A. oxidation;
   B. recovery;
   C. polymerization;
   D. hydrolysis;
   E. weathering.
2. If the conditions of storage of the substance "Calcium lactate pentahydrate" are violated, the loss of crystallization water may occur. What is this process called?
   A. weathering;
   B. oxidation;
   C. restoration;
   D. hydrolysis;
   E. polymerization.
3. When stored in improper conditions, the antiseptic substance "Phenol" changes its color under the influence of moisture and light. The appearance of color is a consequence of the process:

A. oxidation;

B. weathering;

C. recovery;

D. hydrolysis;

E. polymerization.

4. A pharmacist-analyst performs an express analysis of a liquid dosage form containing calcium chloride. He identifies the chloride ion by reaction with the solution:

   A. silver nitrate;

   B. potassium pyroantimonate;

   C. sodium tetraphenylborate;

   D. ammonium oxalate;

   E. barium chloride.

5. An express analysis of the antitussive mixture, which includes sodium bicarbonate and thermopsis grass extract, is carried out. The quantitative content of sodium bicarbonate in this mixture can be determined by the method:

   A. acidimetry;

   B. nitritometry;

   C. cerimetry;

   D. permanganatometry;

   E. argentometry.

6. Express analysis of the mixture containing calcium chloride and sodium bromide is carried out. The summary definition of the ingredients of this dosage form can be determined:

   A. argentometrically;

   B. complexonometrically;

   C. alkalimetrically;

   D. polarimetrically;

E. nitritometrically.

7. The pharmacist-analyst performs an express analysis of powders containing ascorbic acid. The acidic properties of this substance allow for its quantitative determination by the method:
   A. alkalimetry;
   B. iodometry;
   C. cerimetry;
   D. iodometry;
   E. complexonometry.
8. The pharmacist-analyst determines the quantitative determination of the expectorant "Sodium benzoate" by the method of acidimetry. In order to eliminate the effect of benzoic acid on the indicator, the titration should be carried out in the presence of benzoic acid:
   A. diethyl ether;
   B. mannitol;
   C. mercury (II) acetate;
   D. hydrochloric acid;
   E. sodium hydroxide.
9. Acetylsalicylic acid (aspirin) belongs to the group of nonsteroidal anti-inflammatory drugs. Its quantitative determination by the method of direct alkalimetry is recommended to be carried out at a temperature not higher than 20 °C for the purpose of prevention:
   A. hydrolysis of the ester group;
   B. recovery of medicinal substance;
   C. oxidation of medicinal substance;
   D. decarboxylation of the medicinal substance;
   E. precipitation of the resulting salt.
10. To prevent crystalluria, the pharmacist advised the patient to use an alkaline drink while taking the medicine. This medicine belongs to the group:

A. sulfonamides;

B. barbiturates;

C. benzodiazepines;

D. penicillins;

E. catecholamines.

4. Individual tasks for students of higher education on the topic:

1) The structure of the sanitary organization in Ukraine. Basics of sanitary legislation, principles of regulation and regulation of environmental factors.

2) Sanitation. Sanitary supervision: forms, organization and conduct.

3) Sanitary and hygienic measures carried out to ensure the cleanliness of the air in the aseptic block of the pharmacy.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.
2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.
3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.
4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.
5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.
6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.
7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.
8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.
2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне

підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.

5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 10

Topic: Features of preparation and analysis of dosage forms for injections.

Goal: Familiarize yourself with the features of pharmaceutical injection dosage forms.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Name the methods of intrapharmacy control.
2) What medicinal products are subject to in-pharmacy control?
3) How many methods of in-pharmacy control are there?
4) What are the main goals of in-pharmacy control of injectable drugs?
5) What are the mandatory methods of in-pharmacy control of injectable drugs?
6) In what documents are the results of the control of injectable drugs recorded?

Questions for self-control:

1) After preparation, vials with which injection solution should be sterilized immediately?
2) What is the frequency of quality control (quantification) of unstable, perishable drugs?
3) What types of control are performed at the stage of preparation of solutions for injections?
4) On the labels of all weightlifters with medicinal products, which are kept in the medicine storage room (material room), what should be indicated?
5) How long are completed logs of registration of the results of drug control kept?

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Determine the volume of 0.1 N perchloric acid solution (Cf=1.0023), which will be spent on the titration of 0.1487 g of epinephrine hydrate tartrate (M.m. 183.20), if the mass fraction of ftivazide in the medicinal product 99.15%.

Task 2. Determine the mass fraction (%) of sodium hydrocitrate for injections (M.m. 263.11) in the medicinal product, if 21.14 ml of a 0.1 N solution was spent on the titration of a weight of sodium hydrocitrate for injections of 0.350 g sodium hydroxide (Cf = 1.0785).

Task 3. Determine the mass fraction of epinephrine (M.m. 183.20) in the medicinal product, if 8.22 ml of 0.1 N perchloric acid solution was spent on the titration of 0.250 g of epinephrine hydrochloride (Cf = 0.9982).

3. Test tasks for self-control:

1. The pharmacist-analyst conducts quantitative determination of the 0.02% nitrofural solution using the iodometric method. What indicator does it use?
   A. Starch;
   B. Potassium chromate;
   C. Methyl red;
   D. Phenolphthalein;
   E. Crystal violet.
2. The pharmacist-analyst performs an express analysis of anti-inflammatory eye drops containing potassium iodide. Quantitative determination of the active substance is carried out by the method:
   A. argentometry;
   B. complexonometry;
   C. nitritometry;
   D. acidimetry;
   E. alkalimetry.
3. The expectorant mixture includes sodium bicarbonate, potassium iodide and ammonium chloride. During the rapid analysis of this dosage form, the

quantitative determination of sodium bicarbonate can be determined by the following method:

A. acidimetry;
B. alkalimetry;
C. argentometry;
D. complexonometry;
E. nitritometry.

4. The pharmacist-analyst determines the quantitative content of the substance "Ascorbic acid" by the iodometric method. He uses a solution as an indicator:
   A. starch;
   B. methyl orange;
   C. bromophenol blue
   D. phenolphthalein;
   E. murexide.
5. Quantitative determination of the vitamin product "Ascorbic acid" is carried out by the method of iodometry. On what properties of the substance is the method based?
   A. restorative;
   B. oxidizing;
   C. acidic;
   D. basic;
   E. amphoteric.
6. Ethanol is formed as a result of alkaline hydrolysis of the local anesthetic "Benzocaine" (anesthesin). The pharmacist-analyst confirms the breakdown reaction product:
   A. iodoform;
   B. murexidna;
   C. thiochrome;
   D. ninhydrin;

E. hydroxamic.

7. An analytical chemist conducts a qualitative reaction of nitrazepam with potassium tetraiodobismutate and obtains an orange-red precipitate. What fragment of the molecule determines this reaction?
   A. tertiary nitrogen;
   B. phenolic hydroxyl;
   C. carboxyl group;
   D. ester group;
   E. benzene nucleus.
8. The formation of a colored precipitate with potassium tetraiodobismuthate is a characteristic reaction for substances containing tertiary nitrogen. This reaction can be used for identification:
   A. nitrazepam;
   B. chloral hydrate;
   C. camphor;
   D. phenyl salicylate;
   E. phenol.
9. The pharmacist-analyst of the control and analytical laboratory carries out quantitative determination of Goalmizol sodium by the method of iodometry. What indicator does it use:
   A. starch;
   B. murexide;
   C. phenolphthalein;
   D. feroin;
   E. tropeolin 00.
10. An analytical chemist performs quantitative determination of caffeine by iodometry. He uses a solution as an indicator:
   A. starch;
   B. murexide;

C. phenolphthalein;

D. ferroin;

E. tropeolin 00.

4. Individual tasks for students of higher education on the topic:

1) What is the physical control of medicines?

2) Quality categories of medicinal products by assessment.

3) Normative documents regulating the rules of production (manufacturing) of medicinal products in the conditions of a pharmacy.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.

3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.

4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.

5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.

8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.

3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.

5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 11

Topic: Peculiarities of preparation, analysis and storage of children's medicines, including for newborns.

Goal: Familiarize yourself with the peculiarities of pharmaceutical analysis of children's medicines, including those for newborns.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Physical methods of analysis of children's medicinal forms.
2) Chemical methods of analysis of children's dosage forms.
3) Physico-chemical methods of analysis of children's dosage forms.
4) Teratogenic effect of medicines.
5) Embryotoxic effect of medicines.
6) Fetotoxic effect of medicines.

Questions for self-control:

1) Qualitative reactions to phenolic hydroxyls.
2) Qualitative reactions to the primary aromatic amino group.
3) Qualitative reactions to acetyl.
4) Qualitative reactions to the carboxyl group.
5) Qualitative reactions to cations.

Indicative tasks for processing theoretical material:

− Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. When carrying out a quantitative analysis of baby powder, the following deviations from the content of active substances were established: zinc oxide - 7.5%, starch - 13.0%, talc - 4%. Make conclusions about the quality of the received drug.

Task 2. Determine the mass fraction of ibuprofen (M.m. 206.29) in the medicinal product, if 8.21 ml of 0.1 N perchloric acid solution (Cf = 0.9982) was spent on the titration of 0.500 g of ibuprofen.

Task 3. Determine the volume of 0.1 N sodium nitrite solution (Cf=0.9684), which will be spent on the titration of 0.250 g of acetaminophen (M.w. 151.16), if its mass fraction in the medicinal product is 99, 80%.

3. Test tasks for self-control:

1. Adrenaline contains two phenolic hydroxyls in its structure, which determines the chemical instability of the compound. What chemical process occurs when a substance is stored improperly?
   A. oxidation;
   B. recovery;
   C. polymerization;
   D. hydrolysis;
   E. weathering.
2. If the conditions of storage of the substance "Calcium lactate pentahydrate" are violated, the loss of crystallization water may occur. What is this process called??
   A. weathering;
   B. oxidation;
   C. restoration;
   D. hydrolysis;
   E. polymerization.
3. When stored in improper conditions, the antiseptic substance "Phenol" changes its color under the influence of moisture and light. The appearance of color is a consequence of the process:
   A. oxidation;
   B. weathering;
   C. recovery;
   D. hydrolysis;
   E. polymerization.

4. A pharmacist-analyst performs an express analysis of a liquid dosage form containing calcium chloride. He identifies the chloride ion by reaction with the solution:
    A. silver nitrate;
    B. potassium pyroantimonate;
    C. sodium tetraphenylborate;
    D. ammonium oxalate;
    E. barium chloride.
5. An express analysis of the antitussive mixture, which includes sodium bicarbonate and thermopsis grass extract, is carried out. The quantitative content of sodium bicarbonate in this mixture can be determined by the method:
    A. acidimetry;
    B. nitritometry;
    C. cerimetry;
    D. permanganatometry;
    E. argentometry.
6. Express analysis of the mixture containing calcium chloride and sodium bromide is carried out. The summary definition of the ingredients of this dosage form can be determined:
    A. argentometrically;
    B. complexonometrically;
    C. alkalimetrically;
    D. polarimetrically;
    E. nitritometrically.
7. The pharmacist-analyst performs an express analysis of powders containing ascorbic acid. The acidic properties of this substance allow for its quantitative determination by the method:
    A. alkalimetry;

B. iodometry;

C. cerimetry;

D. iodometry;

E. complexonometry.

8. The pharmacist-analyst determines the quantitative determination of the expectorant "Sodium benzoate" by the method of acidimetry. In order to eliminate the effect of benzoic acid on the indicator, the titration should be carried out in the presence of benzoic acid:

A. diethyl ether;

B. mannitol;

C. mercury (II) acetate;

D. hydrochloric acid;

E. sodium hydroxide.

9. Acetylsalicylic acid (aspirin) belongs to the group of nonsteroidal anti-inflammatory drugs. Its quantitative determination by the method of direct alkalimetry is recommended to be carried out at a temperature not higher than 20 °C for the purpose of prevention:

A. hydrolysis of the ester group;

B. recovery of medicinal substance;

C. oxidation of medicinal substance;

D. decarboxylation of the medicinal substance;

E. precipitation of the resulting salt.

10. To prevent crystalluria, the pharmacist advised the patient to use an alkaline drink while taking the medicine. This medicine belongs to the group:

A. sulfonamides;

B. barbiturates;

C. benzodiazepines;

D. penicillins;

E. catecholamines.

4. Individual tasks for students of higher education on the topic:

1) Principles of prescribing and pharmacoceutical analysis of children's medicines.

2) Peculiarities of biotransformation of nonsteroidal anti-inflammatory drugs in childhood.

3) Peculiarities of pharmaceutical analysis of children's suspensions with NSAIDs.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.

3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.

4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.

5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.

8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.

3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.

5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття.

Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 12

Topic: Peculiarities of the use of pharmaceutical analysis in the quality control of medicines manufactured in a pharmacy.

Goal: Familiarize yourself with the features of quality control of extemporaneous medicinal products.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Requirements for quality control of parenteral medicinal products.
2) Requirements for quality control of ophthalmic medicinal products.
3) Labeling of medicines produced (manufactured) in pharmacies.
4) When is the written control passport filled out by the person who prepared the medicinal product?
5) What type of control consists in the identification and determination of the quantitative content of substances included in the composition of extemporaneous medicinal products?
6) What types of internal pharmacy quality control are mandatory for all medicinal products manufactured in the pharmacy?

Questions for self-control:

1) Preparation and quality control of purified water and water for injections.
2) Written control.
3) Organoleptic control.
4) Physical control.
5) Chemical control.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Carry out quality control according to the prescription:

Rp.: Papaverini hydrochloridi 0,15
Anaesthesini 1,5
Divide in partes aequales numero 15
Signa. 1 powder 3 times a day

#

Task 2. Carry out quality control according to the prescription.

Rp.: Atropini sulfatis 0,0002
Sacchari 0,3
Misce, ut fiat pulvis
Da tales doses numero 15
Signa. 1 powder 3 times a day

#

Task 3. Carry out quality control according to the prescription.

Rp.: Natrii hydrocarbonatis
Magnesii oxydi ana 0,25
Misce, ut fiat pulvis
Da tales doses numero 15
Signa. 1 powder 3 times a day

#

3. Test tasks for self-control:

1. A pharmacist-analyst conducts an analysis of chloramphenicol eye drops. To detect the active pharmaceutical ingredient, he adds sodium hydroxide solution; at the same time, a yellow color appeared, turning into red-orange. On which functional group was the reaction carried out?
   A. nitro group;
   B. phenyl radical;
   C. aldehyde group;
   D. imino group;
   E. alcohol hydroxyl.
2. The pharmacist-analyst performs an express analysis of anti-inflammatory eye drops containing potassium iodide. Quantitative determination of the active substance is carried out by the method:
   A. argentometry;
   B. complexonometry;
   C. nitritometry;
   D. acidimetry;
   E. alkalimetry.

3. The pharmacist-analyst performs an express analysis of eye drops containing zinc sulfate. He identifies the zinc cation by reacting it with a solution:
    A. potassium ferrocyanide;
    B. sodium chloride;
    C. potassium permanganate;
    D. sodium nitrite;
    E. ammonium oxalate.
4. The pharmacist-analyst performs an express analysis of eye drops containing zinc sulfate. He identifies sulfates by reacting with a solution:
    A. barium chloride;
    B. ammonium oxalate;
    C. potassium nitrate;
    D. sodium nitrite;
    E. iron (III) chloride.
5. An express analysis of eye drops containing zinc sulfate and boric acid is carried out. The quantitative content of zinc sulfate in this dosage form can be determined by the method:
    A. complexonometry;
    B. alkalimetry;
    C. cerimetry;
    D. polarimetry;
    E. nitritometry.
6. The pharmacist-analyst conducts an express analysis of the extemporaneous mixture. He identifies sodium benzoate in the composition of the mixture by the reaction with the solution:
    A. iron (III) chloride;
    B. sodium bicarbonate;
    C. ammonium oxalate;
    D. sodium acetate;

E. magnesium sulfate.

7. The pharmacist-analyst conducts a quantitative determination of calcium chloride in the composition of the extemporaneous mixture. What titrated solution does he use?
   A. sodium edetate;
   B. potassium bromate;
   C. hydrochloric acid;
   D. potassium permanganate;
   E. sodium hydroxide.
8. An infusional 0.9% sodium chloride solution is used as a physiological solution. What method can be used to quantitatively determine the active substance?
   A. argentometry;
   B. nitritometry;
   C. complexonometry;
   D. acidimetry;
   E. alkalimetry.
9. The quantitative content of the antihistamine "Diphenhydramine hydrochloride" is determined by the method of alkalimetry. A solution is used as a titrant:
   A. sodium hydroxide;
   B. potassium bromate;
   C. sodium thiosulfate;
   D. potassium permanganate;
   E. hydrochloric acid.
10. Acetylsalicylic acid (aspirin) belongs to the group of nonsteroidal anti-inflammatory drugs. Its quantitative determination by the method of direct alkalimetry is recommended to be carried out at a temperature not higher than 20 °C for the purpose of prevention:

A. hydrolysis of the ester group;

B. recovery of medicinal substance;

C. oxidation of medicinal substance;

D. decarboxylation of the medicinal substance;

E. precipitation of the resulting salt.

4. Individual tasks for students of higher education on the topic:

1) Requirements for quality control of parenteral medicinal products manufactured in stock (lots) and subject to sterilization requirements.

2) Requirements for quality control of ophthalmic medicinal products manufactured in stock (lots) and subject to sterilization requirements.

3) Requirements for quality control of other medicinal products manufactured in stock (lots) and subject to sterilization requirements.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.

3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.

4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.

5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.

8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.

3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.

5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 13

Topic: Peculiarities of using pharmaceutical analysis in quality control of medicines. Analysis of eye drops.

Goal: Familiarize yourself with the features of pharmaceutical analysis of ophthalmic drugs.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Characteristics of colloidal solutions, features of their technology. Quality control and registration before release.

2) Methods of sterilization. Characteristics, classification.

3) Types of chemical incompatibilities in ophthalmic medicinal products.

4) Eye ointments. Characteristics of the foundations. Features of manufacturing and pharmaceutical analysis.

5) Requirements for dosage forms with antibiotics. Features of the introduction of antibiotics into the composition of various dosage forms.

6) Requirements for dosage forms with antibiotics. Peculiarities of pharmaceutical analysis.

Questions for self-control:

1) Qualitative reactions to the argentum cation.

2) Qualitative reactions to the sodium cation.

3) Qualitative reactions to sulfate ion.

4) Qualitative reactions to the tartrate ion.

5) General precipitation alkaloid reactants.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Determine the mass fraction (%) of zinc sulfate heptahydrate (M.m. 287.54) in eye drops, if 0.34 ml of 0.05 N trilon B solution (Cf = 1.0308).

Task 2. Determine the volume of a 0.1 N solution of argentum (I) nitrate (Cf = 0.9968), which will be used for the titration of 10.00 ml of a diluted mixture of 3% sodium bromide solution (M.m 102.90), the volume of the measuring flask is 50.00 ml, the volume of the pipette is 5.00 ml.

Problem 3. Determine the mass fraction (%) of potassium iodide (M.m. 166.01) in the mixture, if 2.86 ml of 0.1 N solution of argentum (I) nitrate (Cf = 1.0000) was spent on the titration of 5.00 ml of potassium iodide solution = 1.0532); volumetric flask volume 50.00 ml, pipette volume 5.00 ml.

3. Test tasks for self-control:

1. The quantitative content of the antibacterial agent "Phthalylsulfathiazole" (phthalazole) is determined by the method of alkalimetry. The titrant in this method is a solution:
   A. sodium hydroxide;
   B. perchloric acid;
   C. potassium bromate;
   D. ammonium thiocyanate;
   E. silver nitrate.
2. The pharmacist-analyst conducts quantitative determination of the antihistamine "Diphenhydramine hydrochloride" by the method of acidimetry in a non-aqueous medium. For what purpose does he add a solution of mercury (II) acetate?
   A. to bind chloride ions into a slightly dissociated compound;
   B. to enhance the hydrolysis of diphenhydramine hydrochloride;
   C. to change the density of the solution;
   D. to create the optimal pH value of the solution;
   E. to accelerate precipitation of diphenhydramine base.

3. Paracetamol is a drug that has an analgesic, antipyretic and anti-inflammatory effect. The reaction of identification with a solution of iron (III) chloride is due to its presence in its structure:
    A. phenolic hydroxyl;
    B. aromatic nitro group;
    C. ester group;
    D. aldehyde group;
    E. carboxyl group.
4. The pharmacist-analyst determines the quantitative content of the drug "Hydrocortisone Acetate" using an instrumental method. He measures the optical density of the solution using:
    A. spectrophotometer;
    B. polarograph;
    C. polarimeter;
    D. pH meter;
    E. refractometer.
5. The pharmacist-analyst conducts photocolorimetric quantitative determination of 0.02% nitrofural solution. For this he measures:
    A. optical density of the solution;
    B. pH of the studied solution;
    C. refractive index of the solution;
    D. angle of rotation of the solution;
    E. boiling point of the solution.
6. For the express analysis of a 10% glucose solution, it is necessary to determine its refractive index. What device should the pharmacist-analyst use in this case?
    A. refractometer;
    B. photocolorimeter;
    C. potentiometer;

D. polarimeter;

E. spectrophotometer.

7. Quality control of substances for pharmaceutical use involves determining the content of residual amounts of volatile organic solvents. For this purpose, it is most rational to apply this type of chromatography:

   A. gas;

   B. paper;

   C. liquid;

   D. ion exchange;

   E. thin layer.

8. Chromatographic methods are used in pharmaceutical analysis. What chromatographic method is based on reversible chemisorption of ions of the analyzed solution by ionogenic groups of the sorbent:

   A. ion exchange;

   B. paper;

   C. adsorption;

   D. thin layer;

   E. gas.

9. A specialist in the ampoule shop of a pharmaceutical enterprise carries out quality control of injection solutions. To determine the pH of the solution, he must use it:

   A. potentiometer;

   B. refractometer;

   C. spectrophotometer;

   D. polarimeter;

   E. viscometer.

10. A pharmacist-analyst analyzes the medicinal substance nicotinamide. When carrying out a pharmacopoeial reaction with a solution of cyanobromide and aniline, a yellow color appears. What functional group does it react with?

A. pyridine cycle;

B. amide group;

C. carboxyl group;

D. phenolic hydroxyl group;

E. ester group.

4. Individual tasks for students of higher education on the topic:

1) Modern ophthalmic dosage forms. Types of chemical incompatibility in ophthalmic dosage forms.

2) Features of the technology of eye drops depending on the solubility of medicinal substances. Quality control, packaging, labeling, registration before release.

3) Medicinal forms used in ophthalmology. Characteristic. Classification.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.

3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.

4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.

5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.

8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.

3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.

5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 14

Topic: Peculiarities of using pharmaceutical analysis in quality control of medicines. Analysis of alcohol solutions.

Goal: Get acquainted with the peculiarities of pharmaceutical analysis of alcohol solutions of medicinal products.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Methods of diluting alcohol solutions.
2) Murexide test.
3) Ninhydrin test.
4) Iodoform test.
5) Qualitative reactions to the enol group.
6) Qualitative reactions to alcohol hydroxyl.
7) Qualitative reactions to phenolic hydroxyls.

Questions for self-control:

1) Qualitative reactions to the argentum cation.
2) Qualitative reactions to the sodium cation.
3) Qualitative reactions to sulfate ion.
4) Qualitative reactions to the tartrate ion.
5) General precipitation alkaloid reactants.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Determine the mass fraction (%) of potassium iodide (M.m. 166.01) in a 5% alcohol solution of iodine, if 8.04 ml of 0.1 N argentum nitrate solution was spent on the titration of 2.00 ml of the drug (Cf = 1.0000); the volume of 0.1 M sodium thiosulfate solution (Cf = 1.0000) used for iodine titration is 5.68 ml.

Task 2. Determine the mass fraction (%) of potassium iodide (M.m. 116.01) in a 5% alcoholic solution of iodine, if 8.04 ml of 0.1 N argentum (I) solution was used for the titration of 2.00 ml of the medicinal product nitrate (Cf = 1.0000); and the volume of 0.1 M sodium thiosulfate solution (Cf = 1.0000) was used for iodine titration - 5.68 ml.

Task 3. Determine the mass fraction of salicylic acid (M.m. 138.12) in the medicinal product, if 19.59 ml of 0.1 N sodium hydroxide solution was spent on the titration of a weight of 0.2675 g (Cf = 0.9876).

3. Test tasks for self-control:

1. The pharmacy has a license to manufacture medicinal forms in aseptic conditions. Which premises do not belong to the aseptic block:
   A. Premises for receiving purified water;
   B. Gateway;
   C. Sterilization;
   D. Aseptic assistant;
   E. Premises for receiving water for injections.
2. The pharmacy has a license to manufacture sterile medicinal products. Who is responsible for organizing the operation of the aseptic block and preparation of sterile medicinal products?
   A. The head of the pharmacy;
   B. Analyst analyst;
   C. Pharmacist for taking prescriptions and dispensing medical products;
   D. Authorized person;
   E. Pharmacist.
3. Indicate which of the listed objects require aseptic preparation conditions followed by thermal sterilization with saturated steam under pressure:
   A. Solutions for injections with thermostable substances;
   B. Solutions for injections with thermolabile substances;

C. Concentrated solutions for the burette system;

D. Liquid medicines with antibiotics for internal use;

E. 2% solutions of kolargol for newborns.

4. The pharmacist during pharmaceutical care gave the patient a recommendation not to drink the medicine with milk due to possible deterioration of bioavailability. Choose this medicine from the following:

   A. tetracycline;

   B. sulfanilamide;

   C. phenobarbital;

   D. nifuroxazide;

   E. Metamizol sodium.

5. Prodrugs are drugs that exert their pharmacological action due to the formation of an active metabolite. Choose a medicine from the following:

   A. phthalylsulfathiazole;

   B. chloramphenicol;

   C. diphenhydramine;

   D. metronidazole;

   E. ciprofloxacin.

6. The second phase of Goalbolism of drugs (conjugation phase) includes reactions of interaction of xenobiotics or their Goalbolites, which have active functional groups, with hydrophilic endogenous molecules. This phase includes the process:

   A. glucuronidation;

   B. S-oxidation;

   C. hydroxylation;

   D. restoration;

   E. hydrolysis.

7. An important characteristic of the medicinal product is its lipophilicity. To experimentally determine the lipophilicity coefficient of substances, its distribution between:
    A. water and octanol;
    B. ethanol and acetone;
    C. with isopropanol and hexane;
    D. ethanol and benzene;
    E. ethyl acetate and dichloroethane.
8. In medical practice, optically active medicinal compounds are used in the form of levorotatory, dextrorotatory isomers and their racemic mixtures. The study of the optical activity of substances is carried out by the method:
    A. polarimetry;
    B. refractometry;
    C. conductometry;
    D. spectrometry;
    E. amperometry.
9. Lipophilicity is one of the factors affecting the bioavailability of medicines. Experimentally, it can be determined by the nature of the distribution of the substance in the system:
    A. n-octanol-water;
    B. water-chloroform;
    C. chloroform-glycerol;
    D. acetonitrile-water;
    E. ethanol-paraffin.
10. Medicines are metabolized in several stages. The Metabolism phase, during which the functional groups in the molecule of the medicinal substance undergo biochemical transformation, is called:
    A. functionalization phase;
    B. conjugation phase;

C. secretion phase;

D. phase of mitosis;

E. depolarization phase.

4. Individual tasks for students of higher education on the topic:

1) Classification and methods of extraction of monoatomic alcohols. Identification.

2) Classification and methods of extraction of polyatomic alcohols. Identification.

3) Identification reactions of alcohols and phenols.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.

2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.

3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.

4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.

5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.

7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.

8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.

3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.

5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 15

Topic: Peculiarities of using pharmaceutical analysis in quality control of medicines. Qualitative express analysis of medicines.

Goal: Familiarize yourself with the features of express analysis of medicinal substances.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Use of chromatographic methods of analysis in express analysis.
2) Use of spectroscopic methods of analysis in express analysis.
3) Use of photometric methods of analysis in express analysis.
4) Use of conductometric methods of analysis in express analysis.
5) Use of titrometric methods of analysis in express analysis.
6) Use of electro-chemical methods of analysis in express analysis.

Questions for self-control:

1) Qualitative reactions to the sodium cation.
2) Qualitative reactions to potassium cation.
3) Qualitative reactions to calcium cation.
4) Qualitative reactions to the aldehyde group.
5) Qualitative reactions to the ester group.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Determine the mass fraction of benzoic acid (M.m. 122.12) in a medicinal product, if 15.66 ml of 0.1 N sodium hydroxide solution (Cf = 1.1108) was spent on the titration of a weight of 0.2135 g.

Task 2. Determine the mass fraction of sodium salicylate (M.m. 160.11) in the medicinal product, if 17.38 ml of a 0.5 N solution of hydrochloric acid was spent on the titration of a weight of 1.5668 g of sodium salicylate (Cf = 1.1218) .

Task 3. Determine the mass fraction (%) of glutamic acid (M.m. 147.13) in the medicinal product, if 20.01 ml of 0.1 N sodium hydroxide solution was spent on the titration of a weight of 0.3024 g of glutamic acid (Cf = 1 .0150).

3. Test tasks for self-control:

1. Adrenaline contains two phenolic hydroxyls in its structure, which determines the chemical instability of the compound. What chemical process occurs when a substance is stored improperly?
   A. oxidation;
   B. recovery;
   C. polymerization;
   D. hydrolysis;
   E. weathering.
2. If the conditions of storage of the substance "Calcium lactate pentahydrate" are violated, the loss of crystallization water may occur. What is this process called?
   A. weathering;
   B. oxidation;
   C. restoration;
   D. hydrolysis;
   E. polymerization.
3. When stored in improper conditions, the antiseptic substance "Phenol" changes its color under the influence of moisture and light. The appearance of color is a consequence of the process:
   A. oxidation;
   B. weathering;
   C. recovery;
   D. hydrolysis;
   E. polymerization.

4. A pharmacist-analyst performs an express analysis of a liquid dosage form containing calcium chloride. He identifies the chloride ion by reaction with the solution:
    A. silver nitrate;
    B. potassium pyroantimonate;
    C. sodium tetraphenylborate;
    D. ammonium oxalate;
    E. barium chloride.
5. An express analysis of the antitussive mixture, which includes sodium bicarbonate and thermopsis grass extract, is carried out. The quantitative content of sodium bicarbonate in this mixture can be determined by the method:
    A. acidimetry;
    B. nitritometry;
    C. cerimetry;
    D. permanganatometry;
    E. argentometry.
6. Express analysis of the mixture containing calcium chloride and sodium bromide is carried out. The summary definition of the ingredients of this dosage form can be determined:
    A. argentometrically;
    B. complexonometrically;
    C. alkalimetrically;
    D. polarimetrically;
    E. nitritometrically.
7. The pharmacist-analyst performs an express analysis of powders containing ascorbic acid. The acidic properties of this substance allow for its quantitative determination by the method:
    A. alkalimetry;

B. iodometry;

C. cerimetry;

D. iodometry;

E. complexonometry.

8. The pharmacist-analyst determines the quantitative determination of the expectorant "Sodium benzoate" by the method of acidimetry. In order to eliminate the effect of benzoic acid on the indicator, the titration should be carried out in the presence of benzoic acid:

A. diethyl ether;

B. mannitol;

C. mercury (II) acetate;

D. hydrochloric acid;

E. sodium hydroxide.

9. Acetylsalicylic acid (aspirin) belongs to the group of nonsteroidal anti-inflammatory drugs. Its quantitative determination by the method of direct alkalimetry is recommended to be carried out at a temperature not higher than 20 °C for the purpose of prevention:

A. hydrolysis of the ester group;

B. recovery of medicinal substance;

C. oxidation of medicinal substance;

D. decarboxylation of the medicinal substance;

E. precipitation of the resulting salt.

10. To prevent crystalluria, the pharmacist advised the patient to use an alkaline drink while taking the medicine. This medicine belongs to the group:

A. sulfonamides;

B. barbiturates;

C. benzodiazepines;

D. penicillins;

E. catecholamines.

4. Individual tasks for students of higher education on the topic:

1) Chemical methods of express analysis of medicinal substances.
2) Physical methods of express analysis of medicinal substances.
3) Physico-chemical methods of express analysis of medicinal substances.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.
2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.
3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.
4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.
5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.
6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.
7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.
8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.
2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.
4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.
5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

Independent work No. 16

Topic: Quality control and chemical-pharmaceutical examination of plant raw materials.

Goal: Get acquainted with the peculiarities of pharmaceutical analysis of plant raw materials.

Basic concepts: State Pharmacopoeia of Ukraine, qualitative analysis, quantitative analysis, pharmaceutical analysis, express analysis, monograph.

Plan

1. Theoretical questions:

1) Antibiotics formed by lichens, algae and lower plants: usnic acid, chlorelin. Pharmaceutical analysis.
2) Antibiotics produced by higher plants: allicin, raphanin, phytoalexins: pizatin (in peas), phaseolin (in beans). Pharmaceutical analysis.
3) Give examples of production of enzymes from raw materials of plant origin.
4) Give examples of antibiotics used to combat pathogens of plant diseases.
5) Express analysis of essential oil plant raw materials.
6) Express analysis of vegetable raw materials containing tannins.

Questions for self-control:

1) IR spectroscopy.
2) Polarimetry.
3) Liquid chromatography.
4) High performance chromatography.
5) Thin-layer chromatography.

Indicative tasks for processing theoretical material:

- Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task 1. Determine the mass of menthol (M.m. 156.27), if 22.42 ml of 0.1 N sodium hydroxide solution (Cf = 1.1148) was spent on its titration by the method of direct alkalimetry, and its mass percentage in medicinal means - 99.70%.

Task 2. Determine the volume of 0.5 N hydrochloric acid solution (Cf = 1.0364), which will be spent on titrating a weight of 1.4955 g of sodium benzoate (M.m. 144.11), if its percentage content in the medicinal means - 99.30%.

Task 3. Determine the mass of sodium salicylate (M.m. 160.11), if 18.52 ml of 0.5 N hydrochloric acid solution (Cf = 1.0032) is spent on its titration, and the percentage content of sodium salicylate in the medicinal means - 99.70%.

3. Test tasks for self-control:

1. The pharmacist-analyst conducts quantitative determination of the 0.02% nitrofural solution using the iodometric method. What indicator does it use?
   A. Starch;
   B. Potassium chromate;
   C. Methyl red;
   D. Phenolphthalein;
   E. Crystal violet.
2. The pharmacist-analyst performs an express analysis of anti-inflammatory eye drops containing potassium iodide. Quantitative determination of the active substance is carried out by the method:
   A. argentometry;
   B. complexonometry;
   C. nitritometry;
   D. acidimetry;
   E. alkalimetry.
3. The expectorant mixture includes sodium bicarbonate, potassium iodide and ammonium chloride. During the rapid analysis of this dosage form, the quantitative determination of sodium bicarbonate can be determined by the following method:
   A. acidimetry;
   B. alkalimetry;
   C. argentometry;
   D. complexonometry;
   E. nitritometry.
4. The pharmacist-analyst determines the quantitative content of the substance "Ascorbic acid" by the iodometric method. He uses a solution as an indicator:

A. starch;

B. methyl orange;

C. bromophenol blue

D. phenolphthalein;

E. murexide.

5. Quantitative determination of the vitamin product "Ascorbic acid" is carried out by the method of iodometry. On what properties of the substance is the method based?

A. restorative;

B. oxidizing;

C. acidic;

D. basic;

E. amphoteric.

6. Ethanol is formed as a result of alkaline hydrolysis of the local anesthetic "Benzocaine" (anesthesin). The pharmacist-analyst confirms the breakdown reaction product:

A. iodoform;

B. murexidna;

C. thiochrome;

D. ninhydrin;

E. hydroxamov.

7. An analytical chemist conducts a qualitative reaction of nitrazepam with potassium tetraiodobismutate and obtains an orange-red precipitate. What fragment of the molecule determines this reaction?

A. tertiary nitrogen;

B. phenolic hydroxyl;

C. carboxyl group;

D. ester group;

E. benzene nucleus.

8. The formation of a colored precipitate with potassium tetraiodobismuthate is a characteristic reaction for substances containing tertiary nitrogen. This reaction can be used for identification:
   A. nitrazepam;
   B. chloral hydrate;
   C. camphor;
   D. phenyl salicylate;
   E. phenol.
9. The pharmacist-analyst of the control and analytical laboratory carries out the quantitative determination of Metamizol sodium by the method of iodometry. What indicator does it use?
   A. starch;
   B. murexide;
   C. phenolphthalein;
   D. feroin;
   E. tropeolin 00.
10. An analytical chemist performs quantitative determination of caffeine by iodometry. He uses a solution as an indicator:
   A. starch;
   B. murexide;
   C. phenolphthalein;
   D. ferroin;
   E. tropeolin 00.

4. Individual tasks for students of higher education on the topic:

1) Prospective areas of study and use of medicinal plants.
2) Ways of creating medicinal plant preparations.
3) Ensuring the quality of medicinal herbal preparations during their production.

5. List of recommended literature:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.
2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.
3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.
4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.
5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.
6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.
7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.
8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.
2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.
4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.
5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.