MINISTRY OF HEALTH PROTECTION OF UKRAINE
ODESSA NATIONAL MEDICAL UNIVERSITY

Faculty Pharmaceutical
(faculty name)
Department Pharmaceutical chemistry and drug technology
(name of department)

I APPROVE
Vice-rector for scientific and pedagogical work
_____ Eduard BURYACHKIVSKY
" 01 " September 20 23 _

GUIDELINES
TO THE INDEPENDENT WORK OF STUDENTS OF HIGHER EDUCATION FROM THE ACADEMIC DISCIPLINE

Faculty, course Pharmaceutical, course I V

Academic discipline Drugs technology
(name of academic discipline)

Approved:
Meeting of the Department of Pharmaceutical Chemistry and Drug Technology
Odessa National Medical University

Protocol No. 1 dated August 28 , 2023 .

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Independent work #1

Topic 1: " Regulatory documentation in the production of GLS "

Purpose: The study of factory technology as an educational discipline provides, on the basis of general knowledge and principles, the laws of factory production technology, to form students' knowledge of: theoretical foundations, acquisition of professional skills and skills in the preparation of dosage forms, conducting step-by-step control, standardization, improvement of dosage forms and technologies, studying the influence of storage conditions and the type of packaging on the stability of dosage forms, studying equipment, including new ones, devices and automatic flow lines, modern requirements for the production of dosage forms, for the purity of raw materials, production premises and personnel

Basic concepts: generics, polymorphism of medicinal substances .

Plan

1. Theoretical questions:

1. What is a technological regulation?
2. What is a technological scheme?
3. What is an industrial regulation ?
4. What is the material balance?
5. Name the main provisions of GMP?

Questions for self-control :

1. Name the main regulatory and technical documents that regulate the activity of a technologist and are used for the preparation of medicinal products;
2. What do you know about the general principles of production of ready-made medicinal forms;
3. What are the existing categories and structure of regulatory documentation.
4. Conditions of industrial production of drugs according to the rules of GMR.
5. Name the main terms used in the production of medicinal products.

Approximate tasks for processing the theoretical material :

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

1. List the terms and concepts of the industrial technology of drugs ?
2. Define which documents make up regulatory and technical documentation in the industrial production of drugs ?
3. Define the main provisions of GMP.
4. Qualitative and quantitative information contained in a chemical formula and chemical equation.
5. Define the term industrial regulation.
6. How to correctly draw up a material balance sheet?

3. Test tasks for self-control :

1. The pharmaceutical enterprise masters the production of new products. Which section of the industrial technological regulations describes the appearance and physical and chemical properties of the finished product:

A Characteristics of the final product of production

B. Description of the technological process

C. Characteristics of raw materials, materials and semi-finished products

D Characteristics of auxiliary raw materials and materials

E. Information materials

2. Which section of the regulation describes the sanitary preparation of industrial premises:

A. Description of technological process stages and industrial sanitation

B. Safety technology, fire safety and industrial sanitation

C. Safe production operation and environmental protection

D Information materials

E. General characteristics of production

3. Specify the analytical regulatory document that establishes requirements for the composition of the drug and the process of its production:

A. Technological regulation, pharmacopoeial article

B. Technical regulations

C. State standard (GOST)

D Industry Standard (OST)

E. Technical conditions

4. The industrial and technical department is developing technical regulations. Several pieces of equipment were replaced at the factory. Which section of the technical regulations needs to be changed urgently.

A. Hardware diagram

B. Department of labor protection

C. GDC table

D Accident elimination plan

E. List of instructions

5. At the pharmaceutical enterprise, various ready-made medicinal products are manufactured in accordance with technological regulations. During what term is the industrial regulation valid:

A is 5 years old

B. 3 years

C. 8 years old
D. 1 year
E. 6 months

6. A regulatory document that establishes requirements for specific products and services that regulates the relationship between the supplier and the consumer. Which document corresponds to this definition:

A. Technical conditions;
B. Standard;
C. Technical regulations;
D Technological regulation;
E. Methodological guidelines.

7. What are not regulated by the GMR rules:

A. requirements regarding the bioavailability of the drug;
B. pharmaceutical terminology;
C. requirements for buildings and production premises;
D. personnel requirements;
E. the need for validation.

8. The cost factor is:

A. The ratio of the mass of the initial components to the mass of the finished product.
B. The amount of substance used to obtain a given amount of the drug.
C. The ratio of the mass of the finished product to the mass of the raw materials.
D The ratio of the mass of material losses to the mass of raw materials.
E. The sum of the masses of losses and starting material

9. Validation is a concept related to GMR and means:

A. That the system is working as intended.
B. Profitability of the enterprise.
C. Control over the work of the VTK of the enterprise.
D Product sterility.
E. Inspection of the quality of GLZ.

10. GMP rules regulate:

A. All answers are correct.
B. Pharmaceutical technology.
C. Requirements for buildings and premises of farm production.
D Personnel requirements.
E. The need for validation.

11. GMP rules regulate:

A. Conducting preclinical tests of pharmaceutical preparations.

B. Organization of production of GLZ.

C. Conducting clinical trials.

D Retail Rules.

E. Rules of wholesale trade.

12. GMP rules regulate:

A. Conducting clinical trials

B. Organization of production of GLZ.

C. Conducting preclinical research of pharmaceutical preparations.

D Retail Rules.

E. Rules of wholesale trade.

13. The material balance is:

A. The ratio between the amount of raw materials, finished products, production waste and material losses.

B. Amount of material losses.

C. The ratio between the amount of finished product and waste.

D Description of the technological process.

E. The ratio of the amounts of energy introduced into the technological process and released after its completion.

14. Choose a machine for medium grinding of vegetable raw materials:

A. Grass and root cutter

B. Vibrating mill

C. Drum mill

D Rod mill

E. Jet mill

15. Different equipment is used in the production of solutions at pharmaceutical enterprises. What devices are used for mechanical mixing of liquids?

A. Vane, turbine mixers.

B. Liquid whistles.

C. Pulsators.

D Reactors.

E. Barboter.

16. When choosing grinding equipment, the physical and chemical properties of the material are taken into account. Determine the method of grinding for fibrous

material with a cellular structure.

A. Cutting, erasing

B. Impact, chipping, abrasion

C. Crushing, impact

D Crushing, abrasion

E. Impact

17. In the case of production of solutions at pharmaceutical enterprises, different equipment is used. What devices are used for mechanical mixing of liquids?

A. Shovel agitators

B. Compressors

S. Pulsators

D Liquid whistles

E. Pumps

18. Different types of dryers are used at the pharmaceutical enterprise. Which dryers belong to the contact type?

A. Valtsevi

B. Tapes

C. Air circulation

D Pneumatic

E. Spraying

19. Different types of dryers are used in the process of manufacturing phyto- and organic preparations. Which dryer is the most appropriate to use for drying heat-labile substances?

A. Lyophilic

B. Valtseva

C. Strychkova

D Drying cabinet

E. Barabanna

20. A variety of equipment is used to filter solutions. What filters are used for vacuum filtration:

A. Notch filters

B. Print filters

C. Frame filter presses

D Bag filters

E. Centrifuges

21. What should be the correct set of clothing when working in "clean" rooms according to the GMP recommendation?

A. Overalls, helmet, mask, shoe covers, gloves
B. Pants suit, mask, shoe covers
S. Overalls, mask, shoe covers, gloves
D. Trouser suit, headdress, gloves, overshoes
E. Trouser suit, helmet, overshoes

22. For the production of sterile products in GMP factory conditions, the WHO classifies "clean" areas in accordance with the requirements for air characteristics into the following cleanliness classes:
A. A, B, C, D
B. A, B, C, R, D
C. I, II and III
D. I and II
E. A and B

23. According to the GMP requirements of the WHO, clean rooms for the production of sterile products are classified according to the requirements for characteristics into cleanliness classes. What purity class is not available for pharmaceutical companies?
A. E;
B. In;
C. With;
D. D;
E.A.;

24. Which regulatory and technical document establishes requirements for the quality of medicinal products or medicinal plant raw materials, is approved for a limited period.
A. Provisional pharmacopoeial article (VFS)
B. Pharmacopoeia article (FS)
C. Technological Industrial Regulation (TPR)
D. Industry standard (OSTU)
E. State standard (GOST)

25. A regulatory document that sets requirements for specific products and services and regulates the relationship between the supplier and the consumer. Which document fits this definition?
A. Technical conditions;
B. Methodological guidelines.
C. Technical regulations;
D. Standard;

E. Technological regulations;

26. The ability of the powdered mass to pour out of the container of the funnel or "flow" under the force of its own weight and ensure uniform filling of the matrix channel is called:

A. Fluidity
B. Compressedness
C. Granulation
D. Teasing
E. Spraying

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

1 . How the technological process, production regulations, technical and economic balance is planned;
2. Determine the characteristics, requirements for medicinal products;
3 . List the stages of the technological process (general and partial);
4. What is the modern look of packaging, quality assessment and prospects for further improvement of its manufacturing technology.

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
- A.G. Bashura, O.S. Shpichak, E.E. Bogutska; under the editorship A.I. Tikhonov and S.A. Tikhonova - Kh.: Original, 2016. - 462 p.
- Vishnevska, N.P. Polovka, R.S. Korytniuk et al. - Kh.: National Academy of Sciences: Original, 2016. - 378p.
- Workshop on industrial technology of medicinal products: teaching. manual for students higher education institutions with the specialty "Pharmacy" / O.A. Ruban, D.I. Dmytrievskyi, L.M. Khokhlova [and others]; under the editorship O.A. Ruban. – Kh.: National Institute of Medical Sciences; Original, 2015. – 320 p.
- INDUSTRIAL technology of medicines : education. manual for students' independent work / O.A. RUBAN , V.D. RYBACHUK , L.M. X ohlova etc. - KH.: NF and U, 2015. - 120 p.

- Study guide for preparation for the final modular control and State certification in the Industrial Technology of Medicines for full-time and part-time students of the "Pharmacy" specialty / Ed. O.A. Ruban. - Kh.: National Academy of Sciences, 2016 . - 80 p.
- Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing integrated exam "Step 2. Pharmacy" / O.A. Ruban, V.D. Rybachuk, L.M. Khokhlova, D.S. Pulyaev - KH.: NF and U, 2016. - 63 p.
- Excipients in the production of medicines: training. manual for students higher pharmacy education closing / O.A. RUBAN , I.M. _ Pertsev, S.A. Kutsenko, Yu.S. Oily; under the editorship I.M. Pepper - Kh.: Golden Pages, 2016. - 720 p.
- Modern pharmaceutical technologies: education. manual to laboratory classes of full-time, evening and part-time master's students of the specialty 8.110201 "Pharmacy" / under the editorship. O.A. Ruban. - Kh.: Publishing House of the National Academy of Sciences, 2016. - 256 p.

Auxiliary :

- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
- Regulatory and technical documentation and production validation. Material balance: Educational method. river for audit. and external audit. student work special "Pharmacy" of full-time and part-time education / D.I. Dmytrievskyi, G.D. Slipchenko, I.M. Hrubnyk, D.V. Rybachuk . - Kh.: Publishing House of the National Academy of Sciences, 2008. - 45 p.
- Technology of medicinal products of industrial production: training. manual/ edited by Prof. D.I. Dmitrievsky. – Vinnytsia: Nova kniga, 2008. – 280 p.
- Drug technology. Educational and methodological guide: Education. manual for students higher education hall. / O.I. Tikhonov, P.A. Logvin, S.O. Tikhonova, O.V. Bazulin, T.G. Yarnykh, O.S. Shpychak, O.M. Kotenko; under the editorship O.I. Tikhonova, Kh.: Original, 2009. - 432 p.
- Pharmaceutical encyclopedia / Chief editor. council and the author of the foreword V.P. Black people - 3rd ed., revised. and additional - K.: "MORION", 2016. - 1952 p.
- Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
- European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & Healthcare. - Strasbourg, 2013. - 3638 p.
- Handbook of Pharmaceutical Excipients, 6th edition / RC Rowe, PJ Sheskey,

ME Quinn. - Pharmaceutical Press and American Pharmacists Association, 2009. - 521 p.

- State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicines", 2015. - Vol. 1. - 1128 p.
- State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicines", 2014. - Vol. 2. - 724 p.
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- Powder manufacturing technology: teaching. manual / L.L. Davtyan, R.S. Korytniuk, A.O. Drozdova, I.O. Vlasenko, Z.V. Malenka, V.P. Popovych, V.V. Gladyshev, S.M. Musoev, T.F. Olifirova, L.I. Vishnevska, O.M. Hlushchenko, O.O. Khomich; under the editorship L.L. Davtyan, R.S. Korytnyuk - K.: "Education of Ukraine", 2016. - 141 p.
- S.S. Zuykin. –Kharkiv.: Publishing House of IFNMU-NFaU, 2017. – 44 p.
- Zujkina SS The pharmacotechnological studies of the phytospecies composition for the complex therapy of mastopathy / SS Zujkina, LI Vishnevska // Herald of pharmacy. – 2017. – No. 2 (90). - P. 43-47.
- Bogutska O.E. The main directions of solving the problem of pharmaceutical incompatibilities / O.E. Bogutska // Modern achievements of pharmaceutical technology and biotechnology: a collection of scientific papers. – issue 2. – Kharkiv.: Publishing House of the National Academy of Sciences, 2017. – pp. 29–31.
- Polovko N.P. Assessment of biopharmaceutical factors in the development and production of new medicines / N.P. Polovko, L.I. Vishnevska, O.S. Shpychak // Modern achievements of pharmaceutical technology and biotechnology: collection of scientific works, issue 2. – X.: NFaU Publishing House, 2017. – P. 155-160.
- Prospects for the creation of new original drugs based on substances of plant origin / O.A. Ruban, S.A. Malinovska, Murad Al-Tawaiti, S.I. Mazurets // Phytotherapy. – 2012. – No. 2. - pp. 63–65.
- The current state of creation, production and quality control of capsules / M.B. Chubka, L.V. Vronska, N.O. Zarivna et al. // Pharmaceutical journal. - 2012. - No. 2. - P. 165-168.

- Murachanian D. Two-Piece Hard Capsules for Pharmaceutical Formulations / D. Murachanian // Journal of GXP Compliance. - 2010. - Vol. 14. - P. 31-42.
- Patel H. New pharmaceutical excipients in solid dosage forms – A review / H. Patel, V. Shah, U. Upadhyay // Int. J. of Pharm. & Life Sci. - 2011. - Vol. 2. – P. 1006–1019.
- Recent trends of treatment and medication peptic ulcerative disorder / D. Bhowmik, Chiranjib, KK Tripathi [et al.] // International Journal of PharmTech Research. - 2010. - Vol. 2. – P. 970–980.
- The effects of powder compressibility, speed of capsule filling and pre-compression on plug densification / M. Llusa , E. Faulhammer , S. Biserni [et al.] // Int. J. Pharm. – 2014. – Vol. 471. – P. 182–188.

Electronic resources:

- www.moz.gov.ua is the official website of the Ministry of Health of Ukraine
- fp.com.ua - website of the magazine "Pharmacist Praktik"
- www.provisor.com.ua – the official website of the magazine "Provisor"
- Compendium: drugs. - [Electronic resource]. - Access mode: http://compendium.com.ua/ - as of October 10, 2016.
- State Register of Medicinal Products of Ukraine. - [Electronic resource]. - Access mode: http://www.drlz.com.ua/ - as of January 10, 2017.
- Database "Equalizer" LLC "Business Credit" - [Electronic resource]. - Access mode: http://eq.bck.com.ua/ - as of September 20, 2016.

Independent work #2

Topic 2: "Requirements for sterile products. Determination of the main indicators of the quality of ampoule glass"

Purpose: The study of factory technology as an educational discipline provides, on the basis of general knowledge and principles, the laws of factory production technology, to form students' knowledge of: theoretical foundations, acquisition of professional skills and skills in the preparation of dosage forms, conducting step-by-step control, standardization, improvement of dosage forms and technologies, studying the influence of storage conditions and the type of packaging on the stability of dosage forms, studying equipment, including new ones, devices and automatic flow lines, modern requirements for the production of dosage forms, for the purity of raw materials, production premises and personnel

Basic concepts: ***Technological regulation*** — *Sterility* - complete absence of living microorganisms and their spores.

Thermal stability - the ability of glass products not to be destroyed by sudden temperature fluctuations.

Chemical resistance - guarantees the preservation of medicinal substances and other

components of the drug, determines the properties of glass before leaching.
Mechanical strength - to withstand loads during the processing of ampoules during production, transportation, and storage.

Ampoule glass is a solid amorphous material transparent in one or another part of the optical range (depending on the composition) obtained by solidification of a melt containing glass-forming components (oxides of silicon, boron, aluminum, phosphorus, etc.) and metal oxides (lithium, potassium, magnesium) , lead, etc.).

Plan

1. Theoretical questions:

11. Concept of sterility.
2. Cleanliness classes of industrial premises. Requirements for them.
3. Methods of achieving sterility of premises.
4. Requirements for personnel.
5. Sterile dosage forms: list and purpose.

Questions for self-control:

1. Methods of depyrogenization of injection solutions.
2. Sterilization of injection solutions in ampoules, vials.
3. Chemical and physical methods of sterilization.
4. Use of preservatives.
5. Sterility control.
6. Step-by-step quality control of ampoule glass

Approximate tasks for processing the theoretical material:

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

1. Describe the composition of ampoule glass.
2. Name the main types of ampoules and their features.
3. What operations are provided at the stages of manufacturing ampoules and their further processing; what equipment is used for this?
4. What parameters are determined when assessing the quality of ampoule glass?
5. What is the chemical resistance of ampoule glass and by what methods is it determined?
6. What are the classes and brands of ampoule glass? By what signs?
7. How does the residual voltage of ampoule glass arise? How to eliminate it?
8. What methods are used to determine the thermal stability of ampoule glass?
9. Describe the methods of washing ampoules, their drying and sterilization.

Name the main provisions of G MR regarding the production of preparations for parenteral use (requirements for the technological process,

3. Test tasks for self-control:

1

What brand of glass belongs to the first class?

A. USP-1
B. AB-1 (free glass)
C. NS-2 (neutral glass-2)
D. NS-2 A (neutral glass-2A)
E. MTB (medical container colorless)

2

What brand of glass can be used to make ampoules for tocopherol solution?

A. AB-1
B. NS-3
C. NS-1
D. HT-1
E. SNA-1

3

What brand of glass belongs to the second class?

A. AB-1 (free glass)
B. USP-1
C. NS-1 (neutral glass-1)
D. NS-3 (neutral glass-3)
E. SNS-1 (neutral photosensitive glass)

4

What brand of glass is not used for the manufacture of ampoules:

A. MTB (medical container colorless)
B. AB-1 (free glass)
C. NS-1 (neutral glass-1)
D. NS-3 (neutral glass-3)
E. SNS-1 (neutral photosensitive glass)

5

During the production of ampoules, to change the properties of glass, various components are introduced into its composition. What is the purpose of adding boron oxide to glass?

A. To increase the chemical resistance of glass
B. To reduce the melting temperature of ampoule glass
C. To give the glass the necessary color
D. To increase the mechanical strength of glass
E. To increase the thermal stability of glass

6

When assessing the quality of ampoules, chemical resistance is determined. Specify the methods of determining this indicator:

A. With the help of various acid-base indicators, with the help of a pH meter, weight methods

B. Visual, weight

C. Polarization-optical

D. Method of autoclaving followed by titration with hydrochloric acid solution

E. The method of impacting glass samples with sodium carbonate solution and sodium hydrogen carbonate solution

7

Specify the device for determining the residual voltage in the ampoule glass:

A. Polariscope-polarimeter

B. Densimeter

C. pH meter

D. Photoelectric colorimeter

E. Spectrophotometer

8

To determine the residual voltage in the ampoule glass, the following method is used:

A. Polarization-optical

B. Methylene blue solution

C. Using a pycnometer

D. Using a "drum eraser"

E. Using the Soxhlet apparatus

9

How does the residual stress in the glass affect the quality of ampoules:

A. Mechanical stability decreases

B. Mechanical stability increases

C. Chemical resistance increases

D. The size of the ampoule increases

E. The color of the ampoule changes

10

In the ampoule shop, before using the ampoules, it is necessary to remove the residual voltage. What operation is performed for this:

A. Annealing of ampoules

B. Drying in tunnel ovens

C. Washing with desalted water

D. Capillary cutting

E. Softening of glass with gas burners

11

According to which parameter is the calibration of glass wire at glass factories:

A. By outer diameter
B. By inner diameter
C. By the thickness of the walls
D. By length
E. By mass

12

The technological stage "Preparation of ampoules for filling" includes operations of drying and sterilization of ampoules. Choose the equipment and equipment to perform this operation:

A. Tunnel dryer, drying cabinets, drying cabinets of laminar flow of heated air
B. Drying cabinets of laminar flow of heated air, Krupina chamber, ultrasonic installation
C. AP-7 and AP-18 type steam sterilizers, Rezepina apparatus
D. Ultrasonic installation, tunnel dryer, drying cabinets
E. Krupin's chamber, ultrasonic installation, Rezepin's apparatus, laminar heated air flow drying cabinets

13

In the production of ampoules, glass with the necessary heat resistance is selected. Indicate what this property of ampoule glass provides so that the ampoules meet the requirements of regulatory and technical documentation:

A. Withstand sharp temperature fluctuations
B. Easy cutting of capillaries
C. High-quality sealing of ampoules
D. Load bearing during production and transportation
E. Ability to protect light-sensitive substances

14

What percentage of the ampoules tested for the "heat resistance" indicator should be intact:

A. 98%
B. 75%
C. 30%
D. 50%
E. 95%

15

When testing the thermal stability of 100 ampoules from one batch, 20 ampoules cracked. Whether heat-resistant glass was used in their manufacture:

A. No, there must be 98 integers
B. No, there must be 95 integers
C. No, there must be 90 integers
D. Yes, there should be 80 integers
E. Yes, there should be 75 integers

16

In the production of ampoules, glass with the required low melting point is selected. What provides this property of ampoule glass:

A. High-quality and fast sealing of ampoules
B. Easy cutting of capillaries
C. Load bearing during production and transportation
D. Withstand sharp temperature fluctuations
E. Ability to protect light-sensitive solutions

17

Different brands of glass are used in the production of ampoules for injection solutions. Indicate what brand of glass can be used to make ampoules for solutions that are sensitive to light:

A. SNA-1
B. NS-1
C. NS-3
D. AB-1
E. HT-1

18

What brand of glass should be used in the manufacture of ampoules for 0.01% cyanocobalamin solution?

A. Light protective neutral (SNS-1)
B. Bezborne (AB-1)
C. Neutral (NS-2)
D. Neutral (NS-1)
E. Neutral (NS-2A)

19

The ampoule workshop of the enterprise produces solutions for injections. From the proposed list, select the brands of ampoule glass used in the production of novocaine injection solution:

A. NS-3, NS-1, USP-1
B. NS-1, NS-2, NS-3
C. SNS-1, NS-2A, NS-3
D. OS-1, USP-1, NS-2
E. HT-1, SNS-1, AB-1

20

Which solutions for parenteral administration from the listed substances are subject to special purification in the absence of the "for injection" variety?

A. Magnesium sulfate, calcium chloride, glucose
B. Gelatin, novocaine, sodium sulfite
C. Sodium nitrite, ergot, calcium chloride
D. Hexamethylenetetramine, novocaine

E. Ascorbic acid, analgin

21

At a pharmaceutical enterprise, demineralized water is obtained using membrane separation methods. Choose a method in which the passage of water through a semipermeable membrane is carried out under the influence of external pressure:

A. Reverse osmosis
B. Electrodialysis
C. Evaporation through a membrane
D. Dialysis
E. Sorption

22

Specify the requirements for water for injections that significantly differentiate it from purified water:

A. Absence of pyrogens
B. Absence of heavy metals
C. Absence of sulfates, chlorides
D. Absence of nitrites and nitrates
E. Absence of reducing substances

23

Indicate from which impurities calcium gluconate is purified in the absence of the "for injection" variety.

A. From impurities of calcium oxalate
B. From impurities of iron salts
C. From impurities of manganese and iron salts
D. From impurities of calcium sulfate and iron
E. From dyes and pyrogenic substances

26

For what purpose is activated carbon used in the manufacture of injection solutions:

A. For the purpose of cleaning some injection solutions
B. To create a buffer system
C. As an antioxidant
D. To increase the chemical resistance of ampoule glass
E. To remove residual voltage in ampoules

25

To remove impurities from the glucose injection solution, special cleaning is carried out with the help of the following substances:

A. Adsorption of impurities on activated carbon
B. By adding calcium hydroxide followed by filtration
C. By adding hydrochloric acid followed by adsorption on activated carbon
D. Preliminary treatment with activated carbon followed by stabilization with hydrochloric acid

E. By adding iron oxide followed by adsorption of impurities on activated carbon

26

At a pharmaceutical enterprise, one of the methods of sterilizing heat-labile substances is the tyndalization method. Indicate what the essence of this method is:

A. Three times heating of the solution to 40-60°C with breaks per day for thermostating

B. Autoclaving at a temperature of 119-121°C and a pressure of 1.01.1 atm

C. Sterilization at 100°C with flowing steam

D. Sterilization by dry heat at 180-200°C for a long time

E. High and ultra-high frequency current sterilization

27

The ampoule workshop of the enterprise produces glucose solution. Indicate from which impurities glucose is purified in the absence of the "for injection" variety:

A. From pyrogenic substances and dyes

B. From sulfates and iron

C. From manganese and iron

D. From pyrogenic and protein substances

E. From impurities of protein nature and dyes

28

Specify the methods of control of solutions for parenteral administration on mechanical inclusions:

A. Visual and optical

B. Limulus test

C. Amperometric methods

D. Gravitational methods

E. NMR and UV spectroscopy

29

One of the operations of the technological process of obtaining solutions for injections is filtering solutions. What filters are used for sterile filtration?

A. Candle filters

B. Print filters

C. Filter fungus

D. Nutch filters

E. HNDHFI filter

30

Euphilin solution for injections is manufactured at the pharmaceutical enterprise. Specify the features of preparation of this solution:

A. Cleaning by sterile filtration

B. Cleaning the solution from coloring and pyrogenic substances

C. Dissolution of the medicinal substance during heating

D. Preparation of a solution of higher concentration

E. Adding stabilizer

31

Specify the optimal method of drying sterile powders for injections:

A. In freeze dryers
B. In chamber vacuum-drying devices
C. In spray dryers
D. In fluidized bed dryers
E. In chamber air circulation dryers

32

Name the main operations at the ampoule stage:

A. Filling ampoules with solution, sealing ampoules, quality assessment
B. Washing ampoules, filling ampoules with solution, sealing ampoules
C. Washing ampoules, drying and sterilization, quality assessment
D. Glass cleaning
E. Addition of dyes to slodrot

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

Task 1 . Determination of the residual stress of ampoule glass .

Task 2 . Determination of thermal stability of glass ampoules

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
- A.G. Bashura, O.S. Shpichak, E.E. Bogutska; under the editorship A.I. Tikhonov and S.A. Tikhonova - Kh.: Original, 2016. - 462 p.
- Vishnevska, N.P. Polovka, R.S. Korytniuk et al. - Kh.: National Academy of Sciences: Original, 2016. - 378p.
- Workshop on industrial technology of medicinal products: teaching. manual for students higher education institutions with the specialty "Pharmacy" / O.A. Ruban, D.I. Dmytrievskyi, L.M. Khokhlova [and others]; under the editorship O.A. Ruban. – Kh.: National Institute of Medical Sciences; Original, 2015. – 320 p.

- INDUSTRIAL technology of medicines : education. manual for students' independent work / O.A. RUBAN , V.D. RYBACHUK , L.M. X ohlova etc. - KH.: NF and U, 2015. - 120 p.
- Study guide for preparation for the final modular control and State certification in the Industrial Technology of Medicines for full-time and part-time students of the "Pharmacy" specialty / Ed. O.A. Ruban. - Kh.: National Academy of Sciences, 2016 . - 80 p.
- Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing integrated exam "Step 2. Pharmacy" / O.A. Ruban, V.D. Rybachuk, L.M. Khokhlova, D.S. Pulyaev - KH.: NF and U, 2016. - 63 p.
- Auxiliary substances in the production of medicines: training. manual for students higher pharmacy education closing / O.A. RUBAN , I.M. _ Pertsev, S.A. Kutsenko, Yu.S. Oily; under the editorship I.M. Pepper - Kh.: Golden Pages, 2016. - 720 p.
- Modern pharmaceutical technologies: education. manual to laboratory classes of full-time, evening and part-time master's students of the specialty 8.110201 "Pharmacy" / under the editorship. O.A. Ruban. - Kh.: Publishing House of the National Academy of Sciences, 2016. - 256 p.

Auxiliary :

- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
- Regulatory and technical documentation and production validation. Material balance: Educational method. river for audit. and external audit. student work special "Pharmacy" of full-time and part-time education / D.I. Dmytrievskyi, G.D. Slipchenko, I.M. Hrubnyk, D.V. Rybachuk . - Kh.: Publishing House of the National Academy of Sciences, 2008. - 45 p.
- Technology of medicinal products of industrial production: training. manual/ edited by Prof. D.I. Dmitrievsky. – Vinnytsia: Nova kniga, 2008. – 280 p.
- Drug technology. Educational and methodological guide: Education. manual for students higher education hall. / O.I. Tikhonov, P.A. Logvin, S.O. Tikhonova, O.V. Bazulin, T.G. Yarnykh, O.S. Shpychak, O.M. Kotenko; under the editorship O.I. Tikhonova, Kh.: Original, 2009. - 432 p.
- Pharmaceutical encyclopedia / Chief editor. council and the author of the foreword V.P. Black people - 3rd ed., revised. and additional - K.: "MORION", 2016. - 1952 p.
- Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
- European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & Healthcare. - Strasbourg, 2013. - 3638 p.

- Handbook of Pharmaceutical Excipients, 6th edition / RC Rowe, PJ Sheskey,
ME Quinn. - Pharmaceutical Press and American Pharmacists Association, 2009. - 521 p.
- State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicines", 2015. - Vol. 1. - 1128 p.
- State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicines", 2014. - Vol. 2. - 724 p.
- State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 3. - 732 p.
- Powder manufacturing technology: teaching. manual / L.L. Davtyan, R.S. Korytniuk, A.O. Drozdova, I.O. Vlasenko, Z.V. Malenka, V.P. Popovych, V.V. Gladyshev, S.M. Musoev, T.F. Olifirova, L.I. Vishnevska, O.M. Hlushchenko, O.O. Khomich; under the editorship L.L. Davtyan, R.S. Korytnyuk - K.: "Education of Ukraine", 2016. - 141 p.
- S.S. Zuykin. –Kharkiv.: Publishing House of IFNMU-NFaU, 2017. – 44 p.
- Zujkina SS The pharmacotechnological studies of the phytospecies composition for the complex therapy of mastopathy / SS Zujkina, LI Vishnevska // Herald of pharmacy. – 2017. – No. 2 (90). - P. 43-47.

Independent work #3

Topic 3: " Industrial production of injection solutions "

Purpose: The study of factory technology as an educational discipline provides, on the basis of general knowledge and principles, the laws of factory production technology, to form students' knowledge of: theoretical foundations, acquisition of professional skills and skills in the preparation of dosage forms, conducting step-by-step control, standardization, improvement of dosage forms and technologies, studying the influence of storage conditions and the type of packaging on the stability of dosage forms, studying equipment, including new ones, devices and automatic flow lines, modern requirements for the production of dosage forms, for the purity of raw materials, production premises and personnel

Basic concepts: *Sterility* - the absence of viable microorganisms and their spores in

the environment, organism, any material or product.

Pyrogenicity - the absence of pyrogenic substances, or pyrogens, in LP for parenteral use.

Stabilization - is the ability to preserve the properties that characterize the quality of products in accordance with the requirements of regulatory documentation or a technological process aimed at creating a pharmaceutical dispersed system capable of maintaining a stable state, despite physical, chemical and biological processes aimed at changing the phase state (evaporation, melting, sublimation , delamination, agglomeration of particles, etc.), chemical (reactions of hydrolysis, oxidation, reduction, polymerization, racemization, etc.) or biological changes under the influence of microbiological contamination.

Mechanical inclusions are one of the indicators of the quality of sterile substances used for the preparation of parenteral and eye drops. Mechanical inclusions of injection, IV infusion, and ophthalmic solutions are incidental mobile insoluble particles, with the exception of gas bubbles accidentally present in solutions

Plan

1. Theoretical questions:

1. Concept of injection solutions.
2. Requirements for injection solutions.
3. Methods of obtaining injection solutions in production.
4. Requirements for personnel.

Questions for self-control:

1. Methods of depyrogenization of injection solutions.
2. Sterilization of injection solutions in ampoules.
3. Chemical and physical methods of sterilization.
4. Use of preservatives, stabilizers.
5. Sterility control.
6. Post-stage quality control of injection solutions.

Approximate tasks for processing the theoretical material:

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

1. Conduct research on ampoules according to all quality criteria.

3. Test tasks for self-control:

1

Which solutions for parenteral administration from the listed substances are subject to special purification in the absence of the "for injection" variety?

F. Magnesium sulfate, calcium chloride, glucose

G. Gelatin, novocaine, sodium sulfite
H. Sodium nitrite, ergot, calcium chloride
I. Hexamethylenetetramine, novocaine
J. Ascorbic acid, analgin

2

Which solvent is not used in the production of injection solutions:

A. Mineral oils
B. Fatty oils
C. Water
D. Glycerin
E. Ethyl oleate

3

Which oil is not used to prepare injection solutions:

A. Vaselinova
B. Peach
C. Olive
D. Sonyashnikova
E. Corn

4

The ampoule workshop of the enterprise produces calcium gluconate solution for injections. Indicate from which impurities calcium gluconate is purified in the absence of the "for injection" variety.

F. From impurities of calcium oxalate
G. From impurities of iron salts
H. From impurities of manganese and iron salts
I. From impurities of calcium sulfate and iron
J. From dyes and pyrogenic substances

5

The ampoule workshop produces solutions for injections. Specify the stabilizer for 1% solution of morphine hydrochloride for injection.

A. Hydrochloric acid solution 0.1 N
B. Sodium chloride solution 0.1 N
C. Aminopropylene glycol
D. Rongalite
E. Sodium metabisulfite

6

To stabilize 5%, 10%, 20% solutions of novocaine, which are manufactured in industrial conditions, use:

A. Hydrochloric acid 0.1 n
B. Antioxidants in combination with hydrochloric acid
C. Meadows

D. Buffer solutions
E. Weibel stabilizer

7

What stabilizer should be taken to stabilize glucose solutions:

A. Weibel stabilizer
B. Kurshman stabilizer
C. Stabilizer 0.1M NaOH
D. Stabilizer 0.1M HCl
E. Carboxymethyl cellulose

8

The ampoule workshop of the enterprise produces solutions for injections. Specify the composition of Weibel's reagent, which is used in the production of glucose injection solutions:

A. Hydrochloric acid, sodium chloride, water
B. Water, hydrochloric acid, sodium hydroxide
C. Hydrochloric acid, sodium bromide, water
D. Hydrochloric acid, sodium nitrite
E. Hydrochloric acid, calcium chloride, water

9

In what quantity is the Weibel stabilizer added to parenteral solutions.

A. 5%
B. 13%
C. 15%
D. 7%
E. 1%

10

Solutions for injections are made in the ampoule workshop. Indicate which group of solutions the ascorbic acid solution for injections belongs to:

A. Solutions that are easily oxidized
B. Solutions of substances that require special cleaning
C. Solutions of substances that are not subject to thermal sterilization
D. Salt solutions formed by weak bases and strong acids
E. Salt solutions formed by strong bases and weak acids

11

The ampoule workshop of the enterprise produces a caffeine-benzoathunatrium solution for injections. What stabilizer is added to stabilize the solution:

A. 0.1 M sodium hydroxide solution
B. Sodium metabisulfite
C. 0.1 M solution of hydrochloric acid
D. 0.1 M solution of hydrochloric acid and sodium chloride
E. Sodium bicarbonate and sodium sulfite

12

A solution of magnesium sulfate for injections is produced at a pharmaceutical enterprise. Specify the features of preparation of this solution:

A. Preparation of the solution, cleaning from impurities of manganese and iron salts

B. Preparation of solution without thermal sterilization

C. Preparation of a solution of higher concentration and purification from impurities of calcium sulfate and iron

D. Dissolution of the medicinal substance during heating and purification from impurities of calcium oxalate

E. Cleaning the solution from dyes and pyrogenic substances

13

To remove impurities from the glucose injection solution, special cleaning is carried out with the help of the following substances:

F. Adsorption of impurities on activated carbon

G. By adding calcium hydroxide followed by filtration

H. By adding hydrochloric acid followed by adsorption on activated carbon

I. Preliminary treatment with activated carbon followed by stabilization with hydrochloric acid

J. By adding iron oxide followed by adsorption of impurities on activated carbon

14

Solutions for injections of salts of weak acids and strong bases require stabilization. Specify which stabilizers are used for these solutions:

A. 0.1 M sodium hydroxide solution

B. 0.1 M solution of hydrochloric acid

C. Trylon B

D. Ascorbic acid

E. Butyloxytoluene

15

The ampoule workshop of the enterprise produces oil solutions for injections. What solvent is used in the production of a 20% injection solution of camphor in oil:

A. Peach oil

B. Olive oil

C. Polyethylene glycol 400

D. Vaseline oil

E. Benzyl benzoate

16

The ampoule workshop of the enterprise produces an oil solution of camphor for injections. Indicate what volume of oil solution must be prepared to fill 200 ampoules of 1 ml each.

A. 230 ml

B. 220 ml

C. 210 ml
D. 200 ml
E. 240 ml

17

The ampoule workshop of the enterprise produces glucose solution. Indicate from which impurities glucose is purified in the absence of the "for injection" variety:

F. From pyrogenic substances and dyes
G. From sulfates and iron
H. From manganese and iron
I. From pyrogenic and protein substances
J. From impurities of protein nature and dyes

18

Specify the methods of control of solutions for parenteral administration on mechanical inclusions:

F. Visual and optical
G. Limulus test
H. Amperometric methods
I. Gravitational methods
J. NMR and UV spectroscopy

19

Benzyl alcohol is used as part of solutions for parenteral administration as:

A. Antimicrobial preservative
B. Antioxidant
C. Buffer solution
D. pH regulator
E. Isotonicity regulator

20

One of the operations of the technological process of obtaining solutions for injections is filtering solutions. What filters are used for sterile filtration?

F. Candle filters
G. Print filters
H. Filter fungus
I. Nutch filters
J. HNDHFI filter

21

A solution for injections is prepared in the ampoule workshop. Indicate which group of solutions Eufilin for injections belongs to:

A. Solutions that are not subject to thermal sterilization
B. Salt solutions formed by weak bases and strong acids
C. Solutions of substances that require special cleaning
D. Salt solutions formed by strong bases and weak acids

E. Solutions that are easily oxidized

22

Euphilin solution for injections is manufactured at the pharmaceutical enterprise. Specify the features of preparation of this solution:

F. Cleaning by sterile filtration

G. Cleaning the solution from coloring and pyrogenic substances

H. Dissolution of the medicinal substance during heating

I. Preparation of a solution of higher concentration

J. Adding stabilizer

23

When calculating the isotonic concentration of solutions for injections, the value of blood plasma depression is used. Specify its value:

A. 0.52

B. 0.34

C. 0.10

D. 0.45

E. 0.90

24

Specify the optimal method of drying sterile powders for injections:

F. In freeze dryers

G. In chamber vacuum-drying devices

H. In spray dryers

I. In fluidized bed dryers

J. In chamber air circulation dryers

25

Name the main operations at the ampoule stage:

F. Filling ampoules with solution, sealing ampoules, quality assessment

G. Washing ampoules, filling ampoules with solution, sealing ampoules

H. Washing ampoules, drying and sterilization, quality assessment

I. Washing ampoules, drying, filling ampoules with solution, sealing ampoules, quality assessment

J. Filling ampoules with a solution, sterilization, washing, quality assessment

26

In the ampoule workshop, ampoules are filled with a volume that is greater than the nominal one. For what purpose it is carried out:

A. To ensure the correct dose when filling the syringe

B. To be able to take part of the solution for analysis

C. To remove air bubbles from the solution

D. To account for production losses

E. To ensure the stability of the solution

27

Which of the specified methods of filling ampoules allows you to prevent contamination of capillaries with thick and viscous solutions:

A. Syringe
B. Vacuum
C. Turbo vacuum
D. Vapor condensation
E. Filling in an environment of inert gases

28

The pharmaceutical enterprise produces solutions for injections. Which method can be used to fill ampoules with an oil solution:

A. Syringe
B. Vacuum
C. Vapor condensation
D. Turbo vacuum
E. Ultrasonic

29

The ampoule workshop of the enterprise produces a 5% oil solution of tocopherol acetate for injections. Indicate which method of filling ampoules is rational to use when filling ampoules with this solution.

A. Vapor condensation
B. Vacuum
C. Syringe
D. Syringe and vacuum
E. Syringe and steam-condensing

30

For which injection solutions ampoulation is carried out in an environment of inert gases (nitrogen, argon, carbon dioxide)?

A. A substance that is easily oxidized
B. Essential oils
C. powders
D. Hydrolytically unstable substances
E. Photosensitive substances

31

What infusion solutions are injected into the body when it is necessary to correct the composition of the blood in case of dehydration caused by diarrhea, brain swelling, toxicosis:

A. Regulators of water-salt balance and acid-alkaline balance
B. Hemodynamic antishock drugs
C. Detoxifying solutions
D. Preparations for parenteral nutrition
E. Solutions with the function of oxygen transfer

32
To which group of infusion solutions belong polyvinylpyrrolidone, polyvinyl alcohol, hemodeze, neohemodeze, polydeze:
A. Detoxifying solutions
B. Hemodynamic, anti-shock fluids
C. Regulators of water-salt balance
D. Preparations for parenteral nutrition
E. Solutions with the function of oxygen transfer
33
What is the peculiarity of the calcium gluconate solution technology?
A. Dissolving in hot water
B. Prepared in aseptic conditions without further sterilization
C. Preliminary sterilization of the powder
D. Filling the bottle with a solution for 2/3 of the volume
E. Stabilization with a solution of 0.1 M hydrochloric acid
34
Solutions for injections are made in the ampoule workshop. Indicate which group of solutions the ascorbic acid solution for injections belongs to:
A. Solutions that are easily oxidized
B. Solutions of salts formed by strong bases and weak acids
C. Solutions of substances that are not subject to thermal sterilization
D. Salt solutions formed by weak bases and strong acids
E. Solutions of substances that require special cleaning
35
The pharmacist prepared an injection solution with an easily oxidizing substance that needs stabilization with an antioxidant. Specify this substance:
A. Ascorbic acid
B. Diphenhydramine
C. Sodium chloride
D. Urotropin
E. Calcium gluconate
36
The pharmacist prepared an injection solution of ascorbic acid. Specify the substance needed to stabilize the solution:
A. Sodium sulfite
B. Sodium citrate
C. Sodium acetate
D. Sodium chloride
E. Sodium bromide
37
What is the peculiarity of the calcium gluconate solution technology?

A. Dissolving in hot water
B. Stabilization with a solution of 0.1 M hydrochloric acid
C. Prepared in aseptic conditions without further sterilization
D. Preliminary sterilization of the powder
E. Filling the bottle with a solution for 2/3 of the volume

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

1 . Make a technological block diagram of the industrial production of injection solutions in ampoules.

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
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- Workshop on industrial technology of medicinal products: teaching. manual for students higher education institutions with the specialty "Pharmacy" / O.A. Ruban, D.I. Dmytrievskyi, L.M. Khokhlova [and others]; under the editorship O.A. Ruban. – Kh.: National Institute of Medical Sciences; Original, 2015. – 320 p.
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- Study guide for preparation for the final modular control and State certification in the Industrial Technology of Medicines for full-time and part-time students of the "Pharmacy" specialty / Ed. O.A. Ruban. - Kh.: National Academy of Sciences, 2016 . - 80 p.
- Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing integrated exam "Step 2. Pharmacy" / O.A. Ruban, V.D. Rybachuk, L.M. Khokhlova, D.S. Pulyaev - KH.: NF and U, 2016. - 63 p.
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Auxiliary :

- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
- Regulatory and technical documentation and production validation. Material balance: Educational method. river for audit. and external audit. student work special "Pharmacy" of full-time and part-time education / D.I. Dmytrievskyi, G.D. Slipchenko, I.M. Hrubnyk, D.V. Rybachuk . - Kh.: Publishing House of the National Academy of Sciences, 2008. - 45 p.
- Technology of medicinal products of industrial production: training. manual/ edited by Prof. D.I. Dmitrievsky. – Vinnytsia: Nova kniga, 2008. – 280 p.
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- Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
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- Handbook of Pharmaceutical Excipients, 6th edition / RC Rowe, PJ Sheskey,

ME Quinn. - Pharmaceutical Press and American Pharmacists Association, 2009. - 521 p.

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- State Pharmacopoeia of Ukraine / State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd ed. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicines", 2014. - Vol. 2. - 724 p.
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Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 3. - 732 p.

- Powder manufacturing technology: teaching. manual / L.L. Davtyan, R.S. Korytniuk, A.O. Drozdova, I.O. Vlasenko, Z.V. Malenka, V.P. Popovych, V.V. Gladyshev, S.M. Musoev, T.F. Olifirova, L.I. Vishnevska, O.M. Hlushchenko, O.O. Khomich; under the editorship L.L. Davtyan, R.S. Korytnyuk - K.: "Education of Ukraine", 2016. - 141 p.
- S.S. Zuykin. –Kharkiv.: Publishing House of IFNMU-NFaU, 2017. – 44 p.

Zujkina SS The pharmacotechnological studies of the phytospecies composition for the complex therapy of mastopathy / SS Zujkina, LI Vishnevska // Herald of pharmacy. – 2017. – No. 2 (90). - P. 43-47.

Independent work #4

Topic 4: " Industrial production of infusions solutions »

Purpose: to study the peculiarities of the technology of industrial production of infusion solutions, to study the main technological operations and equipment necessary for the production of infusion solutions under production conditions.

Basic concepts:

Sterility is the complete absence of living microorganisms and their spores.

Isotonic solutions are solutions that have an osmotic pressure equal to the osmotic pressure of physiological body fluids (blood, plasma, lymph, tear fluid, etc.).

Plasma substitute solutions - solutions that, based on the composition of dissolved substances, osmotic pressure, viscosity and pH value compared to blood plasma, are able to support the vital activity of cells and organs and do not cause significant changes in the physiological balance in the body.

Isohydria is the correspondence of the pH of the solution to the pH of the blood.

Isoviscosity is the correspondence between the viscosity of the solution and the viscosity of blood.

Equipment: ampoules, sterilizers, dispenser (for example, auger), packaging container, examples of packaging.

Plan

1. Theoretical questions:

1. Concept of injection solutions.
2. Requirements for injection solutions.
3. Methods of obtaining injection solutions in production.
4. Requirements for personnel.

Questions for self-control:

1. Methods of depyrogenization of injection solutions.
2. Sterilization of injection solutions in ampoules.
3. Chemical and physical methods of sterilization.
4. Use of preservatives, stabilizers.
5. Sterility control.
6. Post-stage quality control of injection solutions.

Approximate tasks for processing the theoretical material:

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

1. Carry out quality control of infusion solutions in vials.

3. Test tasks for self-control:

1

What brand of glass belongs to the first class?

F. USP-1
G. AB-1 (free glass)
H. NS-2 (neutral glass-2)
I. NS-2 A (neutral glass-2A)
J. MTB (medical container colorless)

2

What brand of glass can be used to make ampoules for tocopherol solution?

F. AB-1
G. NS-3
H. NS-1
I. HT-1
J. SNA-1

3

What brand of glass belongs to the second class?

F. AB-1 (free glass)
G. USP-1
H. NS-1 (neutral glass-1)
I. NS-3 (neutral glass-3)
J. SNS-1 (neutral photosensitive glass)

4

What brand of glass is not used for the manufacture of ampoules:

F. MTB (medical container colorless)
G. AB-1 (free glass)

H. NS-1 (neutral glass-1)
I. NS-3 (neutral glass-3)
J. SNS-1 (neutral photosensitive glass)
5
During the production of ampoules, to change the properties of glass, various components are introduced into its composition. What is the purpose of adding boron oxide to glass?
F. To increase the chemical resistance of glass
G. To reduce the melting temperature of ampoule glass
H. To give the glass the necessary color
I. To increase the mechanical strength of glass
J. To increase the thermal stability of glass
6
When assessing the quality of ampoules, chemical resistance is determined. Specify the methods of determining this indicator:
F. With the help of various acid-base indicators, with the help of a pH meter, weight methods
G. Visual, weight
H. Polarization-optical
I. The method of autoclaving followed by titration with a solution of hydrochloric acid
J. The method of impacting glass samples with sodium carbonate solution and sodium hydrogen carbonate solution
7
Specify the device for determining the residual voltage in the ampoule glass:
F. Polariscope-polarimeter
G. Densimeter
H. pH meter
I. Photoelectric colorimeter
J. Spectrophotometer
8
To determine the residual voltage in the ampoule glass, the following method is used:
F. Polarization-optical
G. Methylene blue solution
H. Using a pycnometer
I. Using a "drum eraser"
J. Using the Soxhlet apparatus
9
How does the residual stress in the glass affect the quality of ampoules:
F. Mechanical stability decreases
G. Mechanical stability increases

H. Chemical resistance increases
I. The size of the ampoule increases
J. The color of the ampoule changes

10

In the ampoule shop, before using the ampoules, it is necessary to remove the residual voltage. What operation is performed for this:

F. Annealing of ampoules
G. Drying in tunnel ovens
H. Washing with desalted water
I. Capillary cutting
J. Softening of glass with gas burners

11

According to which parameter is the calibration of glass wire at glass factories:

F. By outer diameter
G. By inner diameter
H. By the thickness of the walls
I. By length
J. By mass

12

The technological stage "Preparation of ampoules for filling" includes operations of drying and sterilization of ampoules. Choose the equipment and equipment to perform this operation:

F. Tunnel dryer, drying cabinets, drying cabinets of laminar flow of heated air
G. Drying cabinets of laminar flow of heated air, Krupina chamber, ultrasonic installation
H. AP-7 and AP-18 type steam sterilizers, Rezepina apparatus
I. Ultrasonic installation, tunnel dryer, drying cabinets
J. Krupin's chamber, ultrasonic installation, Rezepin's apparatus, laminar heated air flow drying cabinets

13

In the production of ampoules, glass with the necessary heat resistance is selected. Indicate what this property of ampoule glass provides so that the ampoules meet the requirements of regulatory and technical documentation:

F. Withstand sharp temperature fluctuations
G. Easy cutting of capillaries
H. High-quality sealing of ampoules
I. Load bearing during production and transportation
J. Ability to protect light-sensitive substances

14

What percentage of the ampoules tested for the "heat resistance" indicator should be intact:

F. 98%
G. 75%
H. 30%
I. 50%
J. 95%

15

When testing the thermal stability of 100 ampoules from one batch, 20 ampoules cracked. Whether heat-resistant glass was used in their manufacture:

F. No, there must be 98 integers
G. No, there must be 95 integers
H. No, there must be 90 integers
I. Yes, there should be 80 integers
J. Yes, there should be 75 integers

16

In the production of ampoules, glass with the required low melting point is selected. What provides this property of ampoule glass:

A. High-quality and fast sealing of ampoules
B. Easy cutting of capillaries
C. Load bearing during production and transportation
D. Withstand sharp temperature fluctuations
E. Ability to protect light-sensitive solutions

17

Different brands of glass are used in the production of ampoules for injection solutions. Indicate what brand of glass can be used to make ampoules for solutions that are sensitive to light:

F. SNA-1
G. NS-1
H. NS-3
I. AB-1
J. HT-1

18

What brand of glass should be used in the manufacture of ampoules for 0.01% cyanocobalamin solution?

F. Light protective neutral (SNS-1)
G. Bezborne (AB-1)
H. Neutral (NS-2)
I. Neutral (NS-1)
J. Neutral (NS-2A)

19

The ampoule workshop of the enterprise produces solutions for injections. From the proposed list, select the brands of ampoule glass used in the production of novocaine

injection solution:

F. NS-3, NS-1, USP-1
G. NS-1, NS-2, NS-3
H. SNS-1, NS-2A, NS-3
I. OS-1, USP-1, NS-2
J. HT-1, SNS-1, AB-1

20

Which solutions for parenteral administration from the listed substances are subject to special purification in the absence of the "for injection" variety?

K. Magnesium sulfate, calcium chloride, glucose
L. Gelatin, novocaine, sodium sulfite
M. Sodium nitrite, ergot, calcium chloride
N. Hexamethylenetetramine, novocaine
O. Ascorbic acid, analgin

21

At a pharmaceutical enterprise, demineralized water is obtained using membrane separation methods. Choose a method in which the passage of water through a semipermeable membrane is carried out under the influence of external pressure:

F. Reverse osmosis
G. Electrodialysis
H. Evaporation through a membrane
I. Dialysis
J. Sorption

22

Specify the requirements for water for injections that significantly differentiate it from purified water:

F. Absence of pyrogens
G. Absence of heavy metals
H. Absence of sulfates, chlorides
I. Absence of nitrites and nitrates
J. Absence of reducing substances

23

Which solvent is not used in the production of injection solutions:

F. Mineral oils
G. Fatty oils
H. Water
I. Glycerin
J. Ethyl oleate

24

Which oil is not used to prepare injection solutions:

F. Vaselinova

G. Peach
H. Olive
I. Sonyashnikova
J. Corn

25

The ampoule workshop of the enterprise produces calcium gluconate solution for injections. Indicate from which impurities calcium gluconate is purified in the absence of the "for injection" variety.

K. From impurities of calcium oxalate
L. From impurities of iron salts
M. From impurities of manganese and iron salts
N. From impurities of calcium sulfate and iron
O. From dyes and pyrogenic substances

26

The ampoule workshop produces solutions for injections. Specify the stabilizer for 1% solution of morphine hydrochloride for injection.

F. Hydrochloric acid solution 0.1 N
G. Sodium chloride solution 0.1 N
H. Aminopropylene glycol
I. Rongalite
J. Sodium metabisulfite

27

To stabilize 5%, 10%, 20% solutions of novocaine, which are manufactured in industrial conditions, use:

F. Hydrochloric acid 0.1 n
G. Antioxidants in combination with hydrochloric acid
H. Meadows
I. Buffer solutions
J. Weibel stabilizer

28

What stabilizer should be taken to stabilize glucose solutions:

F. Weibel stabilizer
G. Kurshman stabilizer
H. Stabilizer 0.1M NaOH
I. Stabilizer 0.1M HCl
J. Carboxymethyl cellulose

29

The ampoule workshop of the enterprise produces solutions for injections. Specify the composition of Weibel's reagent, which is used in the production of glucose injection solutions:

F. Hydrochloric acid, sodium chloride, water

G. Water, hydrochloric acid, sodium hydroxide
H. Hydrochloric acid, sodium bromide, water
I. Hydrochloric acid, sodium nitrite
J. Hydrochloric acid, calcium chloride, water

30

In what quantity is the Weibel stabilizer added to parenteral solutions.

F. 5%
G. 13%
H. 15%
I. 7%
J. 1%

31

Solutions for injections are made in the ampoule workshop. Indicate which group of solutions the ascorbic acid solution for injections belongs to:

A. Solutions that are easily oxidized
B. Solutions of substances that require special cleaning
C. Solutions of substances that are not subject to thermal sterilization
D. Salt solutions formed by weak bases and strong acids
E. Salt solutions formed by strong bases and weak acids

32

For what purpose is activated carbon used in the manufacture of injection solutions:

F. For the purpose of cleaning some injection solutions
G. To create a buffer system
H. As an antioxidant
I. To increase the chemical resistance of ampoule glass
J. To remove residual voltage in ampoules

33

A solution of magnesium sulfate for injections is produced at a pharmaceutical enterprise. Specify the features of preparation of this solution:

F. Preparation of the solution, cleaning from impurities of manganese and iron salts
G. Preparation of solution without thermal sterilization
H. Preparation of a solution of higher concentration and purification from impurities of calcium sulfate and iron
I. Dissolution of the medicinal substance during heating and purification from impurities of calcium oxalate
J. Cleaning the solution from dyes and pyrogenic substances

34

To remove impurities from the glucose injection solution, special cleaning is carried out with the help of the following substances:

K. Adsorption of impurities on activated carbon
L. By adding calcium hydroxide followed by filtration

M. By adding hydrochloric acid followed by adsorption on activated carbon
N. Preliminary treatment with activated carbon followed by stabilization with hydrochloric acid
O. By adding iron oxide followed by adsorption of impurities on activated carbon
35
At a pharmaceutical enterprise, one of the methods of sterilizing heat-labile substances is the tyndalization method. Indicate what the essence of this method is:
F. Three times heating of the solution to 40-60°C with breaks per day for thermostating
G. Autoclaving at a temperature of 119-121°C and a pressure of 1.01.1 atm
H. Sterilization at 100°C with flowing steam
I. Sterilization by dry heat at 180-200°C for a long time
J. High and ultra-high frequency current sterilization
36
Solutions for injections of salts of weak acids and strong bases require stabilization. Specify which stabilizers are used for these solutions:
F. 0.1 M sodium hydroxide solution
G. 0.1 M solution of hydrochloric acid
H. Trylon B
I. Ascorbic acid
J. Butyloxytoluene
37
The ampoule workshop of the enterprise produces a caffeine-benzoathunatrium solution for injections. What stabilizer is added to stabilize the solution:
F. 0.1 M sodium hydroxide solution
G. Sodium metabisulfite
H. 0.1 M solution of hydrochloric acid
I. 0.1 M solution of hydrochloric acid and sodium chloride
J. Sodium bicarbonate and sodium sulfite
38
The ampoule workshop of the enterprise produces oil solutions for injections. What solvent is used in the production of a 20% injection solution of camphor in oil:
F. Peach oil
G. Olive oil
H. Polyethylene glycol 400
I. Vaseline oil
J. Benzyl benzoate
39
The ampoule workshop of the enterprise produces an oil solution of camphor for injections. Indicate what volume of oil solution must be prepared to fill 200 ampoules of 1 ml each.

F. 230 ml
G. 220 ml
H. 210 ml
I. 200 ml
J. 240 ml

40

The ampoule workshop of the enterprise produces glucose solution. Indicate from which impurities glucose is purified in the absence of the "for injection" variety:

K. From pyrogenic substances and dyes
L. From sulfates and iron
M. From manganese and iron
N. From pyrogenic and protein substances
O. From impurities of protein nature and dyes

41

Specify the methods of control of solutions for parenteral administration on mechanical inclusions:

K. Visual and optical
L. Limulus test
M. Amperometric methods
N. Gravitational methods
O. NMR and UV spectroscopy

42

Benzyl alcohol is used as part of solutions for parenteral administration as:

F. Antimicrobial preservative
G. Antioxidant
H. Buffer solution
I. pH regulator
J. Isotonicity regulator

43

One of the operations of the technological process of obtaining solutions for injections is filtering solutions. What filters are used for sterile filtration?

K. Candle filters
L. Print filters
M. Filter fungus
N. Nutch filters
O. HNDHFI filter

44

A solution for injections is prepared in the ampoule workshop. Indicate which group of solutions Eufilin for injections belongs to:

F. Solutions that are not subject to thermal sterilization
G. Salt solutions formed by weak bases and strong acids

H. Solutions of substances that require special cleaning
I. Salt solutions formed by strong bases and weak acids
J. Solutions that are easily oxidized
45
Euphilin solution for injections is manufactured at the pharmaceutical enterprise. Specify the features of preparation of this solution:
K. Cleaning by sterile filtration
L. Cleaning the solution from coloring and pyrogenic substances
M. Dissolution of the medicinal substance during heating
N. Preparation of a solution of higher concentration
O. Adding stabilizer
46
When calculating the isotonic concentration of solutions for injections, the value of blood plasma depression is used. Specify its value:
F. 0.52
G. 0.34
H. 0.10
I. 0.45
J. 0.90
47
Specify the optimal method of drying sterile powders for injections:
K. In freeze dryers
L. In chamber vacuum-drying devices
M. In spray dryers
N. In fluidized bed dryers
O. In chamber air circulation dryers
48
Name the main operations at the ampoule stage:
K. Filling ampoules with solution, sealing ampoules, quality assessment
L. Washing ampoules, filling ampoules with solution, sealing ampoules
M. Washing ampoules, drying and sterilization, quality assessment
N. Washing ampoules, drying, filling ampoules with solution, sealing ampoules, quality assessment
O. Filling ampoules with a solution, sterilization, washing, quality assessment
49
In the ampoule workshop, ampoules are filled with a volume that is greater than the nominal one. For what purpose it is carried out:
F. To ensure the correct dose when filling the syringe
G. To be able to take part of the solution for analysis
H. To remove air bubbles from the solution
I. To account for production losses

J. To ensure the stability of the solution

50

Which of the specified methods of filling ampoules allows you to prevent contamination of capillaries with thick and viscous solutions:

F. Syringe
G. Vacuum
H. Turbo vacuum
I. Vapor condensation
J. Filling in an environment of inert gases

51

The pharmaceutical enterprise produces solutions for injections. Which method can be used to fill ampoules with an oil solution:

F. Syringe
G. Vacuum
H. Vapor condensation
I. Turbo vacuum
J. Ultrasonic

52

The ampoule workshop of the enterprise produces a 5% oil solution of tocopherol acetate for injections. Indicate which method of filling ampoules is rational to use when filling ampoules with this solution.

F. Vapor condensation
G. Vacuum
H. Syringe
I. Syringe and vacuum
J. Syringe and steam-condensing

53

For which injection solutions ampoulation is carried out in an environment of inert gases (nitrogen, argon, carbon dioxide)?

F. A substance that is easily oxidized
G. Essential oils
H. powders
I. Hydrolytically unstable substances
J. Photosensitive substances

54

What infusion solutions are injected into the body when it is necessary to correct the composition of the blood in case of dehydration caused by diarrhea, brain swelling, toxicosis:

F. Regulators of water-salt balance and acid-alkaline balance
G. Hemodynamic antishock drugs
H. Detoxifying solutions

I. Preparations for parenteral nutrition
J. Solutions with the function of oxygen transfer

55

To which group of infusion solutions belong polyvinylpyrrolidone, polyvinyl alcohol, hemodeze, neohemodeze, polydeze:

F. Detoxifying solutions
G. Hemodynamic, anti-shock fluids
H. Regulators of water-salt balance
I. Preparations for parenteral nutrition
J. Solutions with the function of oxygen transfer

56

What is the peculiarity of the calcium gluconate solution technology?

A. Dissolving in hot water
B. Prepared in aseptic conditions without further sterilization
C. Preliminary sterilization of the powder
D. Filling the bottle with a solution for 2/3 of the volume
E. Stabilization with a solution of 0.1 M hydrochloric acid

57

Solutions for injections are made in the ampoule workshop. Indicate which group of solutions the ascorbic acid solution for injections belongs to:

A. Solutions that are easily oxidized
B. Solutions of salts formed by strong bases and weak acids
C. Solutions of substances that are not subject to thermal sterilization
D. Salt solutions formed by weak bases and strong acids
E. Solutions of substances that require special cleaning

58

The pharmacist prepared an injection solution with an easily oxidizing substance that needs stabilization with an antioxidant. Specify this substance:

A. Ascorbic acid
B. Diphenhydramine
C. Sodium chloride
D. Urotropin
E. Calcium gluconate

59

The pharmacist prepared an injection solution of ascorbic acid. Specify the substance needed to stabilize the solution:

A. Sodium sulfite
B. Sodium citrate
C. Sodium acetate
D. Sodium chloride
E. Sodium bromide

What is the peculiarity of the calcium gluconate solution technology?

A. Dissolving in hot water
B. Stabilization with a solution of 0.1 M hydrochloric acid
C. Prepared in aseptic conditions without further sterilization
D. Preliminary sterilization of the powder
E. Filling the bottle with a solution for 2/3 of the volume

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

1 . Make a technological block diagram of the industrial production of infusion solutions in vials.

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
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Auxiliary :

- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
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- Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
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Independent work #5

Topic 5: " Industrial production of eye, ear and nasal dosage forms "

Purpose: to study the peculiarities of the technology of industrial production of eye, ear and nasal dosage forms, to study the main technological operations and equipment necessary for the production of eye, ear and nasal dosage forms in production conditions.

Basic concepts:

Sterility is the complete absence of living microorganisms and their spores.

Isotonic solutions are solutions that have an osmotic pressure equal to the osmotic pressure of physiological body fluids (blood, plasma, lymph, etc.).

Isoionicity is the property of other injection solutions to contain certain ions in the ratio and quantities typical for blood serum.

Prolongation – extension of the duration of action of drugs after their single use or an increase in the concentration of API in the body for a significant period of time.

Plan

1. Theoretical questions:

1. Creation of aseptic conditions during the production of ophthalmic dosage forms.
2. Methods of stabilization of low-stable dosage forms.
3. Modern classification of ophthalmic dosage forms.
4. Requirements for ophthalmic dosage forms.
5. General technological scheme of production of eye drops.

6. General characteristics of medicated eye films. Excipients used in LPG production.
7. Types of eye drops packaging, their advantages and disadvantages.
8. General characteristics. Classification. Requirements

Questions for self-control:
1. Concepts of ocular LF.
2. The concept of ear LF.
3. The concept of nasal LF.
3. Requirements for eye LF.
5. Requirements of nasal LF.
6. Requirements of nasal LF.
7. Methods of obtaining eye, ear and nasal LF.
8. Personnel requirements.
9. Methods of depyrogenization of ophthalmic LF.
10. Sterilization.
11. Use of preservatives, stabilizers.
12 . Control of sterility.
13 . Step-by-step quality control of eye, ear and nasal LF .

Approximate tasks for processing the theoretical material:
— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Conduct a study of ophthalmic dosage forms according to all quality criteria.

3. Test tasks for self-control:
1
Which of the ophthalmic medicinal forms of industrial manufacture are called minimsami:
A. Eye lotions
B. Eye dosage forms of prolonged action
C. Solutions for washing eye lenses
D. Gelatin oval discs for single use
E. Ocular dosage forms and single use
2
Depending on the solubility, eye inserts are divided into:
A. emulsions, fat-soluble, combined
B. Biodissolving, lachrymatory, mixed
C. Single-acting, non-soluble, biosolubility
D. Water-soluble, fat-soluble, combined
E. Water-soluble, insoluble, combined

3
At the pharmaceutical enterprise, single-use ophthalmic dosage forms - lamellae - are produced. Which of the listed substances is used for their preparation?
A. agar
B. collagen
C. methylcellulose
D. is elatin
E. chitosan
4
The following film-forming substances are used for the production of eye films as biosoluble polymers:
A. Phenolformaldehyde and perchlorvinyl resins
B. Collagen, acetyl starch, methyl cellulose, derivatives of acrylic acid
C. Oil and epoxy resins, casein
D. Burshtin, rosin, copal and others
E. To arabamido and melaminoformaldehyde resins
5
At the pharmaceutical enterprise, medicated ophthalmic films with a bio-soluble polymer are manufactured. Specify which of the listed substances are used for their preparation:
A. * Collagen
B. Methylcellulose, Na-carboxymethylcellulose
C. polyvinylpyrrolidone, polyvinyl alcohol
D. Starch, dextran
E. Gelatin, gelatoses
6
Which of the excipients is NOT used to adjust the viscosity of eye drops?
A. hydroxypropylmethyl cellulose
B. magnesium silicate
C. polyvinyl alcohol
D. polyvinylpyrrolidone
E. methylcellulose
7
A suspension of steroid hormones for ophthalmology is manufactured at a pharmaceutical enterprise. Specify which auxiliary substances are used to stabilize the dispersed phase.
A. Methyl cellulose
B. Twin -80
C. Spen -80
D. proxanol
E. PEG-400 and 0.1% sodium chloride solution

At the pharmaceutical enterprise, eye medicines are manufactured in dropper tubes. Specify the method of their sterilization:
A. radiation
B. dry heat
C. autoclaving
D. Nitriding
E. filtration

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

1 . Compile a technological block diagram of the industrial production of eye, ear, and nasal dosage forms.

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
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Independent work #6

Topic 6: " Theoretical foundations of extraction "

Purpose: The study of factory technology as an educational discipline provides, on the basis of general knowledge and principles, the laws of factory production technology, to form students' knowledge of: theoretical foundations, acquisition of professional skills and skills in the preparation of dosage forms, conducting step-by-step control, standardization, improvement of dosage forms and technologies, studying the influence of storage conditions and the type of packaging on the stability of dosage forms, studying equipment, including new ones, devices and automatic flow lines, modern requirements for the production of dosage forms, for the purity of raw materials, production premises and personnel

Basic concepts: *Maceration* is carried out as follows. Crushed raw materials with the proposed amount of extractant are loaded into the maceration tank and infused at a temperature of 15-20 ° C, stirring periodically. If the terms are not specifically stipulated, then insistence is carried out within 7 days. After that, the extract is drained, the residue is squeezed, the extracted extract is washed with a small amount of extractant, it is squeezed again, the extracted extract is added to the extracted extract, after which the combined extract is brought to the required volume with the extractant. *Remaceration* **, or crushed maceration with the separation of extractant, or raw materials and extractant** . The total amount of the extractant is divided into 3-4 parts

and the raw materials are successively insisted with the first part of the extractant, then from the second, third and fourth, draining the hood each time. The time of infusion depends on the properties of the plant material. Such a holding of the extraction process allows you to more fully exhaust the raw materials with less time spent, as a high concentration difference in the raw materials and the extractant is constantly maintained.

Vortex extraction, or turboextraction **,** is based on the vortex, very intensive mixing of raw materials and extractant with simultaneous grinding of raw materials. The turbine mixer rotates at a speed of 8,000-13,000 rpm. The extraction time is reduced to 10 minutes, the tinctures are standard.

Ultrasonic extraction **.** Effective use of ultrasonic vibrations to intensify the maceration process. At the same time, the extraction is accelerated and the complete extraction of the active substances is achieved. The source of ultrasound is placed in the treated environment or attached to the body of the maceration tank in a place filled with extractant and raw materials.

Percolation - (from the Latin "Percolation through ..."), i.e. percolation of the extractant through plant material with the aim of extracting substances soluble in the extractants. The process is carried out in percolators and includes three successive stages: soaking of raw materials, infusion, percolation itself. Soaking can be combined with infusion, but if the raw material is capable of swelling strongly, the soaking stage must be carried out in a separate container. The raw material is poured with half or an equal amount of the extractant, in relation to the mass of the raw material, and left in a closed container for 4-6 hours to swell. Swollen raw materials are loaded into the percolator on a false bottom with optimal density, covered with filter material on top, pressed with a perforated disk and filled with extractant so as to displace air as much as possible.

Plan

1. Theoretical questions:

1. Extracts.
2. Liquid extracts
3. Thick extracts
4. Dry extracts
5. Percolation
6. Maceration, remaceration
7. Vortex extraction, or turboextraction

Questions for self-control:

1. Name the main regulatory and technical documents that regulate the activity of a technologist and are used for the preparation of medicinal products;

2. What do you know about the general principles of production of ready-made medicinal forms;
3. What are the existing categories and structure of regulatory documentation.
4. Conditions of industrial production of drugs according to the rules of GMR.
5. Name the main terms used in the production of medicinal products.
6. How the technological process, production regulations, technical and economic balance is planned;
7. Determine the characteristics, requirements for medicinal products;
8. List the stages of the technological process (general and partial);
9. What is the modern look of packaging, quality assessment and prospects for further improvement of its manufacturing technology

Approximate tasks for processing the theoretical material:
— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:
6. How the technological process, production regulations, technical and economic balance is planned;
7. Determine the characteristics, requirements for medicinal products;
8. List the stages of the technological process (general and partial);
9. What is the modern look of packaging, quality assessment and prospects for further improvement of its manufacturing technology

3. Test tasks for self-control:
1. Name the main regulatory and technical documents that regulate the activity of a technologist and are used for the preparation of medicinal products;
2. What do you know about the general principles of production of ready-made medicinal forms;
3. What are the existing categories and structure of regulatory documentation.
4. Conditions of industrial production of drugs according to the rules of GMR.
5. Name the main terms used in the production of medicinal products.

4. Individual tasks for students of higher education on the topic:
1 . Make a scheme of preparation for extraction .

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
- A.G. Bashura, O.S. Shpichak, E.E. Bogutska; under the editorship A.I. Tikhonov and S.A. Tikhonova - Kh.: Original, 2016. - 462 p.
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- Workshop on industrial technology of medicinal products: teaching. manual for students higher education institutions with the specialty "Pharmacy" / O.A. Ruban, D.I. Dmytrievskyi, L.M. Khokhlova [and others]; under the editorship O.A. Ruban. – Kh.: National Institute of Medical Sciences; Original, 2015. – 320 p.
- INDUSTRIAL technology of medicines : education. manual for students' independent work / O.A. RUBAN , V.D. RYBACHUK , L.M. X ohlova etc. - KH.: NF and U, 2015. - 120 p.
- Study guide for preparation for the final modular control and State certification in the Industrial Technology of Medicines for full-time and part-time students of the "Pharmacy" specialty / Ed. O.A. Ruban. - Kh.: National Academy of Sciences, 2016 . - 80 p.
- Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing integrated exam "Step 2. Pharmacy" / O.A. Ruban, V.D. Rybachuk, L.M. Khokhlova, D.S. Pulyaev - KH.: NF and U, 2016. - 63 p.
- Auxiliary substances in the production of medicines: training. manual for students higher pharmacy education closing / O.A. RUBAN , I.M. _ Pertsev, S.A. Kutsenko, Yu.S. Oily; under the editorship I.M. Pepper - Kh.: Golden Pages, 2016. - 720 p.
- Modern pharmaceutical technologies: education. manual to laboratory classes of full-time, evening and part-time master's students of the specialty 8.110201 "Pharmacy" / under the editorship. O.A. Ruban. - Kh.: Publishing House of the National Academy of Sciences, 2016. - 256 p.

Auxiliary :

- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
- Regulatory and technical documentation and production validation. Material balance: Educational method. river for audit. and external audit. student work special "Pharmacy" of full-time and part-time education / D.I. Dmytrievskyi,

G.D. Slipchenko, I.M. Hrubnyk, D.V. Rybachuk . - Kh.: Publishing House of the National Academy of Sciences, 2008. - 45 p.

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Independent work #7

Topic 7: " Production of tinctures. Spiritometry »

Purpose: To be able to prepare tinctures by the maceration method and evaluate their quality in accordance with the requirements of regulatory and technical documentation.

Basic concepts:

Tinctures (Tincturae) are dyed liquid alcohol or water-alcohol extraction from medicinal plant raw materials, which are obtained without heating and removing the extractant.

Spirometry - is a set of methods used to determine the amount of alcohol (anhydrous alcohol, ethyl alcohol) in various types of alcoholic liquids that have practical or technical significance, for example, in brew, alcohol, vodka, wine, beer, liqueurs, etc. similar liquids , the main components of which are alcohol and water.

Cooking methods

To prepare tinctures, the following methods are used: - maceration and its varieties;

- percolation;
- dissolution of thick and dry extracts.

maceration

Previously, the method of maceration, or infusion, (from the Latin Maceratio - soaking) was widely used to obtain tinctures. Currently, its use is gradually reduced, because during extraction by this method it is difficult to achieve complete extraction of medicinal substances from plant material.

Maceration is carried out as follows. Crushed raw materials with the proposed amount of extractant are loaded into the maceration tank and infused at a temperature of 15-20 ° C, stirring periodically. If the terms are not specifically stipulated, then insistence is carried out within 7 days. After that, the extract is drained, the residue is squeezed, the extracted extract is washed with a small amount of extractant, it is squeezed again, the extracted extract is added to the extracted extract, after which the combined extract is brought to the required volume with the extractant.

Remaceration **, or crushed maceration with the separation of extractant, or raw materials and extractant** . The total amount of the extractant is divided into 3-4 parts and the raw materials are successively insisted with the first part of the extractant, then from the second, third and fourth, draining the hood each time. The time of infusion depends on the properties of the plant material. Such a holding of the extraction process allows you to more fully exhaust the raw materials with less time spent, as a high concentration difference in the raw materials and the extractant is constantly maintained.

Vortex extraction, or turboextraction **,** is based on the vortex, very intensive mixing of raw materials and extractant with simultaneous grinding of raw materials. The turbine mixer rotates at a speed of 8,000-13,000 rpm. The extraction time is reduced to 10 minutes, the tinctures are standard.

Ultrasonic extraction **.** Effective use of ultrasonic vibrations to intensify the maceration process. At the same time, the extraction is accelerated and the complete extraction of the active substances is achieved. The source of ultrasound is placed in the treated environment or attached to the body of the maceration tank in a place filled with extractant and raw materials.

Percolation - (from the Latin "Percolation through ..."), i.e. percolation of the extractant through plant material with the aim of extracting substances soluble in the extractants. The process is carried out in percolators and includes three successive stages: soaking of raw materials, infusion, percolation itself. Soaking can be combined with infusion, but if the raw material is capable of swelling strongly, the soaking stage must be carried out in a separate container. The raw material is poured with half or an equal amount of the extractant, in relation to the mass of the raw material, and left in a closed container for 4-6 hours to swell. Swollen raw materials are loaded into the percolator on a false bottom with optimal density, covered with filter material on top, pressed with a perforated disc and filled with extractant so as to displace air as much as possible.

Plan

1. Theoretical questions:

1. Characteristics and classification of tinctures.
2. Preparation of raw materials and extractant for extraction.
3. Obtaining tinctures by extraction. The essence of the extraction process.
4. Device of maceration tanks and percolators.
5. Methods of intensifying the production of tinctures.
6. Determination of alcohol content in tinctures.
7. Calculation of the amount of raw materials and extractant for obtaining tinctures.
8. Factors affecting the completeness and speed of extraction of active substances.
9. Stages of the method of maceration and remaceration (bismaceration).
10. Sequence of stages during percolation. The equipment used.
11. Methods of purification of tinctures.
12. Standardization. Quality control of tinctures.
13. Storage. Packaging, packaging and labeling of tinctures.

Questions for self-control:

1. Name the methods of obtaining medical ethyl alcohol.

2. How is the concentration of ethanol expressed?
3. Describe the methods and devices for determining the concentration of ethanol:
3.1. using a glass alcohol meter;
3.2. with the help of a metal alcohol meter;
3.3. by density - densimeter (hydrometer);
3.4. for density - pycnometer;
3.5. refractometric method;
3.6. by the amount of surface tension;
4. Give the rules and formulas for diluting ethanol when preparing water-alcohol solutions.
5. Describe the methods of ethanol recovery:
5.1. recovery of ethanol by displacing it with water from spent raw materials;
5.2. recovery by distillation of spent raw materials with steam;
6. Name the purpose and essence of ethanol rectification.
7. Describe the device of the rectification plant installation
8. Name the types of distillation columns .

Approximate tasks for processing the theoretical material:

1. *Compile a dictionary of basic concepts on the topic*

2. From 25 kg of belladonna leaves with an alkaloid content of 0.33%, 245 l of tincture was prepared, which meets the requirements of GF X (0.033% of alkaloids). Draw up a material balance for active substances and calculate output, consumption, expenditure ratio and degree of use of raw materials. Write down the balance in the form of equality and in the form of income and expenditure information.

3. 120 ml of calendula tincture containing 68% ethanol (at 20°C) was obtained, for which 140 liters of 71% ethanol (22°C) were spent. Recover 55 liters of 30% ethanol (24oC) from spent raw materials. Make a material balance for absolute ethanol. Determine the yield, waste, expenditure ratio and degree of use of raw materials.

4. 250 liters of belladonna tincture contain 0.037% alkaloids. How much extractant (40% ethanol) must be added to obtain a standard tincture (0.03%)?

2. Practical works (tasks) to be performed:

1. Make a technological block diagram of the industrial production of tincture.

3. Test tasks for self-control:

1.

Specify the duration of infusion in the production of tinctures by the maceration method:

A. 7 days
B. 1-2 days
C. 24 hours
D. 3-4 hours
E. 14 days

2.

3. Specify the methods of obtaining tinctures:

A. Maceration, percolation, dissolution of extracts
B. Dissolving extracts
C. Percolation, dissolution of extracts
D. Rectification, maceration
E. Percolation, dissolution of plant material

4.

When making liquid dosage forms, the following liquid ingredients are dosed by volume :

A. Valerian tincture.
B. Dimexide
C. Methyl salicylate
D. Polyethylene glycol-400
E. Perhydrol

5.

While preparing an infusion of althea root, the pharmacist made a mistake in the temperature of the water for preparing this extract, and the final product turned out to be cloudy. What temperature is needed for water to extract this raw material?

A. room
B. 40
C. 100
D. 60
E. 80

6.

Transparent liquid water-alcohol extracts from dried or fresh medicinal plant materials, which are obtained without heating and removing the extractant, are called:

A. Tinctures
B. Liquid extracts
C. Thick extracts
D. Extracts-concentrates
E. Oil extracts

7.
Which extraction method is a type of maceration?
A. Bismaceration
B. Percolation
C. Repercolation
D. Dynamization
E. Countercurrent extraction
8.
An alcoholic solution of boric acid is produced in a chemical workshop. What filters are used to filter this solution?
A. Print filters
B. Nutch filters
C. Membrane filters
D. Bag filters
E. Paper filters
9.
The pharmaceutical company produces camphor oil for external use. Specify which oil is used as a solvent:
A. Sonyashnikova
B. Peach
C. Vaseline
D. Olivkova
E. rain
10.
Oil is used in the production of a number of medicinal forms. The method of obtaining this oil is:
A. Pressing
B. Enfleurage
C. Distillation with water
D. Steam distillation
E. Sublimation
11.
During the production of decoctions, the volume of which is 1000-3000 ml, the time of infusion in a boiling water bath of the composition:

A. 40 minutes
B. 25 minutes
C. 30 minutes
D. 45 minutes
E. 15 minutes

12. A pharmacist prepares an extraction ointment. Specify the component that must be used to make this type of ointment:
A. 64 parts of sugar and 36 parts of water
B. 73 parts of sugar, 22 parts of water, 5 parts of 90% alcohol
C. 50 parts of sugar and 50 parts of water
D. 32 parts of sugar, 33 parts of water, 2 parts of 90% alcohol
E. 45 parts of sugar and 55 parts of water
13.
Galenic preparations include:
A. Tinctures
B. Pellets
C. Capsules
D. Aerosols
E. Sponsored
14.
Tween-80 is introduced into emulsion systems. State the role of tween-80 in emulsions:
A. Emulsifier
B. Antioxidant
C. Preservative
D. Corrector of taste
E. Solvent
15.
The pharmacist prepared a solution of cholargol. Specify the type of dispersed system:
A. Colloidal solution
B. The real solution
C. Suspension
D. Emulsion
E. Aerosol
16.
What mainly determines the choice of extractant when obtaining individual substances:
A. Selectivity in relation to active substances
B. The ability to eliminate hydrolysis
C. Heat resistance
D. Pharmacological indifference
E. Cost
17.
The phytochemical workshop of the enterprise produces calendula tincture. Specify which raw materials are used for the manufacture of this drug:

A. Flowers
B. Roots, rhizomes and grass
C. Grass
D. Leaves and essential oil
E. Roots

18.

The enterprise manufactures galena preparations. Galen preparations include:

A. The amount of biologically active substances
B. Only individual active substance
C. Odor correctors
D. Correctors of taste
E. Preservatives

19.

Specify the potent medicinal plant material from which the infusion is prepared in a ratio of 1:400:

A. Foxglove leaves
B. Rhizomes with valerian roots
C. Althea root
D. Sage leaves
E. Stinging nettle herb

20.

The phytochemical workshop produces tinctures. This dosage form is:

A. Alcoholic extracts from medicinal plant raw materials obtained without heating and removing the extractant
B. Aqueous extracts from medicinal plant raw materials
C. Water-ethanol extracts from medicinal plant raw materials containing 25% moisture
D. Oil extracts from medicinal plant raw materials
E. Extracts from medicinal plant raw materials obtained using ether or chloroform

21

Tinctures are made at the pharmaceutical enterprise. For the manufacture of an experimental series of the drug, it is necessary to specify the equipment used for grinding raw materials:

A. Grass cutters
B. excelsior
C. Vibromlin
D. Dismembrator
E. Rolls

22

Which of the following extractants has a number of advantages, including

affordability?

A. Water
B. Ethyl alcohol
C. Methyl alcohol
D. Methylene chloride
E. Ethyl ether

23

Indicate which extractant is used at pharmaceutical enterprises for the manufacture of tinctures:

A. Ethyl alcohol
B. Acetone
C. Chloroform
D. Diethyl ether
E. Peach oil

24

A tincture with an inflated content of active substances was obtained in the phytochemical workshop. To bring the tincture to the standard, it is necessary:

A. Dilute with the extractant to the standard
B. Consider an irreparable defect
C. Deposit excess active substances
D. Leave unchanged
E. Filter through sorbents

25

The phytochemical workshop of the pharmaceutical enterprise produces valerian tincture. Specify the technological features of the production of this drug:

A. It is prepared in 70% ethanol in a ratio of 1:5
B. It is prepared in 70% ethanol in a ratio of 1:10
C. It is prepared in 90% ethanol in a ratio of 1:5
D. It is prepared in 90% ethanol in a ratio of 1:10
E. It is prepared in 95% ethanol in a ratio of 1:10

26

One of the methods of obtaining tinctures in factory conditions is that the total amount of extractant is divided into 3-4 parts and the raw material is successively extracted with the first part of the extractant, then the second, third and fourth, draining the hood each time; the time of infusion depends on the properties of the plant material. What is the name of this method?

A. Remaceration
B. Maceration
C. Percolation
D. Vortex extraction
E. Maceration with forced circulation of the extractant

27

Specify the type of moisture that is tightly bound to the material and that is not completely removed during drying:

A. Crystallization
B. free
C. Hygroscopic
D. Osmotic
E. Balanced

28

Extractive substances are released from plant raw materials due to:

A. Molecular and convective diffusion
B. Molecular and cellular diffusion
C. Convective and cellular diffusion
D. Coacervation
E. Adsorption and readsorption of the extractant by plant raw materials

29

In the manufacture of phytochemical preparations, extraction of extractive substances from plant raw materials occurs due to:

A. Molecular and convective diffusion
B. Molecular and cellular diffusion
C. Convective and cellular diffusion
D. Coacervation
E. Absorption and adsorption of the extractant by plant raw materials

30

Specify the methods of obtaining tinctures:

A. Maceration, percolation, dissolution of extracts
B. Dissolving extracts
C. Percolation, dissolution of extracts
D. Rectification, maceration
E. Percolation, dissolution of plant material

31

The phytochemical workshop of the enterprise produces tinctures by the maceration method. Specify the sequence of technological operations when obtaining tinctures by this method:

A. Insisting for 7 days with periodic mixing of the obtained extract, cleaning the extract, standardization, packaging
B. Soaking for swelling, infusing for 24-48 hours, receiving hood, cleaning hood, standardization, packaging
C. Insisting for 24-48 hours, obtaining a hood, cleaning the hood, standardization, packaging

D. Insisting for 7 days, obtaining a hood, cleaning the hood, standardization, packaging

E. Soaking for swelling, infusing for 7 days, obtaining a hood, cleaning the hood, standardization, packaging

32

Which of the methods of obtaining tinctures is ineffective and characterized by incomplete extraction of extractive substances:

A. Maceration

B. Repercolation with evaporation

C. Percolation

D. Repercolation with the distribution of raw materials into unequal parts

E. Extraction using ultrasound

33

Specify the duration of infusion in the production of tinctures by the maceration method:

A. 7 days

B. 1-2 days

C. 24 hours

D. 3-4 hours

E. 14 days

34

The phytochemical workshop of the enterprise is mastering the production of the drug from fresh plant raw materials. What extraction methods are used when obtaining preparations from fresh plant raw materials:

A. Maceration with 90% ethyl alcohol, bismaceration

B. Percolation, maceration with 70% ethyl alcohol

C. Repercolation, countercurrent extraction

D. Extraction in the liquid-liquid system, maceration

E. Vortex extraction, circulation extraction

35

Which extraction method is a type of maceration?

A. Bismaceration

B. Percolation

C. Repercolation

D. Dynamization

E. Countercurrent extraction

36

The phytochemical workshop of the enterprise produces tinctures by the percolation method. At what speed is percolation carried out:

A. 1/24 or 1/48 part of the working volume of the percolator per hour.

B. 1/50th of the working volume of the percolator in 30 minutes.

C. 1/20 part of the working volume of the percolator per hour.
D. 1/40 part of the working volume of the percolator per hour.
E. 1/10th of the working volume of the percolator in 30 minutes

37

The phytochemical workshop of the enterprise produces tinctures by the percolation method. What ratio of raw materials - extractant must be observed when soaking raw materials:

A. 1:1, 1:0.5
B. 0.5:1, 1:5
C. 1:5, 1:10
D. 1:2, 1:1
E. 0.5:2, 1:2

38

The phytochemical workshop of the enterprise produces tinctures by the percolation method. What amount of raw materials and extractant is necessary to obtain 100 liters of nettle tincture, if K = 1.5:

A. 20 kg of raw materials, 130 liters of extractant
B. 10 kg of raw materials, 45 liters of extractant
C. 100 kg of raw materials, 100 liters of extractant
D. 50 kg of raw materials, 175 liters of extractant
E. 20 kg of raw materials, 150 liters of extractant

39

While preparing an infusion of althea root, the pharmacist made a mistake in the temperature of the water for preparing this extract, and the final product turned out to be cloudy. What temperature is the water needed to extract this raw material?

A. Room temperature
B. 40 º C
C. 100 º C
D. 60 º C
E. 80 º C

40

What methods of cleaning the hood are used in the production of tinctures:

A. Settling at a temperature of 8-10 °C, filtration
B. Extractive cleaning methods in the liquid-liquid system
C. Denaturation, filtration, sorption
D. Dialysis, advocacy
E. Solvent replacement, settling, filtration

41

One of the methods of purification of tinctures is settling. In the production process, it is necessary to determine at what temperature it is rational to use this method:

A. 10-15°C

B. Not higher than 10°C
C. 20°C
D. 18°C
E. 45°C

42

Different equipment is used to filter solutions. What filters are not used to filter alcohol solutions?

A. Nutch filters
B. Print filters
C. Frame filter presses
D. Bag filters
E. Filter funnels

43

What methods are used to determine the alcohol in the tincture:

A. Distillation, by boiling point
B. Distillation, biological
C. Chemical, biological
D. By boiling point
E. With the help of an alcohol meter and a hydrometer

44

In what ratio are tinctures prepared from potent raw materials:

A. 1:10
B. 1:5
C. 1:25
D. 1:40 a.m
E. 1:100

45

The phytochemical workshop of the enterprise produces belladonna tincture. Indicate in what ratio of raw materials and finished products the extractor is loaded:

A. 1:10
B. 1:1
C. 1:2
D. 1:20
E. 1:5

46

The phytochemical workshop of the pharmaceutical enterprise produces valerian tincture from fresh raw materials. Specify the technological features of the production of this drug:

A. It is prepared in 70% ethanol in a ratio of 1:5
B. It is prepared in 90% ethanol in a ratio of 1:5
C. It is prepared in 90% ethanol in a ratio of 1:10

D. It is prepared in 70% ethanol in a ratio of 1:10
E. It is prepared in 95% ethanol in a ratio of 1:10
47
Which quality indicator **is not investigated** during the analysis of tinctures:
A. Residual content of solvents
B. Density
C. Dry residue
D. Quantitative content of active substances
E. Heavy metals
48
The phytochemical workshop of the enterprise produces calendula tincture. Specify which raw materials are used for the manufacture of this drug:
A. Flowers
B. Roots, rhizomes and grass
C. Grass
D. Leaves and essential oil
E. Roots
49
When obtaining ethyl alcohol, a rectification process is used. Specify the principle of the process:
A. This is the separation of a mixture of intermixable liquids with different boiling points into separate fractions
B. This is distillation with inert gases
C. This is the washing of spent raw materials with 3-5 times the amount of ethanol
D. This is a technological technique for obtaining liquid extracts
E. This is deep vacuum distillation
50
Galenic preparations include:
A. Tinctures
B. Granules
C. Capsules
D. Aerosols
E. Spangles
51
Define the term "contact drying":
A. The drying process in phytochemical production when the materials to be dried are heated with a heat carrier through an impermeable wall that conducts heat
B. The process of drying in phytochemical production by direct contact of materials to be dried with a hot gaseous coolant
C. Drying process in phytochemical production by contact heating or infrared heat generation

D. The process of drying in phytochemical production by means of contact introduction or generation of heat by high frequency currents

E. Drying process in phytochemical production by contact feeding or heat generation in a microwave field

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

1 . Make a technological block diagram of industrial production

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
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- INDUSTRIAL technology of medicines : education. manual for students' independent work / O.A. RUBAN , V.D. RYBACHUK , L.M. X ohlova etc. - KH.: NF and U, 2015. - 120 p.
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- Auxiliary substances in the production of medicines: training. manual for students higher pharmacy education closing / O.A. RUBAN , I.M. _ Pertsev, S.A. Kutsenko, Yu.S. Oily; under the editorship I.M. Pepper - Kh.: Golden Pages, 2016. - 720 p.

- Modern pharmaceutical technologies: education. manual to laboratory classes of full-time, evening and part-time master's students of the specialty 8.110201 "Pharmacy" / under the editorship. O.A. Ruban. - Kh.: Publishing House of the National Academy of Sciences, 2016. - 256 p.

Auxiliary :

- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
- Regulatory and technical documentation and production validation. Material balance: Educational method. river for audit. and external audit. student work special "Pharmacy" of full-time and part-time education / D.I. Dmytrievskyi, G.D. Slipchenko, I.M. Hrubnyk, D.V. Rybachuk . - Kh.: Publishing House of the National Academy of Sciences, 2008. - 45 p.
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- Pharmaceutical encyclopedia / Chief editor. council and the author of the foreword V.P. Black people - 3rd ed., revised. and additional - K.: "MORION", 2016. - 1952 p.
- Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
- European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & Healthcare. - Strasbourg, 2013. - 3638 p.
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- Powder manufacturing technology: teaching. manual / L.L. Davtyan, R.S. Korytniuk, A.O. Drozdova, I.O. Vlasenko, Z.V. Malenka, V.P. Popovych, V.V. Gladyshev, S.M. Musoev, T.F. Olifirova, L.I. Vishnevska, O.M. Hlushchenko, O.O. Khomich; under the editorship L.L. Davtyan, R.S. Korytnyuk - K.: "Education of Ukraine", 2016. - 141 p.
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- Zujkina SS The pharmacotechnological studies of the phytospecies composition for the complex therapy of mastopathy / SS Zujkina, LI Vishnevska // Herald of pharmacy. – 2017. – No. 2 (90). - P. 43-47.

Independent work #8

Topic 8: " Physico-chemical and technological properties of powders and granules "

Purpose: To study the material balance at the stages of the technological process and the technological properties of powdered and granular medicinal substances for the optimal tableting process and the selection of auxiliary substances.

Basic concepts: *Powders* (lat. pulveres — powders) are solid medicinal preparations for internal or external use, which consist of one or more medicinal substances and have free-flowing properties. Powders can be mechanical mixtures of crushed free-flowing medicinal substances (organic and inorganic nature) with thick substances and liquids in small quantities that do not affect their flowability.

Requirements: high degree of dispersion, flowability, uniformity of distribution of substances throughout the mass of the powder (homogeneity of mixing), dosing accuracy, stability; for some - sterility and homogeneity of the distribution of active substances in the mass.

Grinding is the process of reducing the size of particles of solid pharmaceuticals with the help of various devices.

The degree of grinding is the ratio of the average initial size of a piece of material to its average cross-sectional size after grinding.

Mixing is a process that results in homogeneity, that is, the same ratio of constituent particles in any part of the resulting mixture.

Sieving is a process whose goal is to obtain a product with the same particle size as determined by sieve analysis.

Material balance is the ratio between the amount of raw materials, materials, semi-finished products and intermediate products used in production, and the amount of finished products, by-products, waste and losses actually obtained, i.e. the ratio of

theoretically possible and practically obtained output of finished products.

This relationship is illustrated by the material balance equation, which has the form:

C1 = (C2 + C3 + C4) + C5,

where C1 is the amount of raw materials; C2 — quantity of finished products; C3 — number of by-products; C4 — amount of waste; C5 is the number of losses.

Plan

1. Theoretical questions:

1. Crystal forms of medicinal substances.
2. The purpose and method of determining the fractional composition of powder and granules.
3. Influence of the size of powder particles and granules on the tableting process.
4. Determination of bulk, true and relative density of powders.
5. Influence of physical and chemical properties on bulk density.
6. Determination of flowability.
7. Influence of flowability on the tableting process.
8. Pressed powdered materials.
9. Value of extrusion pressure during the production of tablets.

Questions for self-control:

1. Determination of the size and shape of powder particles.
2. The purpose and method of determining the fractional composition of powder and granules.
3. Influence of the particle size of powder and granules on the tableting process.
4. Determination of bulk, true and relative density of powders.
5. Influence of physical and chemical properties on bulk density.
6. Determination of flowability.
7. Influence of flowability on the tableting process.
8. Compressibility of powdered materials.
9. The value of extrusion pressure in the production of pills.
10. Crystal forms of medicinal substances
11. Methods of obtaining medicinal substances with a given shape of crystals.
12. Determination of humidity, density of solid medicinal substances.
13. Wettability of powdered materials.

Approximate tasks for processing the theoretical material:

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task No. 1 . Determination of the shape, size and nature of the powder surface

Task No. 2. Determination of fractional composition
Task No. 3. Determination of bulk density
Task No. 4. Determination of flowability
Task No. 5. Determination of the force of pushing tablets out of the matrices

3. Test tasks for self-control:

1. Grinding equipment is classified by the grinding method. What machines does a roller crusher belong to?

A) They are crushed
B) Abrasive
C) Impact-centrifugal
D) Percussion
D) Cutting

2. Specify which devices are used for packaging ointments in industrial conditions:

A. Screw machines
B. Disc dispensers
C. Vacuum dispensers
D. percolator
E. Mazeterki

3. To which group of auxiliary substances does calcium stearate belong?

A) Anti-friction
B) Plasticizers
C) Dyes
D) Fillers
D) Loosening agents

4. Specify the auxiliary substance that is added to the mass for tableting in an amount of more than 1% in accordance with the DFU:

A) Aerosil
B) Twin-80
C) Stearic acid
D) Calcium stearate
D) Magnesium stearate

5. Tablets are produced in the tablet workshop. Tell the disintegration time of soluble tablets according to the requirements of the Federal Ministry of Ukraine:

A. 15 min
B. 5 min
C. 3 min
D. 60 min

6. Physical incompatibility was detected. Specify the combination of medicinal substances that, when mixed, form a eutectic:

A. Camphor and menthol.

B. Glucose and phenylsalicylate.

B. Streptocide and Antipyrine.

G. Ascorbic acid and glucose.

D. Basic bismuth nitrate and magnesium oxide

7. The ability of the powdered mass to pour out of the container of the watering can or "flow" under its own weight and ensure uniform filling of the matrix channel is called:

A. Turnover

B. Compressedness

C. Granulation

D. Teasing

E. Spraying

8. Choose the maximum permissible concentration of calcium stearate in tablets according to DFU:

A. 1%

B. 13%

C. 5%

D. 7%

E. 10%

9. During packaging and transportation, raw materials are partially crushed and ground. Too much grinding spoils the appearance and reduces the quality of raw materials. Specify what is used to separate the crushed particles:

A. Sieve

B. Mortars

C. Tweezers

D. Scalpel

E. Filters

10. N.a pharmaceutical company plans to release potassium bromide tablets. Which method of obtaining is optimal?

A. Direct pressing

B. Formation

C. Pressing with preliminary wet granulation

D. Pressing with preliminary dry granulation

E. Direct pressing with auxiliary substances

11. Powders are a solid dosage form for internal or external use. There is a MISSING stage in the production of powders:

A. Granulation

B. Sifting

C. Grinding

D. Packaging

E. Mixing

12. Various medicines are manufactured at the pharmaceutical enterprise. Specify the name of the dosage form consisting of solid individual dry particles of varying degrees of pulverization:

A. Powders
B. Emulsions
C. Suspensions
D. Dry extract
E. Tablets

13. To which group of excipients does calcium stearate belong?

A) Anti-friction
B) Plasticizers
C) Dyes
D) Fillers
D) Loosening agents

14. Which group of excipients improves wetting and water permeability of the tablet:

A. Baking powders
B. Fillers
C. Binders
D. Anti-friction
E. Corrections

15. Different groups of excipients are used in the production of tablets. Which of the listed groups of substances ensure the strength of tablets:

A. They bind
B. Loosening agents
C. Sliding
D. Corrections
E. Lubricants

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

1 . Make a technological block diagram of the industrial production of powders.

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he

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Auxiliary :

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- S.S. Zuykin. –Kharkiv.: Publishing House of IFNMU-NFaU, 2017. – 44 p.
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Independent work #9

Topic 9: " PRODUCTION of tablets by the method of direct pressing and with

preliminary granulation "

Goal: To study technological schemes for the production of tablets by direct pressing and using preliminary granulation. Be able to rationally select auxiliary materials and equipment, carry out quality control, packaging and labeling of the finished product.

Basic concepts:

Pressing **- (** actual tableting). This is the process of forming tablets from granular or powdery material under pressure. In modern pharmaceutical production, tableting is carried out on special presses - rotary tablet machines (RTM). Pressing on tablet machines is carried out by a press - a tool consisting of a matrix and two punches.

The technological cycle of tableting on RTM consists of a series of consecutive operations: dosing of material, pressing (tablet formation), its ejection and reset. All the listed operations are carried out automatically one by one with the help of the corresponding executive mechanisms.

Direct pressing. This is a pressing process of NOT granulated powders. Direct pressing allows you to eliminate 3-4 technological operations and thus has an advantage over tableting with preliminary granulation of powders. However, despite the apparent advantages, direct pressing is slowly being introduced into production. This is explained by the fact that for the productive operation of tablet machines, the pressed material must have optimal technological characteristics (flowability, compressibility, moisture, etc.). Such characteristics are possessed only by a small number of non-granular powders - sodium chloride, potassium iodide, sodium and ammonium bromide, hexomethylenetetramine, bromocamphor, etc. substances having an isometric shape of particles of approximately the same granulometric composition, which do not contain a large number of small fractions. They press well.

One of the methods of preparation of medicinal substances for direct pressing is directional crystallization - they seek to obtain a tabletable substance in crystals of a given flowability, compressibility and humidity through special crystallization conditions. Acetylsalicylic acid and ascorbic acid are obtained by this method.

The wide use of direct pressing can be ensured by increasing the flowability of non-granulated powders, high-quality mixing of dry medicinal and auxiliary substances, and reducing the tendency of substances to delaminate.

Dedusting Dust removers are used to remove dust fractions from the surface of tablets coming out of the press. Tablets pass through a rotating perforated drum and are cleaned of dust, which is sucked by a vacuum cleaner.

Granulation is a directed agglomeration of particles, that is, the process of transforming a powdery material into grains of a certain size, which is necessary to improve the flowability of the tablet mixture and prevent its delamination. The improvement in flowability occurs as a result of a significant decrease in the total surface area of the particles during their gluing into granules and, therefore, a corresponding decrease in the friction that occurs between the particles during movement. Stratification of the powdery mixture usually occurs due to the difference in the particle sizes and specific

density values of the medicinal and auxiliary components included in its composition. Stratification of the tablet mass is a dangerous and unacceptable process that causes a violation of the dosage of components. **Plan**

1. Theoretical questions:

1. Characteristics of tablets as a dosage form. Types and groups of tablets.
2. Positive and negative aspects of direct pressing.
3. The main directions of production of tablets by direct pressing.
4. Stages of the technological process of obtaining tablets by direct pressing.
5. Purposes and main types of granulation in the production of tablets.
6. Wet granulation. Positive and negative aspects of this process.
7. Methods of structural granulation.
8. Cases of use of dry granulation (granulation by grinding).
9. Groups of auxiliary substances in the production of tablets.
10. Stages and equipment for the production of pre-granulated tablets.

Questions for self-control:

1. Requirements for pills.
2. Positive and negative aspects of tablets as a dosage form.
3. Influence of physicochemical and technological properties of medicinal and auxiliary substances on the tableting process.
4. The principle of operation of tablet machines, granulators, dryers.
5. The essence, positive and negative aspects of direct pressing.

Approximate tasks for processing the theoretical material:

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task No. 1. Define the term pharmacoeconomic analysis and indicate its stages

Task No. 2. Preparation of acid tablets

Task No. 3. Preparation of 0.3 g hexamethylenetetramine tablets by direct pressing

Task No. 4. Preparation of 0.5 g analgin tablets by pressing with preliminary granulation

Task No. 5. Preparation of mukaltin tablets 0.05 g by pressing with preliminary granulation

Task No. 6. Preparation of streptocide tablets of 0.3 g by pressing with preliminary granulation

3. Test tasks for self-control:

1

Specify the auxiliary substance added to the mass for tableting in an amount of more than 1% according to the DFU:

A. Aerosil
B. Twin-80
C. Stearic acid
D. Calcium stearate
E. Magnesium stearate

2

Tablets are manufactured at a pharmaceutical company. The following are used as lubricants in the production of tablets:

A. Calcium stearate
B. Starch paste
C. water
D. Solutions of the Navy
E. Tartrazine

3

In the process of producing tablets at an industrial enterprise, substances are used that improve their ejection from the matrix. What substance is used for this purpose?

A. Stearic acid
B. Monopalmitin
C. Indigo carmine
D. Alginic acid
E. Ultramylopectin

4

Which group of auxiliary substances in the production of tablets improves wetting and water permeability of tablets:

A. Baking powders
B. Fillers
C. Binders
D. Anti-friction
E. Corrigents

5

Various groups of excipients are used in the production of tablets. Which of the listed groups of substances ensure the strength of tablets:

A. Binders
B. Loosening
C. sliding
D. Corrigents
E. Lubricating

6

What binder is used for wet granulation :

A. Starch paste
B. Pectin
C. Gum
D. Mucus
E. Aerosil

7

Tablets are manufactured at a pharmaceutical company. Specify the methods of preparation of tablets according to the DF of Ukraine.

A. Pressing, forming, teasing
B. Pressing, extrusion, forming, freeze drying
C. Formation, teasing
D. Pressing, teasing, extrusion
E. Pressing, granulation, freeze drying

8

Sodium chloride tablets are manufactured at a pharmaceutical enterprise . Specify the method by which they are prepared.

A. Direct pressing, without auxiliary substances
B. Formation
C. Direct pressing with the addition of auxiliary substances
D. Pressing with preliminary wet granulation
E. Pressing with previous dry granulation

9

What technology should a technologist offer for the industrial production of sodium chloride tablets:

A. Direct pressing
B. Wet granulation
C. Granulation with spray drying
D. Teasing
E. Dry granulation

10

The pharmaceutical company plans to produce potassium bromide tablets. Which method of obtaining is optimal?

A. Direct pressing
B. Formation
C. Direct pressing with auxiliary substances
D. Pressing with preliminary wet granulation
E. Pressing with previous dry granulation

11

In the tablet shop, tablets are produced by various methods. From which medicinal substances are tablets obtained by the method of direct pressing without auxiliary substances:

A. Sodium chloride, potassium bromide, ammonium bromide
B. Hexamethylenetetramine, sulfadimezin, streptocid
C. Sodium chloride, bromocamphor, streptocid
D. Potassium iodide, sulfadimesin, PASK-sodium
E. Phenyl salicylate, lactose, hexamethylenetetramine

12

The pharmaceutical company plans to produce phenobarbital, ephedrine hydrochloride, and sodium bicarbonate tablets. Which method of obtaining is optimal?

A. Direct pressing with the addition of auxiliary substances
B. Formation
C. Direct pressing without additives
D. Pressing with preliminary wet granulation
E. Pressing with previous dry granulation

13

The pharmaceutical company plans to release riboflavin tablets with ascorbic acid. Specify a rational method of preparation of these tablets.

A. Formation
B. Pressing with previous dry granulation
C. Direct pressing without additives
D. Pressing with preliminary wet granulation
E. Direct pressing with the addition of auxiliary substances

14

Granulation in tablet production is:

A. Directional agglomeration of powder particles for subsequent tableting
B. Fine grinding of the powder mass
C. Compression of the powder in the matrix
D. Pouring powder from the container of the watering can
E. Distribution of powder by size

1 5

Powders that have:

A. Poor fluidity
B. Good compression capacity
C. Good flowability
D. Bulk density
E. Porosity

1 6

For the granulation of tablet mixtures, an apparatus is used, in which the components are mixed, the mixture is moistened, granulated, the granulate is dried, and the powder is powdered. Specify this device:

A. Apparatus with a fluidized bed for granulation of SG-30 mixtures
B. Dragging boiler

C. Spray dryer
D. Press granulator
E. The granulator is vertical

1 7

Mixers are used to mix moistened powdery materials:
A. With rotating blades
B. With a rotating body
C. Pneumatic
D. With fluidization
E. Centrifugal action

1 8

Which dryers apply in those cases when _ in material are contained valuable liquids [alcohol , ether , chloroform and other] or he is thermolabile ?
A. Sorptive
B. Radiation
C. Pneumatic dryers
D. Pseudo-liquefaction
E. Sublimation

1 9

What is the main advantage of dielectric drying?
A. Uniform heating of the material over the entire thickness
B. Preservation of native properties of the material being dried
C. Possibility of drying liquid and pasty materials
D. The compactness of the equipment
E. Relatively low drying temperature

2 0

Convective drying is carried out:
A. By direct contact of wet materials with a hot gas coolant
B. By heating wet materials with a coolant through an impermeable wall that conducts heat
C. By supplying heat with high-frequency currents
D. Ultrasonic radiation
E. sublimation of ice under deep vacuum

2 1

Designs of dryers are very diverse, but they all have several elements common to all dryers. Choose a structural element common to all convective type dryers:
A. Radiator for heating
B. Several rectangular chambers with shelves where the material dries in a stationary state
C. Shiber (damper), with the help of which part of the warm exhaust air is mixed with fresh air

D. Horizontal belt conveyor
E. Gas distribution chamber with a fan

2 2

In the drying chamber, 1 or 2 empty metal drums, which are heated from the inside by steam, rotate slowly. The surface of the drum is moistened with a thin layer and dries after an incomplete rotation of the drum. For which dryer is this description typical:

A. Roller vacuum dryer
B. Strichkova
C. Spraying
D. Dryer with dielectric heating
E. Sublimation dryer

2 3

Choose the equipment for granulation that should be used in the production of tablets that contain heat-labile substances:

A. Spray dryer
B. Rotary tablet machine
C. Teasing cauldron
D. Installation of a fluidized bed
E. "Draykota" type machine

24

Tablets are manufactured in aseptic conditions at the enterprises. A feature of the technology of which tablets is sterilization by dry heat:

A. Implantation
B. Prolonged
C. Framework
D. Trituration
E. Sublingual

25

Quality control of tablets at pharmaceutical enterprises involves determination of abrasion resistance. Indicate how many tablets are taken for the test, if the weight of the tablet is less than 0.65 g:

A. 20
B. 5
C. 50
D. 100
E. 2

26

The solubility test is used for quality control:

A. Tablets
B. Aerosols
C. Ointment

D. Liniments
E. Tincture
27
At the pharmaceutical enterprise, tests are conducted to determine the dissolution and disintegration of tablets. At what temperature are the tests conducted:
A. 37 °C
B. 20 °C
C. 50 °C
D. 18 °C
E. 30 °C
28
The quality of tablets is evaluated according to various indicators. Specify the devices that are used to determine the dissolution of tablets (according to DFU).
A. A device with a rotating basket, a device with a shovel, a flow device
B. A device with a basket, a flow device
C. A device with a shovel; swinging basket
D. Flow device
E. Rotating basket
29
Indicate how the tablet dissolution test is regulated according to the DFU:
A. The amount dissolved in 45 min. the substance must be at least 75% in water
B. The amount dissolved in 30 min. the medicinal substance must be at least 97% in water
C. The amount dissolved in 15 min. the medicinal substance must be at least 75% in water
D. The amount dissolved in 15 min. the pepsin solution of the medicinal substance must be at least 75%
E. The amount dissolved in 20 min. in a 0.9% solution of sodium chloride, the substance must be at least 75%
30
The main indicators of the quality of tablets according to the requirements of the DFU are divided into organoleptic, physical, chemical and biological. Define chemical indicators.
A. Disintegration
B. Average tablet weight
C. Appearance
D. Content of microorganisms
E. Strength indicators
31
The quality of tablets is evaluated according to various indicators. Specify the device that is used to determine the disintegration of tablets.

A. A swinging basket
B. Flow device
C. The KhNDHFI device
D. A device with a shovel
E. Friabilator

32

The pharmaceutical enterprise produces Aspirincardio tablets, during quality control the disintegration of the tablets was determined. Specify the device with which, according to the State Federal Office of Internal Affairs, this control can be carried out:

A. A device of the type "swinging basket"
B. A device of the type "rotating basket"
C. Densimeter
D. X-ray machine
E. Gas-liquid chromatograph

33

Tablets are manufactured at a pharmaceutical company. The disintegration time of tablets not covered with a shell is no more than:

A. 15 minutes
B. 20 minutes
C. 30 minutes
D. 5 minutes
E. 10 minutes

34

Tablets are produced in the tablet shop. Tell the disintegration time of soluble tablets according to the requirements of the Federal Ministry of Ukraine:

A. 15 minutes
B. 5 minutes
C. 25 minutes
D. 60 minutes
E. 40 minutes

35

During the production of tablets, continuous quality control of the finished product is carried out according to various indicators. Select the correct mode for the "disintegration" test if the tablets are coated with a water-soluble coating:

A. No more than 30 minutes
B. At least 1 hour
C. At least 30 minutes
D. No more than 45 minutes
E. No more than 15 minutes

36

Tablets covered with enteric coatings are manufactured at pharmaceutical enterprises.

Indicate how long they should not disintegrate in an acidic environment according to the requirements of the Federal Drug Administration:

A. 1:00
B. 2 hours
C. 4 hours
D. 3 hours
E. 5 hours

37

In the tablet shop, tablets are made, covered with a shell that dissolves in the intestines. Specify the disintegration time of the tablets:

A. Should not disintegrate within 1 hour in a 0.1 M hydrochloric acid solution, and after washing with water should disintegrate within 1 hour in a 0.1 M sodium bicarbonate solution
B. Should not disintegrate within 30 minutes in a 0.1 M hydrochloric acid solution, and after washing with water should disintegrate within 30 minutes in a 0.1 M sodium bicarbonate solution
C. No more than 15 minutes
D. No more than 30 minutes
E. No more than 45 minutes

38

Granules are produced at the pharmaceutical enterprise. Specify the disintegration time of effervescent granules:

A. No more than 5 minutes
B. 15 minutes
C. 20 minutes
D. 45 minutes
E. 60 minutes

39

During the evaluation of the appearance of the tablets, the marbling of the surface was found, which is:

A. Uneven color, local, local discoloration
B. Violation of the roundness of the form
C. Holes, chips, parts of tablets
D. Exfoliation, since the tablets
E. Uneven coating surface

40

When conducting quality control of tablets at pharmaceutical enterprises, a test is carried out to determine the abrasion resistance of tablets. Specify which device is used to perform this test:

A. Drum wiper (friabilator)
B. Goniometer

C. Spring dynamometer
D. Laboratory indicator of the decay process
E. Laboratory indicator of the dissolution process

41

The pharmaceutical company manufactures Septefril tablets. Specify the device for determining the wearability of tablets according to the DFU:

A. Friabilator
B. Areometer
C. Device with a "swaying basket"
D. Polarimeter
E. Densimeter

42

A pharmaceutical company produces tablets. What device is used to determine their splitting strength:

A. The KhNDHFI device
B. Adj. VP-12A
C. Friabilator
D. Device "swinging basket"
E. Device model 545R-AK-3

43

Tablets are manufactured at a pharmaceutical company. Indicate for which tablets the mechanical strength is not determined:

A. Nitroglycerin tablets
B. Tablets of sodium chloride
C. Streptocide tablets
D. Acetylsalicylic acid tablets
E. Potassium bromide tablets

44

Triturating tablets are made in the tablet shop. What quality indicators are not determined for these tablets?

A. Abrasion, resistance to crushing
B. Homogeneity of content
C. Microbiological purity
D. Disintegration and dissolution
E. Uniformity of dosage

45

Controlling the number of tablets at pharmaceutical enterprises involves determining the average weight. Specify how many tablets with a mass of 0.5 g for the test:

A. 20
B. 5
C. 50

D. 100
E. 10

46

Quality control of the manufactured tablets includes determination of the content of auxiliary substances talc and aerosol. Indicate by what method the determination is made:

A. Gravimetric
B. Titrimetric
C. Photocolorimetric method
D. Spectrophotometric
E. Chromatographic

47

Indicate for what purpose binders are used in the production of tablets:

A. * To achieve the required particle adhesion force
B. To improve the taste
C. To increase flowability
D. To obtain the required mass
E. To improve tablet disintegration

48

Indicate for what purpose fillers are used in the manufacture of tablets:

A. To obtain a certain mass of tablets
B. To improve taste
C. To improve the fluidity of the granulate
D. To improve the adhesion of particles to each other
E. To improve tablet disintegration

49

When pressed, the tablets stick to the press tool. Choose the reason for sticking from the following:

A. Excess moisture of the tablet mass and pressure
B. Heterogeneity of granulate
C. Unsatisfactory fluidity of the tablet mass
D. High specific density of powders
E. Tableted powder has plate-shaped crystals

50

Tablets without a shell, the main mass of which consists of acids and carbonates, have the name:

A. Effervescent
B. Pressed
C. Acidic
D. Soluble
E. Caplets

According to the DFU, different types of tablets for oral administration are classified. What type of pulsatile-release tablets are APIs?

A. Modified-release tablets
B. Effervescent tablets
C. Chewable tablets
D. Soluble tablets
E. Dispersible tablets

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

1 . Make a technological block diagram of the industrial production of tablets by the method of direct pressing.

2 . Make a technological block diagram of the industrial production of tablets with preliminary granulation.

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
- A.G. Bashura, O.S. Shpichak, E.E. Bogutska; under the editorship A.I. Tikhonov and S.A. Tikhonova - Kh.: Original, 2016. - 462 p.
- Vishnevska, N.P. Polovka, R.S. Korytniuk et al. - Kh.: National Academy of Sciences: Original, 2016. - 378p.
- Workshop on industrial technology of medicinal products: teaching. manual for students higher education institutions with the specialty "Pharmacy" / O.A. Ruban, D.I. Dmytrievskyi, L.M. Khokhlova [and others]; under the editorship O.A. Ruban. – Kh.: National Institute of Medical Sciences; Original, 2015. – 320 p.
- INDUSTRIAL technology of medicines : education. manual for students' independent work / O.A. RUBAN , V.D. RYBACHUK , L.M. X ohlova etc. - KH.: NF and U, 2015. - 120 p.
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- Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing integrated exam "Step 2. Pharmacy" / O.A. Ruban, V.D. Rybachuk, L.M. Khokhlova, D.S. Pulyaev - KH.: NF and U, 2016. - 63 p.
- Auxiliary substances in the production of medicines: training. manual for students higher pharmacy education closing / O.A. RUBAN , I.M. _ Pertsev, S.A. Kutsenko, Yu.S. Oily; under the editorship I.M. Pepper - Kh.: Golden Pages, 2016. - 720 p.
- Modern pharmaceutical technologies: education. manual to laboratory classes of full-time, evening and part-time master's students of the specialty 8.110201 "Pharmacy" / under the editorship. O.A. Ruban. - Kh.: Publishing House of the National Academy of Sciences, 2016. - 256 p.

Auxiliary :

- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
- Regulatory and technical documentation and production validation. Material balance: Educational method. river for audit. and external audit. student work special "Pharmacy" of full-time and part-time education / D.I. Dmytrievskyi, G.D. Slipchenko, I.M. Hrubnyk, D.V. Rybachuk . - Kh.: Publishing House of the National Academy of Sciences, 2008. - 45 p.
- Technology of medicinal products of industrial production: training. manual/ edited by Prof. D.I. Dmitrievsky. – Vinnytsia: Nova kniga, 2008. – 280 p.
- Drug technology. Educational and methodological guide: Education. manual for students higher education hall. / O.I. Tikhonov, P.A. Logvin, S.O. Tikhonova, O.V. Bazulin, T.G. Yarnykh, O.S. Shpychak, O.M. Kotenko; under the editorship O.I. Tikhonova, Kh.: Original, 2009. - 432 p.
- Pharmaceutical encyclopedia / Chief editor. council and the author of the foreword V.P. Black people - 3rd ed., revised. and additional - K.: "MORION", 2016. - 1952 p.
- Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
- European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & Healthcare. - Strasbourg, 2013. - 3638 p.
- Handbook of Pharmaceutical Excipients, 6th edition / RC Rowe, PJ Sheskey, ME Quinn. - Pharmaceutical Press and American Pharmacists Association, 2009. - 521 p.
- State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicines", 2015. - Vol. 1. - 1128 p.

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- Powder manufacturing technology: teaching. manual / L.L. Davtyan, R.S. Korytniuk, A.O. Drozdova, I.O. Vlasenko, Z.V. Malenka, V.P. Popovych, V.V. Gladyshev, S.M. Musoev, T.F. Olifirova, L.I. Vishnevska, O.M. Hlushchenko, O.O. Khomich; under the editorship L.L. Davtyan, R.S. Korytnyuk - K.: "Education of Ukraine", 2016. - 141 p.
- S.S. Zuykin. –Kharkiv.: Publishing House of IFNMU-NFaU, 2017. – 44 p.
- Zujkina SS The pharmacotechnological studies of the phytospecies composition for the complex therapy of mastopathy / SS Zujkina, LI Vishnevska // Herald of pharmacy. – 2017. – No. 2 (90). - P. 43-47.

Independent work #10

Topic 10: " INDUSTRIAL production of coated tablets." Quality control "

Purpose: To study technological schemes for the production of coated tablets, granules, dragees. Be able to rationally select a coating method, auxiliary substances and equipment, conduct quality control, packaging and labeling of the finished product.

Basic concepts:

Film coatings are created on tablets by applying a solution of a film-forming substance followed by removal of the solvent. At the same time, a thin (0.05 - 0.2 mm) shell is formed on the surface of the tablets. Depending on the solubility, film coatings are divided into the following groups: water-soluble, soluble in gastric juice, soluble in the intestines, and insoluble coatings.

Water-soluble coatings protect against mechanical damage, but do not protect against the influence of air moisture. Water-soluble shells form PVP, MC, oxypropylene methyl cellulose, Na KMC, etc. They are applied in the form of water-ethanol or water solutions.

Coatings soluble in gastric juice. These are films that protect tablets from moisture, but do not prevent their rapid destruction in the stomach (within 10-30 minutes). These include polymers that have basic substituents in the molecule, mainly amino groups, such as diethylaminomethylcellulose, benzylaminocellulose, paraaminobenzoates of sugars and acetylcellulose, etc. Solutions of these substances

in organic solvents are used for coating: ethanol, isopropanol, acetone.

Insoluble coatings are films with a microporous structure. They are solutions of ethyl and acetyl in ethanol, isopropanol, acetone, toluene, chloroform, ethyl acetate, etc. With the addition of plasticizers. The mechanism of release of the medicinal substance: digestive juices quickly penetrate through the pores of the insoluble membrane and dissolve the medicinal substance or cause its swelling. In the first case, the medicinal substance diffuses through the film in the reverse direction, in the second case, the membrane ruptures, after which the medicinal substance is released in the usual way.

Dragee - solid dosed LF for internal use, which is obtained by multiple layering (dragging) of medicinal and auxiliary substances on sugar granules (grit). Dragees have a spherical shape, weight 0.1 - 0.5 g. In the form of dragees, medicinal substances that are difficult to tablet are released. Dragee allows you to hide the unpleasant taste of medicinal substances, reduce their irritating effect, and protect against the influence of external factors. However, in this LF it is difficult to ensure dosage accuracy, disintegration in the required terms, and quick release of medicinal substances. Dragee is not recommended for children. In view of the above, this LF is not promising.

Granules are LF in the form of round or cylindrical grains containing a mixture of medicinal and auxiliary substances (sugar, lactose, starch, glucose, talc, etc.). They are easy to swallow, which makes it possible to use them in pediatric practice.

Plan

1. Theoretical questions:

1. The purpose of coating tablets.
2. Types of coatings and their application technology.
3. Excipients used in the coating of tablets with shells.
4. Suspension method of teasing. Its advantages.
5. Requirements for the geometric shape of tablet-cores during Dragging.
6. Parameters affecting the process of covering tablets with shells during Dragging.
7. Film coatings. Types and properties. Application methods.
8. Pressed coatings. Stages of the technological process and equipment.
9. Determination of granules and dragees as dosage forms.
10. Excipients used in the production of granules and dragees.
11. Granule and dragee production technology.
12. Quality control of granules and dragees.

Questions for self-control:

1. Name the main regulatory and technical documents that regulate the activity of a technologist and are used for the preparation of medicinal products;
2. What do you know about the general principles of production of ready-made medicinal forms;

3. What are the existing categories and structure of regulatory documentation.
4. Conditions of industrial production of drugs according to the rules of GMR.
5. Name the main terms used in the production of medicinal products.
6. How the technological process, production regulations, technical and economic balance is planned;
7. Determine the characteristics, requirements for medicinal products;
8. List the stages of the technological process (general and partial);
9. What is the modern look of packaging, quality assessment and prospects for further improvement of its manufacturing technology

Approximate tasks for processing the theoretical material:
— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

Task No. 3 . Preparation of mukaltin tablets 0.05 g by pressing with preliminary granulation

Composition per tablet:
Mukaltin - - 0.050 g
Sodium bicarbonate - 0.087 g
Food citric acid - 0.020 g
Calcium stearate - 0.003 g
Sugar -0.140 g
The weight of the tablet is 0.300 g

Task No. 4 . Preparation of tablets of streptocide 0.3 g by pressing with preliminary granulation

Composition per tablet:
Streptocide - 0.30000 g
Potato starch - 0.02446 g
Calcium stearate or stearic acid - 0.00224 g
Sugar - 0.00330 g
The weight of the tablet is 0.33,000 g

3. Test tasks for self-control:

1
Tablets obtained by the formation of moistened masses are called:
A. Coated tablets
B. Effervescent tablets
C. Trituration tablets
D. Film-coated tablets
E. Tablets with modified release
2

In the tablet shop, tablets are made by the molding method. Indicate in which cases tablets are prepared by this method:

A. If the use of pressure is undesirable; when the dose of the medicinal substance is insufficient, and the addition of auxiliary substances is undesirable

B. If the medicinal substance interacts with water

C. If the medicinal substance is explosive

D. If the medicinal substance changes its properties under pressure

E. If a very large dose of the medicinal substance

3

Nitroglycerin tablets are manufactured at a pharmaceutical enterprise. Specify the method by which they are prepared:

A. Formation

B. Direct pressing without additives

C. Direct pressing with the addition of auxiliary substances

D. Pressing with preliminary wet granulation

E. Pressing with previous dry granulation

4

Tablets are manufactured at a pharmaceutical company. Specify the correct sequence of technological stages in the production of tablets by the molding method:

A. Auxiliary work, mixing dry powders, obtaining a wet mass, forming tablets, drying, quality control, packing, packaging

B. Auxiliary work, mixing dry powders, forming tablets, drying, quality control, filling, packing

C. Auxiliary work, obtaining a wet mass, forming tablets, drying, quality control, packing, packaging

D. Auxiliary work, mixing of dry powders, forming tablets, quality control, packing, packaging

E. Auxiliary works, forming tablets, drying, quality control, filling, packaging

5

Nitroglycerin tablets are manufactured at a pharmaceutical enterprise. Specify the correct sequence of technological stages and operations in the production of these tablets:

A. Auxiliary work, mixing dry powders, moistening the mixture with binding liquids, rubbing the wet mass into perforated plates, pushing out the rubbed mass with punches, drying tablets, standardization, packing, packaging

B. Mixing dry powders, moistening the mixture with binding liquids, forming tablets, standardization, packaging

C. Auxiliary work, mixing dry powders, wiping wet mass through a granulator, tableting, standardization, packing, packaging

D. Wetting the mixture with binding liquids, rubbing the wet mass into perforated plates, tableting, standardization, packaging

E. Auxiliary works, granulation, tableting, standardization, packing, packaging

6

Nitroglycerin tablets are made in the tablet shop. Specify the equipment used in the manufacture of these tablets:

A. Special tablet machines for forming tablets
B. Tablet machine "Draykota"
C. RTM-24 rotary tablet machine
D. Teasing cauldron
E. Eccentric "shoe" machine

7

In the tablet shop, tablets are made by the molding method. Indicate which quality indicator is not determined for these tablets:

A. Mechanical strength
B. Disintegration
C. Solubility
D. Quantitative content of active substances
E. Uniformity of dosage

8

The medicinal form for internal use in the form of round or irregularly shaped grains, containing a mixture of medicinal and auxiliary substances, which is not covered with a shell, is called:

A. Pellets
B. Dragee
C. Powder
D. Tablets
E. Sponsored

11

According to the DFU, granules can be classified as:

A. "Effervescent"; covered with a shell; with modified release; enteric soluble
B. Covered with a shell; with modified release
C. Enteric soluble, gastric soluble
D. "Effervescent"; solid
E. With a modified release; covered with a shell

12

Different types of tablets are manufactured at the pharmaceutical company. Specify the structure of the framework tablets.

A. Mesh matrix in which the medicinal substance is included
B. Film-coated tablets
C. Tablets covered with a fat-soluble coating
D. Coated tablets
E. Dispersions of medicinal substances in polyethylene

13

What is the name of tablets that have a large weight and the length of which exceeds the width and height?

A. Briquettes
B. Effervescent
C. Caplets
D. Vaginal
E. Pressed

14

The plant produces tablets with a pressed coating. Specify the equipment used for this:

A. Double pressing tablet machine
B. Dragging boiler
C. S. Marmeriser
D. Eccentric tablet machine
E. Trituration machine

15

When coating tablets with shells, various auxiliary substances are used. Which of the following substances belong to the adhesives that ensure the adhesion of the core coating materials:

A. Sugar syrup, PVP, KMC, MC, AFC, OPMC
B. Magnesium oxide, calcium oxide, talc, magnesium carbonate
C. Aerosil, shellac, polyacrylic resins, zein
D. Tropeolin 00, tartrazine, acid red 2C, indigo carmine
E. Sugar, citric acid, cocoa, vanillin

16

Tablets are covered with a shell in order to protect them from the effects of moisture, light, mechanical damage, masking unpleasant taste and smell. Specify substances that ensure moisture resistance of the coating.

A. Zein
B. PEG
C. Tartrazine
D. tweens
E. Calcium oxide

17

Film-coated tablets are manufactured at a pharmaceutical enterprise. Which of the proposed substances is used to obtain a water-soluble film coating?

A. Hydroxypropylene-methylcellulose
B. Talc
C. Camphor
D. Zinc oxide
E. Starch

18
What film coatings do not exist:
A. Fat soluble
B. Water soluble
C. Soluble in gastric juice
D. Enteric soluble
E. Insoluble
19
Which of the coatings allows you to protect the stomach from the negative effects of the active components of the tablets?
A. Enteric soluble
B. Water soluble
C. Gastrically soluble
D. Fat soluble
E. Any
20
Enteric coatings are one of the types of tablet coatings. Specify the place of their dissolution:
A. In the intestines
B. In the stomach
C. In the oral cavity
D. In the rectum
E. In the vagina
21
Preparation of drugged coatings on tablets is carried out in the following devices:
A. Obductors
B. Double pressing machines
C. Machines with a suspended layer
D. Apparatus of centrifugal action
E. Spray dryers
22
Specify the correct technological scheme for applying a dry pressed coating to tablets:
A. Feeding granulate to the matrix for coating, feeding the core tablet, feeding granulate from above, pressing
B. Feeding the granulate for the lower part of the coating into the matrix, the subsequent filling of the granulate for the upper part of the coating, pressing
C. Feeding the tablet core into the matrix, filling the granulate, pressing
D. Feeding the granulate for the lower part of the coating into the matrix, feeding the core tablet, pressing
E. Feeding granulate coating into the matrix, feeding core tablets, pressing
23

Tablets covered with a shell are manufactured at a pharmaceutical enterprise. Specify the required speed of rotation of the cauldron for coating the tablets with powdered sugar suspension:

A. 18-20
B. 30
C. 40
D. 15-20
E. At least 45

24

The tablet workshop of the enterprise produces tablets covered with a suspension coating. Suggest the composition of the suspension for the technological operation of coating the core tablets:

A. Granulated sugar, water, polyvinylpyrrolidone, aerosol, basic magnesium carbonate, titanium dioxide, dye
B. Granulated sugar, methylcellulose solution, titanium dioxide, polyvinylpyrrolidone
C. Granulated sugar, dye, magnesium carbonate, magnesium oxide, sodium carboxymethyl cellulose
D. Sugar-sand, alcohol-water mixture, sodium carboxymethylcellulose, magnesium oxide, aerosol, dye
E. Sodium carboxymethylcellulose, granulated sugar, water, glycerin, magnesium oxide, Aerosil, titanium dioxide

25

The tablet workshop of the enterprise produces tablets covered with a suspension coating. From the listed ingredients, choose substances that act as a suspension carrier when applying a suspension coating:

A. 70% sugar syrup
B. Aerosil
C. Polyvinylpyrrolidone
D. Basic magnesium carbonate
E. Titanium dioxide

26

What quality parameter is not determined for tablets covered with a shell:

A. Abrasion resistance
B. Solubility
C. Ability to disintegrate
D. Average mass and deviation from it
E. Uniformity of dosage

27

At the pharmaceutical enterprise, multiple layering of medicinal and auxiliary substances on sugar granules is carried out in a cauldron. What is the finished

medicinal form called?

A. Dragee
B. Granules
C. Tablets
D. Medulla
E. Microcapsules

28

A pharmaceutical enterprise produces dragees. Specify the equipment necessary for the industrial production of the dosage form:

A. Dragging boiler
B. Vertical granulator
C. Friabilator
D. Tablet machine "Draykota"
E. RTM-12

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

1. Make a technological block diagram of the industrial production of coated tablets.

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
- A.G. Bashura, O.S. Shpichak, E.E. Bogutska; under the editorship A.I. Tikhonov and S.A. Tikhonova - Kh.: Original, 2016. - 462 p.
- Vishnevska, N.P. Polovka, R.S. Korytniuk et al. - Kh.: National Academy of Sciences: Original, 2016. - 378p.
- Workshop on industrial technology of medicinal products: teaching. manual for students higher education institutions with the specialty "Pharmacy" / O.A. Ruban, D.I. Dmytrievskyi, L.M. Khokhlova [and others]; under the editorship O.A. Ruban. – Kh.: National Institute of Medical Sciences; Original, 2015. – 320 p.
- INDUSTRIAL technology of medicines : education. manual for students' independent work / O.A. RUBAN , V.D. RYBACHUK , L.M. X ohlova etc. - KH.: NF and U, 2015. - 120 p.

- Study guide for preparation for the final modular control and State certification in the Industrial Technology of Medicines for full-time and part-time students of the "Pharmacy" specialty / Ed. O.A. Ruban. - Kh.: National Academy of Sciences, 2016 . - 80 p.
- Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing integrated exam "Step 2. Pharmacy" / O.A. Ruban, V.D. Rybachuk, L.M. Khokhlova, D.S. Pulyaev - KH.: NF and U, 2016. - 63 p.
- Auxiliary substances in the production of medicines: training. manual for students higher pharmacy education closing / O.A. RUBAN , I.M. _ Pertsev, S.A. Kutsenko, Yu.S. Oily; under the editorship I.M. Pepper - Kh.: Golden Pages, 2016. - 720 p.
- Modern pharmaceutical technologies: education. manual to laboratory classes of full-time, evening and part-time master's students of the specialty 8.110201 "Pharmacy" / under the editorship. O.A. Ruban. - Kh.: Publishing House of the National Academy of Sciences, 2016. - 256 p.

Auxiliary :

- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
- Regulatory and technical documentation and production validation. Material balance: Educational method. river for audit. and external audit. student work special "Pharmacy" of full-time and part-time education / D.I. Dmytrievskyi, G.D. Slipchenko, I.M. Hrubnyk, D.V. Rybachuk . - Kh.: Publishing House of the National Academy of Sciences, 2008. - 45 p.
- Technology of medicinal products of industrial production: training. manual/ edited by Prof. D.I. Dmitrievsky. – Vinnytsia: Nova kniga, 2008. – 280 p.
- Drug technology. Educational and methodological guide: Education. manual for students higher education hall. / O.I. Tikhonov, P.A. Logvin, S.O. Tikhonova, O.V. Bazulin, T.G. Yarnykh, O.S. Shpychak, O.M. Kotenko; under the editorship O.I. Tikhonova, Kh.: Original, 2009. - 432 p.
- Pharmaceutical encyclopedia / Chief editor. council and the author of the foreword V.P. Black people - 3rd ed., revised. and additional - K.: "MORION", 2016. - 1952 p.
- Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
- European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & Healthcare. - Strasbourg, 2013. - 3638 p.
- Handbook of Pharmaceutical Excipients, 6th edition / RC Rowe, PJ Sheskey, ME Quinn. - Pharmaceutical Press and American Pharmacists Association, 2009. - 521 p.

- State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicines", 2015. - Vol. 1. - 1128 p.
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- Powder manufacturing technology: teaching. manual / L.L. Davtyan, R.S. Korytniuk, A.O. Drozdova, I.O. Vlasenko, Z.V. Malenka, V.P. Popovych, V.V. Gladyshev, S.M. Musoev, T.F. Olifirova, L.I. Vishnevska, O.M. Hlushchenko, O.O. Khomich; under the editorship L.L. Davtyan, R.S. Korytnyuk - K.: "Education of Ukraine", 2016. - 141 p.
- S.S. Zuykin. –Kharkiv.: Publishing House of IFNMU-NFaU, 2017. – 44 p.
- Zujkina SS The pharmacotechnological studies of the phytospecies composition for the complex therapy of mastopathy / SS Zujkina, LI Vishnevska // Herald of pharmacy. – 2017. – No. 2 (90). - P. 43-47.

Independent work #11

Topic 11: "Industrial production of medical capsules "

Goal: To study the industrial production of gelatin capsules and microcapsules, to master the technologies of their production, to carry out quality control, packaging and labeling of the finished product.

Basic concepts:

The term "capsules" refers to two types of factory-produced products:

1) special tanks made of gelatin mass for placing different doses of medicinal substances in them;

2) ready dosed LF - gelatin capsules and microcapsules filled with powdered, granular, pasty and liquid medicinal substances.

Hard capsules are intended for dosing loose powdery and granular substances. They have the shape of a cylinder with hemispherical ends and consist of two parts: a body and a cover; both parts freely fit into each other without creating gaps.

Soft capsules - for liquid and pasty medicinal substances. They have a spherical, ovoid, oblong or cylindrical shape with hemispherical ends.

Obtaining soft gelatin capsules. It consists of the following operations:

- preparation of gelatin solution;
- production of capsule shells;
- filling of capsules;
- sealing of capsules;
- capsule control;
- drying capsules;
- capsule grinding;
- washing capsules;
- regeneration of rejected capsules.

Tubatins are children's LF, which are soft gelatin capsules with an "extended neck" and are intended for small children who cannot swallow pills. When biting the neck of the capsule, the child sucks out the contents.

Spansules are hard gelatin capsules for internal use, containing a mixture of microcapsules (microdrags) with different drug dissolution times, i.e. prolonged action.

Plan

1. Theoretical questions:

1. Definition of capsules as a dosage form.
2. Types of capsules, their purpose.
3. Methods of making capsules. The equipment used.
4. Characteristics of soft gelatin capsules. Tubatins.
5. Technological scheme of production of soft gelatin capsules.
6. Characteristics of hard gelatin capsules.
7. Packaging and storage of capsules.
8. Characteristics of the microcapsule shell, its varieties.
9. Physical methods of microencapsulation.
10. Characteristics of chemical methods of obtaining microcapsules.
11. Standardization of microcapsules.
12. Medicinal forms from microcapsules.

Questions for self-control:

1. Definition of capsules as LF, requirements for them. Types of capsules, their purpose.
2. Explosives in the production of capsules.
3. Characteristics of soft gelatin capsules. Tubatins.
4. Characteristics of hard gelatin capsules.

Quality control of capsules according to DFU and GF XI edition.

5. Factors affecting the bioavailability of LV in gelatin capsules.
6. Characteristics of the microencapsulation process. Shape, size and structure of microcapsules.
7. Characteristics of the microcapsule shell, its varieties.

8. Range and properties of BP used in the production of microcapsules.
10. Areas of possible application of microcapsules in medicine. LF with microcapsules.
9. Methods of making capsules. Used equipment.
10. Filling of soft and hard capsules. Classification of fillers, requirements for them. Spines and medulla.
11. Rectal gelatin capsules. Characteristics and method of obtaining.
12. Standardization, packaging and storage conditions of capsules.
13. Biopharmaceutical aspects of encapsulated drugs.
14. Characteristics of physical methods of microencapsulation. Hardware equipment of the process.
15. Chemical methods of obtaining microcapsules. Hardware equipment of the process.
16. Advantages and disadvantages of physical and chemical methods of microencapsulation. Hardware equipment of the process.
17. Standardization of microcapsules.

Approximate tasks for processing the theoretical material:
— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:
Task 1. Preparation of gelatin mass to obtain soft capsules (without gelatin swelling process)
Task 2. Obtaining shells and researching soft gelatin capsules l.
Task 3. Obtaining shells and research of hard gelatin capsules

3. Test tasks for self-control:
1. The workshop of the enterprise produces soft gelatin seamless capsules. Specify the capsule production method:
A. The drip method
B. Immersion method
C. Stamping method
D. Pouring method
E. Dissolution method.

2. Various methods are used for the production of microcapsules. Specify the method that refers to physical and chemical:
A. Simple and complex coacervation
B. Dispersion method in a liquid-liquid system
C. Interphase polycondensation
D. Interphase polymerization
E. Teasing method

3. Modern methods of micro-encapsulation are divided into three main groups: physical, chemical and physico-chemical. Specify the method that refers to physical:
A. Extrusion
B. Coacervation
C. Polymerization
D. Polycondensation
E. Spray drying

4. When evaluating the quality of gelatin capsules, solubility is determined. Indicate in which case the series is considered standard when determining this indicator:
A. If at least 75% of the active substance has dissolved in water in 45 minutes
B. If 75% of the active substance dissolves in water in 60 minutes
C. If at least 55% of the active substance has dissolved in water in 30 minutes
D. If at least 85% of the active substance has dissolved in water in 90 minutes
E. If at least 70% of the active substance has dissolved in water in 45 minutes

5. Define the medicinal form of tubatin:
A. Soft capsules with an elongated neck
B. Spherical capsules obtained by the dipping method
C. Egg-shaped capsules obtained by pressing
D. Hard capsules with a cap filled with microcapsules
E. Soft rectal capsules in the form of an elongated drop

6. During quality control of capsules, the average weight is determined. Specify the number of capsules that must be taken to determine this indicator according to the DFU:
A. 20
B. 15
C. 10
D. 5
E. 3

7. The production of gelatin capsules is based on different principles. What is the peculiarity of obtaining capsules by pressing:
A. Forming capsules from gelatin ribbons by stamping
B. Forming capsules by dipping pins
C. Formation of a spherical drop with simultaneous inclusion of the active substance in it
D. Forming capsules using concentric nozzles
E. Formation of capsules during evaporation of a volatile solvent

8. What technological method ensures the delivery of the medicine inside the cells?
A. Liposomization
B. Granulation
C. Application of the shell
D. Solubilization
E. Microencapsulation

9. A pharmaceutical company produces gelatin capsules. To ensure the antimicrobial resistance of the shells, the following are introduced into the gelatin mass:
A. Preservatives
B. Plasticizers
C. Film formers
D. Dyes
E. Stabilizers

10. Production of gelatin capsules is based on various principles. What are the features of the technological process of the production of capsules by the dipping method:
A. Capsules are formed using pins
B. Capsule formation using two concentric toothed shafts
C. Formation of a spherical droplet with the simultaneous inclusion of a liquid active substance in it
D. Formation of a ribbon from gelatin mass, formation of capsule halves with simultaneous filling and sealing
E. Preparation of capsules by coacervation method

11. Changing what conditions can lead to the process of coacervation?
A. All answers are correct
B. Change in electrolyte concentration
C. Change in concentration of IUD
D. Changing the pH of the medium
E. Change in temperature

12. Microencapsulation of the medicinal product does not allow:
A. Increase solubility
B. Stabilize the drug during storage
C. Program release
D. Modified Release Parameters
E. To mask taste, smell.

13. When evaluating the quality of capsules, do not determine:
A. Taste

B. Average mass
C. Uniformity of dosage
D. Decay rate
E. Dissolution rate

14. In Drazhyrovochnaya boilers, uncoated and coated micro-drags are obtained, which are used to fill hard gelatin capsules. Specify the finished dosage form:
A. spansules
B. Tubatin
C. Pearls
D. Tablets of the "ORD" type
E. microcapsules

15. The shop for the production of solid dosage forms produces various ready-made medicinal products. What are microcapsules?
A. The smallest particles of a solid, liquid or gaseous substance covered with a shell made of a polymer or other material
B. Solid dosage form, which is prepared by layering active and auxiliary substances on sugar granules
C. Medicinal form for internal use, which is obtained by pressing active substances
D. Dosage form for internal use with an insoluble framework
E. Granules covered with a film of high molecular weight compounds

16. At a pharmaceutical enterprise, microcapsules are produced by the teasing method. Specify the equipment used when obtaining microcapsules by this method:
A. Drazirovochnaya boiler
B. Mixer - granulator
C. Friabilator
D. dismembrator
E. Disintegrator

17. Different methods are used in the production of microcapsules. What methods belong to chemical:
A. Polymerization, polycondensation
B. Simple coacervation
C. Dispersion
D. Dissolution
E. Teasing

18. Specify the name of the finished dosage form, which is gelatin capsules filled with microgranules:

A. spansules
B. Tubatins
C. Pearls
D. Tablets of the "ORD" type
E. Microcapsules

19. Artificially obtained, hermetic spherical particles formed by bimolecular lipid layers, more often phospholipids, in the cavities between which the forming sphere is placed. They are called:
A. Liposomes;
B. Granule;
C. Capsules;
D. spansules;
E. Tubatins.

20. What is the purpose of microencapsulation of medicines?
A. To adjust release parameters
B. To adjust the taste of the medicinal substance
C. To increase the uniformity of dosage
D. To increase the ability to press
E. To simplify the technology of obtaining the drug

21. During the production of capsules, auxiliary substances of various groups are added to the gelatin base. Specify the substance belonging to the group of plasticizers:
A. Polypropylene
B. Potassium metabisulfite
C. Eosin
D. The essence is aromatic
E. Mint oil

22. During the production of capsules, auxiliary substances of various groups are added to the gelatin base. Specify the group of excipients used to increase the strength and reduce the fragility of capsules:
A. Plasticizers
B. Hydrophobinizers
C. Dyes
D. Preservatives
E. Adhesives

23. Modern microencapsulation methods are divided into three main groups: physical, chemical and physico-chemical. Specify the method of obtaining for microcapsules containing thermolabile substances:
A. Vacuum deposition
B. Teasing
C. suspension
D. Extrusion
E. Dispersion

24. To prevent the possible loss of volatile fillers, 40 capsules are subjected to additional sealing. Specify the sealing methods used for this purpose:
A. Thermomechanical welding
B. Separate filling
C. Drying
D. Removal of solvent
E. Coating of capsules with metals

25. The immersion method is used to obtain hard gelatin capsules. Specify the equipment used for this method:
A. "Washing bath", frames with pins
B. Machine for pressing capsules drying unit
C. Draycott type machine, ball mill
D. Fluidized bed installation, cutting unit
E. RPA, piston for depression

26. Different methods are used in the production of microcapsules. What methods are chemical:
A. Polymerization, polycondensation
B. Simple coacervation
C. dispersion
D. Dissolution
E. Teasing

27. Physico-chemical methods of obtaining microcapsules include:
A. Coacervation method
B. Teasing method
C. Spray method
D. Spraying in a fluidized bed
E. Liquid dispersion method

28. Modern methods of microencapsulation are divided into three main groups: physical, chemical and physico-chemical. Specify the method that refers to physical:
A. Extrusion
B. Coacervation
C. Polymerization
D. Polycondensation
E. Spray drying

29. Physical methods of microencapsulation include:
A. Spraying in a fluidized bed
B. Physical adsorption
C. Coacervation
D. Polymerization
E. Extractive substitution

30. According to the DFU, the content of solid medicinal products - capsules can be:
A. Solid, liquid or pasty
B. Assertive
C. Soft
D. Gaseous
E. Hard, soft

31. Medicines in the form of capsules, the shell of which is made of rice flour, are called:
A. Wafers
B. medulla
C. spansules
D. Tubatins
E. Caplets

32. During the production of capsules, auxiliary substances of various groups are added to the gelatin base. Specify the group of excipients used to increase the strength and reduce the fragility of capsules:
A. Plasticizers
B. Hydrophobizers
C. Dyes
D. Preservatives
E. Adhesives

33. The immersion method is used to obtain hard gelatin capsules. Specify the equipment used for this method:

A. "dip bath", frames with pins
B. Capsule pressing machine, drying unit
C. "Draykota" type machine, ball mill
D. Fluidized bed installation, cutting unit
E. RPA, piston for depression

34. The pharmaceutical company manufactures hard gelatin capsules. What method is used to obtain shells of hard capsules?
A. Immersion
B. Molding
C. Pressing
D. Rotational matrix

E. Drip
35. During the organoleptic assessment, the shells of hard gelatin capsules contained air inclusions. What technological error was made in the process of making gelatin mass
A. Is the vacuum connected?
B. Exceeded mixing speed
C. Increased temperature
D. Long mixing time
E. Insufficient number of stabilizers

36. A pharmaceutical company produces gelatin capsules. To ensure the antimicrobial resistance of the shells, the following are introduced into the gelatin mass:
A. Preservatives
B. Plasticizers
C. Film formers
D. Dyes
E. Stabilizers

37. The immersion method is used in the production of hard gelatin capsules. Name the technological equipment used for this method of obtaining capsules:
A. dipping bath ", frames with pins, drying unit, automatic unit for trimming
B. Discs, piston for compression, metered hopper
C. Grids, drying unit, trimming unit
D. Frames - chassis, drying unit, rotor with scrapers
E. Matrix table, hopper for filling, receiver

38. A pharmaceutical enterprise organizes the release of an oily solution of retinol acetate in the form of capsules. Specify the method that should be chosen for the

production of this drug
A. The drip method
B. Pressing method
C. Scaling method
D. Casting method
E. Layering method

39. According to the technology of the drop method of making capsules, encapsulation is subject to:
A. light-flowing liquid non-aqueous medicinal substances
B. Powdery substances
C. Granular medicinal substances
D. microgranular substance
E. Pastes and liquids with high viscosity

40. Gelatin capsules are manufactured at a pharmaceutical enterprise. What is the purpose of glycerin in gelatin mass?
A. Gives elasticity to the shell
B. Increases the porosity of the shells
C. Increases resistance to the effects of gastric juice
D. Has antimicrobial properties
E. Accelerates the disintegration of shells

41. At a pharmaceutical enterprise, microcapsules are produced by the teasing method. Specify the equipment used in obtaining microcapsules by this method.
A. Dragging boiler
B. Friabilator
C. Disintegrator
D. Mixer-granulator
E. dismembrator

42. To improve the properties of the filler when filling hard gelatin capsules, sliding auxiliary substances are added - 0.1% - 0.3% aerosols or magnesium stearate together with 0.5% - 1% talc.
A. To improve flowability;
B. For compact forming ability.
C. To regulate moisture content;
D. For uniformity;
E. For mixing homogeneity;

43. When developing the technological process of obtaining an enzyme preparation,

the stage of inclusion of the enzyme in the microcapsule gel is introduced. Is a means of increasing the stability of the enzyme used at this stage?
A. Immobilization
B. lyophilization
C. Sterilization
D. Canning
E. Concentration

44. Define the medicinal form of tubatin:
A. Soft capsules with an elongated neck.
B. Soft rectal capsules in the form of an elongated drop.
C. Spherical capsules obtained by the dipping method.
D. Egg-shaped capsules obtained by pressing.
E. Hard capsules with a cap filled with microcapsules .

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

1 . Make a technological block diagram of industrial production

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
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- Workshop on industrial technology of medicinal products: teaching. manual for students higher education institutions with the specialty "Pharmacy" / O.A. Ruban, D.I. Dmytrievskyi, L.M. Khokhlova [and others]; under the editorship O.A. Ruban. – Kh.: National Institute of Medical Sciences; Original, 2015. – 320 p.
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- Technology of medicinal products of industrial production: training. manual/ edited by Prof. D.I. Dmitrievsky. – Vinnytsia: Nova kniga, 2008. – 280 p.
- Drug technology. Educational and methodological guide: Education. manual for students higher education hall. / O.I. Tikhonov, P.A. Logvin, S.O. Tikhonova, O.V. Bazulin, T.G. Yarnykh, O.S. Shpychak, O.M. Kotenko; under the editorship O.I. Tikhonova, Kh.: Original, 2009. - 432 p.
- Pharmaceutical encyclopedia / Chief editor. council and the author of the foreword V.P. Black people - 3rd ed., revised. and additional - K.: "MORION", 2016. - 1952 p.
- Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
- European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & Healthcare. - Strasbourg, 2013. - 3638 p.
- Handbook of Pharmaceutical Excipients, 6th edition / RC Rowe, PJ Sheskey, ME Quinn. - Pharmaceutical Press and American Pharmacists Association, 2009. - 521 p.

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- Zujkina SS The pharmacotechnological studies of the phytospecies composition for the complex therapy of mastopathy / SS Zujkina, LI Vishnevska // Herald of pharmacy. – 2017. – No. 2 (90). - P. 43-47.

Independent work #12

Topic 12: " Industrial production of soft drugs "

Goal: To study the definition of emulsion, suspension as a dosage form, scope of application. Features of preparation of emulsion and suspension preparations. Production methods and equipment used in the production of suspensions and emulsions.

Basic concepts:

Ointment — a soft medicinal form for external use. The ointment consists of a medicinal substance and the so-called medicinal base (vaseline, lanolin, naphthalene, etc.). In their basis, ointments contain fats (pork, beef).

Cream is an emulsion containing half water and half oil. Creams also contain solid particles of drugs intended for absorption by the skin.

Gel is a structured system consisting of high-molecular and low-molecular substances.

The paste is a suspension ointment with the amount of powdery substances, in accordance with the recommendations of the Federal State Administration of Ukraine, more than 20% (previously 25%).

Liniments - medicinal form for external use only (more often, by rubbing) is a liquid ointment or a mixture of various irritating substances with oils, oils with alkali solutions, soap-water or soap-alcohol solutions.
Homogeneity is one of the key properties of space in classical mechanics. It means that the parallel transfer of the closed frame of reference in it as a whole does not change the mechanical properties of the system, and, in particular, does not affect the result of measurements.
Sterility is the absence of viable microorganisms and their spores in the environment, organism, any material or product.
Homogeneous ointments are systems characterized by the absence of an interphase interface between medicinal substances and the base of the ointment.
Heterogeneous ointments are systems that have a phase separation with different boundary layers. These include suspension (or trituration), emulsion and combined ointments .

Plan

1. Theoretical questions:

1. What are soft dosage forms and their classification
2. Definition of emulsion, suspension, as LF, scope of application.
3. Features of preparation of emulsion and suspension preparations.
3. Method of obtaining and equipment used in the production of soft dosage forms .
4. By what methods are suspensions and emulsions obtained at pharmaceutical plants?

Questions for self-control:

1. What factors determine the stability of suspensions and emulsions?
2 . What role do auxiliary substances play in the production of suspensions and emulsions
3 . What are the stages of the process of obtaining dispersion preparations?
4 8. What preparations are used in the production of suspensions and emulsions?
5. What is the principle of operation of turbine mixers and RPA? B. Tests for self-control with standard answers. B. Tasks for self-control with answers.

Approximate tasks for processing the theoretical material:

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

1. The droplet sizes of the obtained emulsion are 45-70 μm. Can an emulsion with the same particle size be used for parenteral nutrition?

2. In factory conditions, two emulsions were obtained by different methods. Homogenization of the first emulsion was carried out with the help of a turbine mixer, the second - by the method of ultrasonic dispersion. What distinctive features will these drugs have?

3. Test tasks for self-control:

1

The pharmaceutical company manufactures soft drugs. Specify the name of a soft medicine that melts at body temperature:

A. Liniment
B. Ointment
C. Gel
D. Cream
E. Paste

2

The ointment workshop of the enterprise is mastering the production of new ointment. Specify the technological operation that ensures the uniformity of the distribution of the medicinal substance in the base:

A. Homogenization
B. Preparation of the base
C. Standardization
D. Packaging
E. Packaging

3

At pharmaceutical enterprises, a technological stage - homogenization - is carried out during the production of zinc ointment. What equipment is used to carry out this stage:

A. Two- and three-roll maseters, RPA
B. Mixers with anchor stirrers
C. Electric boilers of various brands
D. Boilers with steam heaters
E. Drum mills

4

The pharmaceutical enterprise plans to produce heterogeneous ointments. Specify the equipment needed for homogenization of ointments:

A. Three-roll maseter, rotary-pulsation device (RPA.)
B. Electric panel for melting bases
C. Reactor-mixer
D. Mixer with paddle stirrers
E. Disintegrator

5

Ointments are subject to homogeneity requirements. Which equipment can be used to achieve a high degree of homogenization in the production of ointments:

A. RPA
B. Propeller stirrer
C. Autolyzer

D. bubbler
E. Anchor stirrer

6

The ointment workshop of the enterprise produces soft medicinal forms. A rotary-pulsation apparatus is used for homogenization of ointments. The use of a rotary-pulsation device allows you to combine:

A. Preliminary grinding of powdered components, homogenization of the ointment
B. Standardization of the dosage form, melting of the base
C. Melting of the base, preliminary grinding of powdery components
D. Homogenization of ointment, filling and packaging of ointment
E. Packing and packaging of the ointment, melting the base

7

When preparing ointments containing amorphous substances (sulfur, zinc oxide, starch), with the help of a rotary-pulsation apparatus (RPA), it is possible to exclude the following stage:

A. Stages of preliminary grinding of medicinal substances
B. Mix
C. Homogenization
D. Standardization
E. Introduction of medicinal substance into the base

8

The ointment workshop of the enterprise produces ointments (gels) on water-soluble bases. Specify the component to get them:

A. Methyl cellulose
B. Hydrogenated fats
C. Silicones
D. Vaseline
E. Wax

9

Sterile liniments are manufactured at a pharmaceutical enterprise. Specify the equipment that allows you to receive a sterile liniment:

A. Magnetostrictive emitters
B. Rotary-pulsation apparatus
C. Propeller mixers
D. Turbine mixers
E. Colloid mills

10

The pharmaceutical company manufactures soft drugs. Specify which quality indicator is determined only for heterogeneous soft medicinal products:

A. Particle size
B. pH

C. Identification
D. Microbiological purity
E. Quantitative definition

11

The ointment workshop of the enterprise may use the following equipment during the production of ointment at the packaging stage:

A. Screw and piston dosing machines
B. Rezepin's machine gun
C. Rotary machines
D. Eccentric machines
E. Disc machines

12

Specify which devices are used for packaging ointments in industrial conditions:

A. Screw machines
B. Disc dispensers
C. Vacuum dispensers
D. Percolators
E. Mazeterka

13

Choose the dosage form when using the active substance that does not undergo primary metabolism in the liver:

A. Suppositories
B. Capsules
C. Syrups
D. Oral suspensions
E. Tablets

14

The workshop for the production of soft dosage forms produces suppositories of various shapes. Define pessaries:

A. Vaginal suppositories with a rounded end
B. Rectal cone-shaped suppositories
C. Torpedo-shaped rectal suppositories
D. Egg-shaped vaginal suppositories
E. Spherical vaginal suppositories

15

The pharmaceutical company manufactures suppositories. Indicate which method is the most optimal to use for the manufacture of suppositories with thermolabile substances.

A. Pressing
B. Pouring into forms
C. S. Pumping

D. Teasing
E. Lyophilization

16

The workshop for the production of soft dosage forms produces suppositories on various bases. Choose suppository bases that have lipophilic properties:

A. Cocoa butter, alloys of cocoa butter with hydrogenated fats, vegetable and animal hydrogenated fats, solid fat, lanol, wax, paraffin

B. Alloys of cocoa butter with hydrogenated fats, alloys of polyethylene glycols with different molecular weights, gelatin-glycerol gels, vegetable and animal hydrogenated fats

C. Gelatin-glycerin gels, vegetable and hydrogenated fats, solid fat, lanol, wax, paraffin, alloys of polyethylene glycols with different molecular weights

D. Vegetable and animal hydrogenated fats, solid fat, lanol, wax, paraffin, gelatin-glycerin gels

E. Alloys of polyethylene glycols with different molecular weights, gelatin-glycerol gels, vegetable and animal hydrogenated fats

17

Lipophilic suppository bases include:

A. *Alloys of hydrogenated fats
B. Polyethylene oxide base
C. Gelatin-glycerin base
D. Collagen base
E. Soap-glycerin base

18

The workshop for the production of soft dosage forms produces suppositories on various bases. What bases are lipophilic:

A. Cocoa butter, vitebsol, hydrogenated fats
B. Gelatin-glycerin base, soap-glycerin base, polyethylene glycol
C. Cocoa butter, polyethylene glycol
D. Polyethylene glycols, hydrogenated fats
E. Lanol, vitebsol, soap-glycerin base

19

In the manufacture of rectal suppositories, the following auxiliary substances are added to ensure the hardening process:

A. Cocoa butter
B. Glycerin
C. Paraffin
D. Vaseline
E. Dry powders

20

In the production of suppositories in industrial conditions, one of the stages of the

technological process is the production of concentrates. What in this case are concentrates:

A. Obtained solutions or suspensions of medicinal substances of low concentration
B. Concentrated solutions of medicinal substances prescribed in small quantities
C. Internal pharmacy preparation of medicinal substances
D. Medicinal substances soluble in the base
E. Medicinal substances soluble in water

21

Suppositories on hydrophilic bases are manufactured at the pharmaceutical enterprise. Specify which parameter is determined during the standardization of these suppositories:

A. Dissolution time
B. Dry residue
C. Boiling temperature
D. Resuspension
E. Mechanical strength

22

The pharmaceutical company manufactures various medicinal products. For which dosage form does the State Pharmacopoeia of Ukraine regulate the "time of complete deformation":

A. Suppositories
B. Tablets
C. Dragee
D. Pellets
E. Capsules

23

Specify which devices are used for packaging ointments in industrial conditions:

A. * Screw machines
B. Vacuum dispensers
C. Maseterki
D. Percolators
E. Disc dispensers

24

Specify the optimal method of manufacturing suppositories in industrial conditions:

A. * Pouring into molds
B. Pressing
C. Pumping
D. Lyophilization
E. Stamping

25

To prepare the ointment, the pharmacist additionally used paraffin. Indicate what role

paraffin plays in technology:

A. Sealant
B. Foundation
C. For dispersing powders
D. Preservative
E. Emulsifier

26

The pharmaceutical company produces ointments. Specify the name of the stage that allows you to obtain a homogeneous ointment:

A. Homogenization
B. Obtaining the base
C. Dispersion
D. Production of ointment concentrate
E. Mixing components with the base

27

Water lanolin consists of:

A. * 70 parts of anhydrous lanolin and 30 parts of water
B. 80 parts anhydrous lanolin and 20 parts water
C. 5 parts anhydrous lanolin and 95 parts water
D. 90 parts lanolin anhydrous and 10 parts water
E. 50 parts of anhydrous lanolin and 50 parts of water

28.

When preparing the ointment base, the components are loaded:

A. In strict order of decreasing melting point
B. In strict order of decreasing adsorption properties
C. In random order
D. In order of increasing mass of components
E. All answers are correct

29.

To pump the molten ointment base from the boiler to the reactor, it is most appropriate to use gear pumps. Specify the reason:

A. Because they work well in viscous environments
B. Because only they can be heated
C. Therefore, the diameter of the pump corresponds to the reactor pipeline
D. The most economical type of pumps
E. All answers are correct

30

Define the term "inverse substitution coefficient"

A. The amount of fatty base that replaces one mass part of LR
B. The amount of LR that replaces one mass part of a fatty base with a specific mass of 0.95

C. The amount of LR that occupies the same volume as one mass part of the fat base
D. The number of hydrophilic compounds that replace water molecules in the base
E. The number of hydrogenated fats that bind to the base
31.
State the advantages of the disk method of dosing capsules:
A. The method allows you to adjust the dosage; the mass of the filler can be adjusted by changing the pressure and increasing or decreasing the level of the filler
B. The method allows partial filling of capsules
C. The method is intended for dosing two fillers into one capsule
D. The method is intended for the use of fillers of clearly defined sizes (tablets, cores, dragees, capsules, etc.)
E. All answers are correct
32.
State the advantages of the double slide method when dosing capsules:
A. The method allows partial filling of capsules
B. The method allows you to adjust the dosage; the mass of the filler can be adjusted by changing the pressure and increasing or decreasing the level of the filler
C. The method is intended for dosing two fillers into one capsule
D. The method is intended for the use of fillers of clearly defined sizes (tablets, cores, dragees, capsules, etc.)
E. All answers
33.
Specify the advantages of the method of forming rolls when dosing capsules:
A. The method is intended for the use of fillers of clearly defined sizes (tablets, cores, dragees, capsules, etc.)
B. The method allows you to adjust the dosage; the mass of the filler can be adjusted by changing the pressure and increasing or decreasing the level of the filler
C. The method is designed for dosing two fillers into one capsule
D. The method allows partial filling of capsules
E. All answers are correct
34.
Specify the features of rectal capsules:
A. They consist of a thin layer of gelatin, the surface of which becomes slimy when moistened with water
B. Such capsules are not stable at elevated temperatures, which facilitates the release of LR
C. The release of LR is slow compared to suppositories, so their use is not widespread

D. Due to the poor permeability through the gelatin shell, in order to achieve a therapeutic effect, the amount of LR in the rectal capsule should be a dose one and a half times greater than the dose in the suppository

E. All answers are correct

35.

When determining the uniformity of the mass of a unit of a dosed medicinal product with an average weight of a capsule of less than 300 mg per DFU, the permissible deviation should:

A. Do not exceed 10%

B. Not to exceed 5%

C. Not to exceed 7.5%

D. Not to exceed 20%

E. Do not exceed 15%

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

1. Make a work order for obtaining 10.0 kg of white mercury ointment, taking into account that the consumption factor at the stage of preparation of the base is 1.003, at the stage of mixing mercury amidochloride with the base - 1.002, at the stage of homogenization - 1.005.

at the stage of homogenization - 1.005.

The composition of mercury white ointment:

Mercury amidochloride 1.0 kg

Vaseline 6.0 kg

Anhydrous lanolin 3.0 kg

2. Make a work order for obtaining 10.0 kg of streptocide ointment, assuming that the consumption factor at the homogenization stage is 1.005.

Ointment composition: streptocide 10%, petroleum jelly 90%.

3. Write the material balance equation when Teymurov's paste is obtained. Determine its main indicators, assuming that the losses of individual starting ingredients have the same values. Calculate the consumption rates for the preparation of the drug according to its prescription. The total amount of the starting ingredients of the drug according to the prescription is 50.0 kg, the amount of the finished product is 49.5 kg.

The composition of Teymurov paste:

Boric acid 7.0

Zinc oxide 25.0

Sodium tetraborate 7.0

Salicylic acid 1.4

Hexamethylenetetramine 3.5

Formaldehyde solution 3.5

Lead acetate 0.3

Peppermint oil 0.3

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
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- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
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Independent work #13

Topic 13: " Industrial production of suppositories "

Goal: Study technological schemes of suppository production. Be able to rationally select auxiliary materials and equipment, carry out quality control, packaging and labeling of the finished product.

Basic concepts:

Pouring method - pouring the molten mass into molds and pressing it on special equipment . Industrial production of suppositories in this way is most often carried out according to a technological scheme, which consists of the following stages:

1) preparation of the base;
2) preparation of medicinal substances and preparation of concentrate;
3) introduction of medicinal substances into the base;
4) formation (and packaging) of suppositories;
5) packaging of suppositories.

By the method of pressing - on eccentric tablet machines with cooling of the punch, matrix and casing, it is possible to obtain from 40 to 100 thousand suppositories per hour. The suppository mass is usually cooled in a refrigerator to 3-5 °C, crushed and sieved. Lactose, sucrose, aerosol, starch are added to the granulate to adjust the technological properties

Basics - from the point of view of physical and chemical science, suppositories are considered as dispersed systems consisting of a dispersed medium represented by the base and a dispersed phase, the role of which is performed by medicinal substances. Depending on the properties of medicinal substances, suppositories can create different dispersion systems.

Plan

1. Theoretical questions:

1. Characteristics of the suppository as a dosage form. Let them go .
2. Positive and negative aspects of using suppositories .
3. Methods of production of suppositories in industry .
4. Stages of the technological process of obtaining suppositories .
5 . Pouring method in the production of suppositories .

6. Method of pressing in the production of suppositories .
7. Basics that will be used for the manufacture of suppositories .
8. Groups of auxiliary substances in the production of suppositories .
10. Paratour equipment for the production of suppositories .

Questions for self-control:

1. Definition of emulsion, suspension, as LF, scope of application.
2. Features of preparation of emulsion and suspension preparations.
3. Method of obtaining and equipment used in the production of suspensions and emulsions.
4. By what methods are suspensions and emulsions obtained at pharmaceutical plants?
5. What factors determine the stability of suspensions and emulsions?
6. What role do auxiliary substances play in the production of suspensions and emulsions
7. What stages does the process of obtaining dispersion preparations consist of?
8. What drugs are used in the production of suspensions and emulsions?
9. What is the principle of operation of turbine mixers and RPA?

Approximate tasks for processing the theoretical material:

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

1. Make a technological block diagram of the industrial production of suppositories.

3. Test tasks for self-control:

1. Suppositories are manufactured at a pharmaceutical enterprise. Indicate which method is the most optimal to use for the production of suppositories in industrial conditions:

A Molding
B Rolling C Pressing D Stamping E Lyophilization

2. Lipophilic suppository bases include:

A Hydrogenated fat alloys
B Polyethylene oxide base
C Gelatin-glycerol base D Collagen base E Soap-glycerin base

3. Suppositories are manufactured at a pharmaceutical enterprise. Indicate which method is the most optimal to use for manufacturing suppositories in industrial conditions:

A. _ Molding

B. _ Rolling out
C. _ Pressing
D. _ Stamping
E. _ Lyophilization

4 . Lipophilic suppository bases include :
A. _ Alloys of hydrogenated fats
B. _ Polyethylene oxide base
C. _ Gelatin-glycerin base
D. _ Collagen base
E. _ Soap-glycerin base

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

Task. Preparation of the thesis emulsion.

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V. [etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).
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Independent work #14

Topic 14: " Production of plasters and TTS "

Goal: To study the production technology of plasters and TTS. Be able to rationally select auxiliary materials and equipment, carry out quality control, packaging and labeling of the finished product.

Basic concepts:

Mustard sticks are sheets of paper coated on one side with a thin layer of defatted dry powder obtained from black mustard seeds. In medical practice, it is this powder that acts on the skin for the purpose of irritation and distraction.

Plaster - (from buckwheat. Emplastron - ointment), dosage form for external use - a plastic mass that softens at body temperature and sticks to the skin. It consists of fatty acid salts mixed with wax, rosin, medicinal and other aromatic and medicinal substances. A sticky plaster (glucose plaster) is used to fix non-bandaged bandages

Plan

1. Theoretical questions:

1. Characteristics of plasters as a medicinal form. Types of patches .
2. Positive and negative aspects of using plasters and TTS .
3. The main areas of production of plasters and TTS .
4. Stages of the technological process of obtaining plasters and TTS .
5. Targets and main types of plasters and TTS .

6. Wet granulation. Positive and negative aspects of this process.
7. Groups of auxiliary substances in the production of tablets.
8 . Stages and equipment of production of tablets with preliminary granulation.

Questions for self-control:

1. 1. Plasters and mustard plasters, their characteristics and classification.
2. Technology of obtaining plasters.
3. Equipment: reactors, USPL-I installations, chamber-loop dryer, etc. Lead, complex, epilin, resin wax, rubber, adhesive plaster elastic smeared, bactericidal, callus, pepper, liquid (cleol, collodion, glue BF-6, colaplast, microplast, furoplast, Novikov's liquid, callus liquid).
4. Mustard seeds. Technology of mustard seeds. Packaging. Storage

Approximate tasks for processing the theoretical material:

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

1.

3. Test tasks for self-control:

1.

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

1 . How are plasters classified depending on the medical purpose?
2. How are plasters classified according to the composition of the plaster mass?
3. What auxiliary substances are used in the production of resin-wax and lead plasters?
4. What are the main technological stages in the production of rubber plasters?
5. What medicinal substances are included in the pepper patch?
6. How is the quality of mustard obtained and evaluated?
7. What auxiliary substances in liquid plasters form a protective film?
8. What are the advantages of liquid plasters in aerosol packaging?

5. List of recommended literature (main, additional, electronic information resources) :

Main:

- Industrial technology of medicines: a basic textbook for students. higher education Pharm. institution (Pharmacy) / Gladukh E.V., Ruban O.A., Saiko I.V.

[etc.].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, vtpr. But he added. - - Kh.: National Institute of Scientific Research: Novy Svit, 2018. - 486 p. : fig. – (National textbook series).

- A.G. Bashura, O.S. Shpichak, E.E. Bogutska; under the editorship A.I. Tikhonov and S.A. Tikhonova - Kh.: Original, 2016. - 462 p.
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- Workshop on industrial technology of medicinal products: teaching. manual for students higher education institutions with the specialty "Pharmacy" / O.A. Ruban, D.I. Dmytrievskyi, L.M. Khokhlova [and others]; under the editorship O.A. Ruban. – Kh.: National Institute of Medical Sciences; Original, 2015. – 320 p.
- INDUSTRIAL technology of medicines : education. manual for students' independent work / O.A. RUBAN , V.D. RYBACHUK , L.M. X ohlova etc. - KH.: NF and U, 2015. - 120 p.
- Study guide for preparation for the final modular control and State certification in the Industrial Technology of Medicines for full-time and part-time students of the "Pharmacy" specialty / Ed. O.A. Ruban. - Kh.: National Academy of Sciences, 2016 . - 80 p.
- Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing integrated exam "Step 2. Pharmacy" / O.A. Ruban, V.D. Rybachuk, L.M. Khokhlova, D.S. Pulyaev - KH.: NF and U, 2016. - 63 p.
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Auxiliary :

- Mathematical planning of an experiment when conducting scientific research in pharmacy / T.A. Groshovyi, V.P. Martsenyuk, L.I. Kucherenko and others. – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
- Regulatory and technical documentation and production validation. Material balance: Educational method. river for audit. and external audit. student work special "Pharmacy" of full-time and part-time education / D.I. Dmytrievskyi, G.D. Slipchenko, I.M. Hrubnyk, D.V. Rybachuk . - Kh.: Publishing House of the National Academy of Sciences, 2008. - 45 p.
- Technology of medicinal products of industrial production: training. manual/ edited by Prof. D.I. Dmitrievsky. – Vinnytsia: Nova kniga, 2008. – 280 p.

- Drug technology. Educational and methodological guide: Education. manual for students higher education hall. / O.I. Tikhonov, P.A. Logvin, S.O. Tikhonova, O.V. Bazulin, T.G. Yarnykh, O.S. Shpychak, O.M. Kotenko; under the editorship O.I. Tikhonova, Kh.: Original, 2009. - 432 p.
- Pharmaceutical encyclopedia / Chief editor. council and the author of the foreword V.P. Black people - 3rd ed., revised. and additional - K.: "MORION", 2016. - 1952 p.
- Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
- European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & Healthcare. - Strasbourg, 2013. - 3638 p.
- Handbook of Pharmaceutical Excipients, 6th edition / RC Rowe, PJ Sheskey, ME Quinn. - Pharmaceutical Press and American Pharmacists Association, 2009. - 521 p.
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- Powder manufacturing technology: teaching. manual / L.L. Davtyan, R.S. Korytniuk, A.O. Drozdova, I.O. Vlasenko, Z.V. Malenka, V.P. Popovych, V.V. Gladyshev, S.M. Musoev, T.F. Olifirova, L.I. Vishnevska, O.M. Hlushchenko, O.O. Khomich; under the editorship L.L. Davtyan, R.S. Korytnyuk - K.: "Education of Ukraine", 2016. - 141 p.
- S.S. Zuykin. –Kharkiv.: Publishing House of IFNMU-NFaU, 2017. – 44 p.
- Zujkina SS The pharmacotechnological studies of the phytospecies composition for the complex therapy of mastopathy / SS Zujkina, LI Vishnevska // Herald of pharmacy. – 2017. – No. 2 (90). - P. 43-47.

Independent work #15

Topic 15: " Production of nano- and radiopharmaceuticals "

Goal: To study technological schemes for the production of radio- and nanopharmaceuticals . Be able to rationally select auxiliary materials and equipment, carry out quality control, packaging and labeling of the finished product.

Basic concepts:

Radiopharmaceutical drug (eng. radioparmaceutica drag) — any pharmaceutical product that contains one or more radionuclides (radioactive isotopes) included in the formulation for diagnostic or therapeutic purposes.

Radionuclide impurities are impurities of other radioactive nuclides (in percentage) to the activity of the main nuclide for a certain time (date);

Radiochemical impurities are impurities of chemical compounds different from the main substance that makes up the drug, but contain the same radionuclide.

Plan

1. Theoretical questions:

1. The role and place of nanomedicines in modern medicine.
2. History of creation of nanopreparations.
3. Materials used in the production of nanopreparations.
4. Advantages and disadvantages.
5. Technology of obtaining nanopreparations.

Questions for self-control:

1. Describe the concept of "nanotechnology". What is the role and place of nanopreparations in medicine and pharmacy?
2. The use of nanotechnology in the production of medicinal products.
3. Define the term "address delivery of drugs." Name the requirements for targeted drug delivery systems.
4. Describe nanomaterials, name the types and classification of nanomaterials.
5. Basic principles and directions of nanotechnology. Nanopreparations. Features of their production. Nanosystems, methods of obtaining nanosystems.
6. Describe the concept of "radiopharmaceutical preparation". Describe the production, application and main diagnostic properties of radiopharmaceuticals.
7. Assortment and composition of radiopharmaceuticals on the pharmaceutical market of Ukraine. Features of their technology and quality control.

Approximate tasks for processing the theoretical material:

— Compile a dictionary of basic concepts on the topic.

2. Practical works (tasks) to be performed:

1.

Term	Definition
1. Radioactivity	A. Ratio of radionuclide activity to total radionuclide

2. Radiochemical purity	activity in this drug.
3. Nuclear isomers	B. The ratio of the activity of the main radionuclide to the total activity of the drug
4. Radionuclide purity	B. Nuclides that have the same mass number and atomic number, but different energy states of their nuclei
	D. The property of some nuclides to undergo radioactive decay.

Task 2. Insert the missing words.

Increasing _____ of the drug with the help of nanoparticles consists in the use of _____ sizes of these particles, which have a much _____ surface area and at the same time are purposefully absorbed by specific tissues .

Task 3 . Match the pairs.

Classification of nanomaterials	Nanomaterials
A. By appointment	1. One-dimensional objects, two-dimensional objects, three-dimensional particles, nanocomposites
B. According to aggregate state and morphological features	2. Functional, compositional, structural
A. By the nature of the carrier	3. Nanosuspensions, microemulsions, nanoemulsions, nanocapsules, surfactants
G. By the number of measurements	4. Polymer nanoparticles, lipid nanoparticles, organometallic nanoparticles)

Task 4. Insert the missing words.

Being in the state of _____, medicinal products have a number of advantages: they are protected from destruction during transport to the destination, nanoparticles are actively or passively accumulated in _____ and release _____ dose of the drug at the right time, it is possible to use nanoparticles as contrast agents of diagnostic systems.

Task 5 . Match the pairs

Term	Definition
1. Radiopharmaceutical preparation	A. This is a macromolecular biological structure, which is probably related to a certain function, the violation of which leads to a disease and on which it is necessary to carry out a certain action.
2. Nanotechnology	B. This is a system of nanoobjects, the activity of which and the method of delivery to the target tissue (organ) are determined by the properties of this object.
3. Address delivery of medicines	B. Science that deals with a set of theoretical justifications, practical methods of research, analysis and synthesis, as well as methods of production and
4. Target	

application of products with a given atomic structure
D. A medicinal product, approved for administration to a person for diagnostic or therapeutic purposes, which contains a certain radioactive nuclide in its molecule.

3. Test tasks for self-control:

1. The effective half-life never exceeds the time:
A. Biological half-life.
B. Can exceed both physical and biological .
C. Physical half-life .
D. Physical half-life .
E. Neither physical nor biological.

1 2 . Radiochemical pollution can become:
A. The reason for the change in the biological behavior of RFP.
B. The reason for the change in the overall activity of the drug .
C. The reason for the lack of biological effect of RFP.
D. All of the above.
E. Cause of radiation damage .

2 3. Radiochemical purity can be established by the following methods:
A. Chromatographic .
B. Definition of general activity .
C. Electrophoretic .
D. Biological effect of RFP .
E. To all of the above .

3 4. Radiochemical purity is:
A. The presence of unlabeled chemicals in the RFP.
B. The fate of the radionuclide in the RFP in the required chemical form.
C. The share of the total activity of the drug due to the radionuclide .
D. Change in the biological behavior of RFP.
E. Absence of biological effect of RFP.

4 5. Over time, radiochemical purity ...:
A. Increases over time.
B. Increases .
C. Does not change .
D. C decreases with time.
E. Decreases .

6. Depending on the purpose, nanomaterials are classified into:
A. Nanosuspensions, polymers, nanoparticles.
B. Functional, compositional, structural.
C. Organometallic, mixed, microemulsions.

D. Single-layer liposomes, mycelium, nanocapsules.
E. Multilayered liposomes, lipoproteins, monolithic nanoparticles.
7. Nanoobjects are ..
A. Structural elements whose linear size in at least one dimension is 10 - 100 nm;
B. Structural elements of microcapsules;
C. Small spherical particles obtained by combining powders of active substances and fillers;
D. Structural elements of the drug provide connection with peptides;
E. Substances that provide solidification of reactive oligomers.
8 . Types of nanomaterials have the following classification:
A. Nanoparticles, nanotubes, nanofibers.
B. Liposomes, dendrimers, micelles.
C. H anoporous structures, nanoparticles, nanodisperse, nanostructured surfaces, nanoclusters.
D. Nanosystems, nanoobjects.
E. Nanobiotechnological, nanomedical, nanoorganic.
9. Fullerenes are:
A. Graphene grids rolled into tubes with a distance between the walls of 0.35 nm.
B. Molecular compounds that have the form of convex closed polyhedra, consisting of even, formed only by an even number of carbon atoms in sp^2-hybridization.
C. Lipid nanoparticles.
D. Nanoparticles in aggregate state.
E. Ferromagnetic particles.
10. Nanoparticles are obtained by:
A. Using a dismembrator.
B. Grinding, homogenization.
C. Ultrasonic crystallization, coacervation.
D. Mechanical activation, homogenization with microprecipitation.
E. Sublimation drying.

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

1 . Equipment used in the production of nanopreparations. Quality control.
2. Production and use of radiopharmaceuticals.
3. Assortment and composition of radiopharmaceuticals on the pharmaceutical market of Ukraine.
4. Features of technology and quality control of radiopharmaceuticals.
5. Use of nanotechnology in the production of medicinal products.
6 . Special conditions necessary for the manufacture of radiopharmaceuticals
7. Groups of auxiliary substances in the production of nano- and radiopharmaceuticals .
8 . And equipment for the production of nano- and radiopharmaceuticals .

5. List of recommended literature (main, additional, electronic information resources) :

Main:

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