Topic 1. **«Auxiliary operations in the manufacture of drugs. I manufactured solid drugs (powders)».**

1. *Grinding machines are classified according to the method of grinding the material into:*

A. disk, ball, rotary machines;

B. disk, cutting, fine grinding machines;

C. crushers of medium, fine, colloidal, fine grinding;

D. cutting, erasing, crushing, percussion, centrifugal machines;

E. grass cutters, root cutters.

2. When determining the technological properties of powders determine the flowability. What devices are used to determine this indicator?

A. vibrating funnel;

B. disintegrator;

C. dysmembrane;

D. a set of sieves;

E. friabilizer.

3. *At pharmaceutical enterprises in the production of powders use the operation of grinding drugs. What machines are used for fine grinding of the substance:*

A. dismebrators;

B. drum mills, vibrating mills;

C. grass and root cutters;

D. roller shredders;

E. disintegrators.

4. *The pharmaceutical company produces powders for various purposes. Specify the degrees of grinding of powders given in the SPU:*

A. large, medium, thin;

B. large, medium-sized, medium-sized, small, smaller, smallest;

C. large, medium-sized, medium-sized, smaller, colloidal;

D. large, medium, small, colloidal;

E. large, medium, small, the smallest.

5. *Grinding equipment is classified according to the method of grinding. Which machines are the roller crusher:*

A. percussion;

B. erasing;

C. crushing;

D. cutting;

E. shock-centrifugal.

6. *To obtain a homogeneous mixture of bulk materials using mixers. Which faucets do not have rotating parts:*

A. two-cone mixers;

B. drum mixers;

C. paddle mixers;

D. fluidized bed faucets;

E. centrifugal mixers.

7. *On which sieves can wet material be sifted?*

A. vibrating screens;

B. sieves;

C. multi-tiered rocking sieves;

D. mechanical sieves;

E. gyration sieves

8. *The pharmaceutical company produces powders. Specify the equipment used for packing powders:*

A. dismembers;

B. disintegrators;

C. screw and vacuum dispensers;

D. screw and piston dosing machines;

E. tube filling dosing machines.

9. *Various medicines are manufactured at a pharmaceutical enterprise. Indicate the name of the dosage form, which consists of solid individual dry particles of varying degrees of fineness:*

A. suspensions;

B. tablets;

C. powders;

D. emulsions;

E. dry extract.

10. *The pharmaceutical company produces powders. Specify the correct order of stages of the technological process of manufacturing simple powders:*

A. preparation for production; screening of components; grinding of components; quality control; packing, marking, packing;

B. production preparation; grinding of raw materials; screening of components; quality control; packing, marking, packing

C. production preparation; grinding of raw materials; mixing of components; quality control; packing, marking, packing;

D. production preparation; grinding of raw materials; quality control; packing, marking, packing

E. production preparation; screening of components; grinding of raw materials; quality control; mixing of components; packing, marking, packing.

Topic 2. «Manufacturing technology of solid dosage forms».

1. *To ensure the required technological properties, most tablet mixtures are subjected to pre-granulation. Name the main types of granulation:*

A. structural;

B. moisture;

C. mixed;

D. all listed;

E. dry.

2. *Different groups of excipients are used in the production of tablets. Which of the following groups of substances provide the strength of tablets?*

A. binders;

B. loosening;

C. sliding;

D. correctors;

E. lubricating.

3. *Several are used in the technology of obtaining tablet drugs methods of structural granulation:*

A. in a dragee boiler, in a fluidized bed;

B. briquetting, in a coating pan, by spraying;

C. in a coating pan, no spraying;

D. in a coating pan, by spraying;

E. in a dragee boiler, spraying, in a fluidized bed.

4. *Granulation of the powder mass during tableting affects:*

A. solubility;

B. disintegration;

C. mass fluidity, dosing accuracy;

D. bioavailability;

E. mechanical strength.

5. *From the following substances, specify the substances for coating tablets with film coatings:*

A. aerosil;

B. methylcellulose;

C. talc;

D. castor oil;

E. polyethylene oxides.

6. *Different fillers are used to ensure the required weight of tablets. Choose the one you use most often:*

A. sorbitol;

B. glucose;

C. calcium hydrogen phosphate;

D. MCC;

E. all listed.

7. *Povidone is used as a binder in modern tablet production. Which polymer derivatives do they belong to?*

A. MC;

B. MCC;

C. GPMC;

D. alginates;

E. PVP.

8. *The corrective substances that are added to the tablets include:*

A. sweeteners;

B. all listed;

C. pectins;

D. essential oils;

E. syrups.

9. *Synthetic dyes of natural origin include:*

A. carotenoids;

B. iron oxide;

C. titanium dioxide;

D. indigo;

E. eosin.

10. *What type of collidone is not used in tablet production:*

A. collidone 90;

B. collidone 25;

C. collidone 30;

D. collidon 12 PF («PF» - «pyrogenfre» - «pyrogen-free») F;

E. all listed.

11. *Dyes are added to improve the appearance of tablets, to stabilize light-sensitive drugs, as well as to:*

A. improving the therapeutic effect;

B. improving the appearance;

C. providing a therapeutic action;

D. correction of taste and smell;

E. improving the force of adhesion of particles.

12. *Of all the currently available types of coatings, the most commonly used are:*

A. all these options;

B. coated

C. pressed;

D. gastric soluble;

E. tapes.

Topic 3. «Solid dosage forms of prolonged action. Microcapsulation of medicinal substances».

1. *The main goal of creating long-acting drugs is:*

A. maintaining the therapeutic concentration of drugs for a long time in the body;

B. reduction to a minimum of side effects;

C. reducing the dose of the drug;

D. reduction in the number of medications taken;

E. everything is correct.

2. *To create matrix tablets, the following is used as a matrix former:*

A. starch;

B. cellulose derivatives;

C. lactose;

D. calcium stearate

E. talc.

3. *How are modified release dosage forms classified by release kinetics:*

A. with continuous, intermittent, delayed, pulsating release;

B. diffuse, osmotic, magnetic;

C. monolithic, reservoir, pumping;

D. by the time of the onset and duration of the effect;

E. prolonged and controlled release.

4. *The following are used as swellable polymers to obtain matrix tablets of prolonged action:*

A. polyvinyl chloride;

B. natural waxes;

C. alginates;

D. microcrystalline cellulose;

E. palmitic acid esters.

5. *Microencapsulation of the medicinal product does not allow:*

A. to mask the taste, smell.

B. stabilize the drug during storage;

C. program the release;

D. modify the release parameters;

E. increase solubility.

6. *How are modified release dosage forms classified according to the release mechanism:*

A. by the time of the onset and duration of the effect;

B. monolithic, reservoir, pumping;

C. with prolonged and controlled release;

D. diffuse, osmotic, magnetic;

E. with continuous, intermittent, delayed, pulsating release.

7. *How are modified release dosage forms classified according to the degree of process control:*

A. monolithic, reservoir, pumping;

B. diffuse, osmotic, magnetic;

C. with prolonged and controlled release;

D. by the time of the onset and duration of the effect;

E. with continuous, intermittent, delayed, pulsating release.

8. *Sustained-release drugs are prescribed to achieve the following goals:*

A. all faithful;

B. reduction in the number of medications taken up to 1-2 times a day;

C. reduction in the total amount of the drug;

D. reduction of side effects and unwanted manifestations on the mucous membranes;

E. rapid achievement of the therapeutic concentration of the drug in the body and maintaining it for 8 - 12 hours.

9. *Prolonged dosage forms include:*

A. Gastrointestinal Therapeutic Systems (GITS) and. zero order kinetic systems (ZOK, SODAS);

B. tablets with periodic release of the drug from the stock;

D. implantation therapy systems;

E. systems of continuous subcutaneous insulin administration.

10. *Various methods are used to make microcapsules. Indicate the method that relates to physical and chemical:*

A. interfacial polymerization;

B. method of dispersion in liquid-liquid system

C. interfacial polycondensation;

D. simple and complex coacervation;

E. method of pelleting.

11. *In the workshop for the production of solid dosage forms, various finished medicines are produced. What are microcapsules?*

A. granules coated with a film of high molecular weight compounds;

B. solid dosage form, which is prepared by layering medicinal and auxiliary substances on sugar granules;

C. dosage form for internal use, which is obtained by pressing medicinal substances;

D. dosage form for internal use with an insoluble framework;

E. the smallest particles of a solid, liquid or gaseous substance, covered with a shell of polymer or other material.

12. *At a pharmaceutical enterprise microcapsules are produced by the pelleting method. Specify the equipment used to obtain microcapsules by this method:*

A. disintegrator;

B. mixer - granulator;

C. freeabilizer;

D. dismembrator;

E. dragee boiler.

13. *Various methods are used in the production of microcapsules. What methods are chemical?*

A. polymerization, polycondensation;

B. simple coacervation;

C. dispersing;

D. dissolution;

E. pelleting.

14. *A pharmaceutical company produces microcapsules using manufacturing methods. From the proposed methods, select those that belong to this group:*

A. phase separation method, electrostatic, dredging method, liquid-liquid dispersion method;

C. method of interfacial polymerization of monomers, interfacial polycondensation of monomers, centrifugal microencapsulation;

B. dragee method, liquid-liquid dispersion, fluidized bed spraying, centrifugal microencapsulation;

D. method of simple coacervate, method of two-complex coacervates, three complex coacervates, interfacial polymerization of monomers;

E. Centrifugal microencapsulation, simple coacervation method, two-complex coacervate method, three-complex coacervate method, draining method.

15. *Specify the method that is advisable to use in order to encapsulate a drug in a gaseous state?*

A. dispersing;

B. Drazhuvannya;

C. spraying;

D. coacervation;

E. polymerization.

Topic 4. : «Extraction drugs. Technology of making tinctures . Novogalene preparations».

1. *The driving force of the diffusion process in the extraction of plant raw materials are:*

A. high temperature of the extractant;

B. the difference in the concentration of the active substance in the raw material and the extractant;

C. high polarity of the extractant;

D. Brownian motion of particles;

E. the presence of a film membrane.

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

A. diethyl ether;

B. acetone;

C. chloroform;

D. ethyl alcohol;

E. peach oil.

3. *Herbal preparations DO NOT include*:

A. tablets;

B. tinctures;

C. thick extracts;

D. dry extracts;

E. liquid extracts.

4. *The galenic preparations include:*

A. only active ingredient;

B. the amount of active ingredients;

C. thickeners;

D. flavoring agents;

E. sweeteners.

5. *The phytochemical workshop produces tinctures. This dosage form is:*

A. extracts from medicinal plants obtained using ether or chloroform;

B. aqueous extracts from medicinal plant materials;

C. water-ethanol extracts from medicinal plants, containing 25% moisture;

D. oil extracts from medicinal plant materials;

E. alcoholic extracts from medicinal plant materials obtained without heating and removing the extractant.

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

A. vortex extraction;

B. maceration;

C. percolation;

D. remaceration;

E. maceration with forced circulation of the extractant.

7. *The release of extractive substances from plant materials occurs due to:*

A. adsorption and re-adsorption of the extractant by plant material;

B. molecular and cellular diffusion;

C. convective and cellular diffusion;

D. coacervation;

E. molecular and convective diffusion.

8. *The extraction process consists of the following stages: capillary impregnation, formation of primary sap and:*

A. dissolution;

B. mass transfer;

C. maceration;

D. squeezing primary juice

E. washing plant materials with an extractant.

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

A. maceration;

B. repercolation with evaporation;

C. with percolation;

D. repercolation with distribution of raw materials into unequal parts;

E. extraction using ultrasound.

10. *Tinctures are obtained by all methods, except for:*

A. percolation of medicinal plant materials;

B. maceration of medicinal plant materials;

C. fractional maceration of medicinal plant materials;

D. dissolution of medicinal plants in ethanol;

E. dissolution of thick or dry extracts in ethanol.

11. *Herbal preparations include:*

A. boluses;

B. spansula;

C. tinctures;

D. durula;

E. aerosols.

12. *Straining the extractant through the medicinal plant material in order to obtain an extract of the substances dissolved in the extractant is:*

A. maceration with forced circulation of the extractant;

B. remaceration;

C. maceration;

D. vortex extraction;

E. percolation.

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

A. repercolation with evaporation;

B. maceration;

C. with percolation;

D. repercolation with distribution of raw materials into unequal parts;

E. extraction using ultrasound.

14. *The pharmaceutical company produces novogalenic drugs. Indicate, upon receipt of which of them, the circulation apparatus of the «Soxhlet» type is used?*

A. adoniside;

B. digoxin;

C. korglikon;

D. lantoside;

E. celanide.

15. *In the production of the most purified preparations, specific methods of cleaning the lifts are used. Specify the method related to salting out:*

A. ultrasonic treatment;

B. heating;

With dialysis;

D. the effect of UV radiation;

E. action of saturated solutions of strong electrolytes.

16. *In the production of maximally purified preparations, the extracts are purified by liquid extraction, which is:*

A. dialysis;

B. the process of affecting the heating coil;

C. the process of action of electrolytes;

D. the process of extracting substances from one liquid using another, which does not mix with the first;

E. the process of exposure to ultrasound.

17. *The phytochemical department of the enterprise produces highly purified drugs. In this case, specific methods of cleaning the lifts are used. What the dialysis method is based on:*

A. exposure of the hood to heat;

B. on the extraction of substances from one liquid using another, does not mix with the first;

C. on the properties of biopolymer molecules not to pass through semipermeable membranes;

D. on the action of the electrolyte;

E. on the process of gas absorption.

18. *Methods of BAS purification by sorption are widely used in the chemical and pharmaceutical industry. One of the types of sorption is chemisorption, which is:*

A. absorption of substances with the formation of chemical compounds;

B. absorption of a substance by the entire volume of a solid or liquid phase;

C. absorption of substances on the surface of the sorbent;

D. absorption of matter by the whole volume

E. separation of high-molecular and low-molecular compounds on selective membranes.

19. *What is the most significant sign that distinguishes novogalenic drugs from*

galenic:

A. using countercurrent extraction;

B. content of the amount of active ingredients;

C. use for the extraction of aqueous solutions of ethanol;

D. use of adsorption cleaning methods;

E. the possibility of parenteral administration of drugs.

20. *The pharmaceutical company produces the drug "Korglikon". Specify the raw materials to receive it:*

A. wormwood herb;

B. grass of lily of the valley;

C. dandelion root;

D. plantain leaves;

E. buckthorn bark.

Topic 5. «Preparation and analysis of aqueous solutions. Alcoholic solutions».

1. *A pharmaceutical company produces Lugol's solution. By the type of solvent, this solution refers to:*

A. alcohol solution;

B. glycerin solution;

C. oil solution;

D. aqueous solution;

E. chloroform solution.

2. *Which of the following extractants has a number of advantages, which include affordability?*

A. water;

B. ethyl alcohol;

C. methyl alcohol;

D. methylene chloride;

E. ethyl ether.

3. *A pharmaceutical plant produces aromatic waters. Indicate in what ratio the fragrant dill water is prepared:*

A. 1: 1;

B. 1:10;

C. 1: 1000;

D. 1: 2000;

E. 1: 4000.

4. *A pharmaceutical plant produces flavored water. Indicate the equipment that is required for the production of aromatic water by distillation:*

A. mixer, distillation cube, distillate collector;

B. bubbler, refrigerator, distillate collector;

C. grass cutters, alembic, refrigerator,

D. paddle mixer, filter, distillate collector;

E. steam-heated distillation cube, bubbler, refrigerator, distillate collector.

5. *In what concentration is Lugol's solution prepared for internal use?*

A. 10%;

B. 1%;

C. 5%;

D. 0.5%;

E. 3%.

6. *A pharmaceutical company produces aqueous solutions. Specify solutions that are made by chemical interaction of substances:*

A. aluminum hydroxoacetate solution, lead hydroxyacetate solution, calcium hydroxide solution;

B. aluminum hydroxyacetate solution, lead hydroxyacetate solution, hydrochloric acid solution;

C. calcium hydroxide solution, sodium hydroxide solution;

D. aluminum hydroxoacetate solution, polyvinyl alcohol solution;

E. lead hydroxyacetate solution, nitric acid solution.

7. *What type of mixer is used for high-speed mixing of solutions with low viscosity?*

A. planetary;

B. turbine;

C. screw;

D. anchor;

E. drum.

8. *When receiving bitter almond water, the raw material is soaked for 12 hours at room temperature for:*

A. hydrolysis of sugars;

B. hydrolysis of fats;

C. protein hydrolysis;

D. hydrolysis of sinigrin;

E. hydrolysis of amygdalin.

9. *The alcohol content is determined with an alcohol meter, pycnometer and hydrometer. The hydrometer is used when determining:*

A. mass of water-alcohol solution;

B. the density of the water-alcohol solution;

C. volume of water-alcohol solution;

D. surface tension of a water-alcohol solution;

E. percentage.

10. *Ethyl alcohol is widely used in pharmaceutical practice as a solvent, preservative and extractant. Which of the following properties of alcohol is negative:*

A. alcoholic solutions are stable;

B. has a bactericidal effect;

C. ease of preparation of aqueous-alcoholic solutions;

D. dissolves water-insoluble substances;

E. has the ability to coagulate proteins, enzymes, mucus at high concentrations.

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B. disk, cutting, fine grinding machines;

C. crushers of medium, fine, colloidal, fine grinding;

D. cutting, erasing, crushing, percussion, centrifugal machines;

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D. emulsions;

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10. *The pharmaceutical company produces powders. Specify the correct order of stages of the technological process of manufacturing simple powders:*

A. preparation for production; screening of components; grinding of components; quality control; packing, marking, packing;

B. production preparation; grinding of raw materials; screening of components; quality control; packing, marking, packing

C. production preparation; grinding of raw materials; mixing of components; quality control; packing, marking, packing;

D. production preparation; grinding of raw materials; quality control; packing, marking, packing

E. production preparation; screening of components; grinding of raw materials; quality control; mixing of components; packing, marking, packing.

Topic 6. «Syrups Solutions for injection in ampoules».

1. *Which of the following syrups is used as a means of improving the taste of the main active ingredients of drugs?*

A. rhubarb syrup;

B. marshmallow syrup;

C. sugar syrup;

D. licorice root syrup;

E. rosehip syrup.

2. *Indicate which type of mixer should be used to prepare sugar syrup:*

A. anchor;

B. propeller;

With turbine;

D. pneumatic;

E. circulating.

3. *In order to prevent burning, inversion and caramelization, the preparation of sugar syrup is carried out:*

A. with the addition of citric acid;

B. in reactors with a steam jacket and an anchor stirrer;

C. at 60-64% concentration;

D. by dissolving in boiling water;

E. using refined sugar.

4. *Sugar syrup is filtered hot in order to:*

A. removing excess moisture;

B. prevention of microbial contamination;

C. preventing sugar crystallization,

D. speed up the filtration process.

E. prevent caramelization.

5. *Why, at the optimal concentration of sugar syrup, microorganisms practically do not develop in it?*

A. due to low pH;

B. due to high pH;

C. due to a decrease in the surface tension between the solution and the microcell;

D. only due to the introduction of preservatives;

E. osmotic pressure in solution is higher than in a microcell;

6. *Syrups that do not contain active ingredients are used in industrial production as:*

A. corrective agents such as adhesives and thickeners;

B. as a basis for the preparation of non-aqueous dosage forms;

C. as emulsifiers;

D. as solvents for the preparation of liquid dosage forms;

E. as stabilizers.

7. *Simple sugar syrup contains:*

A. 65 parts sugar 33 parts water and 2 parts 90% alcohol;

B. 73 parts sugar 22 parts water and 5 parts 90% alcohol;

With 50 parts sugar and 50 parts water;

D. 64 parts sugar and 36 parts water;

E. 45 parts sugar and 55 parts water.

8. *At a pharmaceutical enterprise, a solution is prepared consisting of 12 parts of a liquid thyme extract and 1 part of sodium bromide mixed with 82 parts of sugar syrup and 5 parts of 96% alcohol. Indicate the name of the drug:*

A. holosas;

B. ambroxol;

C. pertusin;

D. flamin;

E. adoniside.

9. *One of the operations of the technological process of obtaining solutions for injection is the filtration of solutions. What filters are used for sterile filtration?*

A. filter fungus;

B. Nutsch filters;

C. filter HNIHFI;

D. Druk filters;

E. filter candles;

10. *One of the indicators of quality control of finished ampoules is the absence of residual stresses in the glass. Indicate which operation from the stage «Preparing ampoules for filling» eliminates this drawback:*

A. washing ampoules;

B. opening of capillaries;

C. annealing of ampoules;

D. drying ampoules;

E. sterilization of ampoules.

11. *In the manufacture of injectable dosage forms at pharmaceutical enterprises, various methods of sealing ampoules are used. For which injection solutions are capillaries sealed in a stream of inert gases (nitrogen, argon, carbon dioxide):*

A. photosensitive;

B. narrow;

C. heat-resistant;

D. hydrolytically unstable;

E. easily oxidized.

12. *The ampoule shop produces solutions for injections. Specify the methods for determining the tightness of ampoules filled with oil solutions for injection.*

A. using a soap solution;

B. using methylene blue;

C. using ultrasound;

D. with methyl orange;

E. using the flow method;

13. *The ampoule shop of the enterprise produces solutions for injections. Indicate which filters are used for sterile filtration of injection solutions.*

A. druk filter;

B. membrane and depth filters;

C. nutch filter;

D. KhNIHFI filter;

E. frame filter press.

14. Name the filters that are used for sterile filtration of injection solutions.

A. HNIHFI filter;

B. filter «fungus»;

C. filters of the firm «Millipor», «Vladipor»;

D. Boom filters with pore size 4,5-7 microns;

E. glass filters with a pore size of 1,5-3 microns.

15. *For what purpose is activated carbon used in the process of making injection solutions?*

A. to create a buffer system;

B for the purpose of cleaning some injection solutions;

C. as an antioxidant;

D. to increase the chemical resistance of ampoule glass;

E. to relieve residual stress in ampoules.

16. *Laboratory quality control of injectable dosage forms, eye drops consists in checking for:*

A. total volume of the preparation, percentage of the yield of the contents of the package, identity, pH;

B. identity, no mechanical impurities, uniformity, tightness of the package;

C. mass of package contents, heavy metals, pH, identity, specific gravity;

D. Identity, utility, clarity, pH, nominal volume, no mechanical impurities

E. average volume, deviations from it, absence of mechanical impurities, homogeneity.

17. *Which of the stages is the last in the manufacture of injection solutions?*

A. quality control;

B. sterilization;

C. filtering;

D. marking;

E. quantitative control.

18. What brand of glass should be used to make ampoules for 0.01% cyanocobalamin solution:

A. neutral (HC-2);

B. light-protective neutral (SNS-1);

C. neutral (HC-1);

D. neutral (HC-2A)

E. bezborne (AB-1).

19. *Which of the indicated methods of filling ampoules with injection solutions allows you to protect capillaries from contamination with thick and viscous solutions?*

A. pushing the solution;

B. vacuum;

C. turbo-vacuum;

D. steam condensation;

E. syringe.

20. *To remove impurities from the glucose injection solution, special cleaning is carried out using the following substances:*

A. adsorption of impurities on activated carbon;

B. adding calcium hydroxide followed by filtration;

C. adding hydrochloric acid followed by adsorption on activated carbon;

D. Pretreatment with activated carbon followed by stabilization with hydrochloric acid

E. addition of iron oxide, followed by absorption of impurities on activated carbon.

Topic 7. «Liquid chromatography. Methods of microbiological control of drugs (beginning)».

1. *What is the main advantage of liquid chromatography over gas chromatography?*

A. developed sensitive detecting systems, allowing to determine the concentration of substances in the range of 10^{-8}-10^{-9} mg / ml;

B. in the difference in the sorption capacity of the separated substances by the adsorbent (a solid with a developed surface);

C. the possibility of separation at lower temperatures and for the analysis of substances with molecular weights from several hundred to several million a.m.;

D. in different ability of the components to precipitate on a solid stationary phase.

2. *Gradient elution in HPLC is ...*

A. 100% step change in the eluting strength of the eluent;

B. change in the temperature of the eluent;

C. changing the flow rate of the eluent;

D. change in pressure at the inlet to the column.

3. *Name the chromatography method that allows you to work with thermolabile compounds...*

A. all of the above is correct;

B. high performance liquid chromatography;

C gas-liquid chromatography;

D. high speed liquid chromatography.

4. *Normal phase high performance liquid chromatography is mainly based on the process...*

A. ion exchange;

B. distribution;

C. exclusion;

D. sorption and desorption.

5. *HPLC can be used for...*

A. all of the above is true;

B. exclusion;

C. section of a mixture of substances;

D. identification of substances.

6. *What is the term for the undesirable introduction of foreign substances into medicines during their manufacture (manufacture)?*

A. absorption;

B. elimination;

C contamination;

D. pyrogenation;

E. lyophilization.

7. *The reason for the pyrogenicity of drugs is...*

A. plant diseases;

B. human malaise;

C. is microbial pollution of the environment;

D. is microbial contamination of water.

8. *Control of sterility of medicines is carried out by...*

A. sowing on thioglycolic medium to identify various bacteria;

B. agar yeast of a milk-salt medium (АУММ);

C. medium Blaurocca;

D. medium type GAM.

9. *The method of industrial decontamination is called...*

A. ionizing radiation;

B. thermal method for increasing the microbial purity of non-sterile medicines;

C. liquid chromatography;

D. aseptic method.

10. *A set of measures aimed at preventing the penetration of microorganisms into the wound and into the body as a whole...*

A. disinsection;

B. disinfection;

C. disinfection;

D. asepsis.

11. *The presence in sterile drugs of decomposition products of bacteria (lipopolysaccharides) is called...*

A. disinfection;

B. disinfection;

C. pyrogenicity;

D. asepsis.

12. *Determination of pathogenic staphylococci is carried out by sowing on...*

A. yolk salt agar;

B. medium Blaurocca;

C. agarized yeast-milk-salt medium (АУММ);

D. Medium type GAM.

13. *Determination of bacteria of the family Enterobacteriaceae is carried out by sowing on...*

A. medium Blaurocca;

B. yolk-salt agar;

C. endo- and bismuth sulfite agar;

D. medium type GAM.

14. *The minimally statistically confirmed suitability of the technique, which is carried out on three different batches of the drug, taking into account all possible factors of influence on the reliability of the results of experimental studies is called ...*

A. pyrogenicity;

B. validation;

C. asepsis;

D. disinfection.

15. *Determination of pathogenic Pseudomonas aeruginosa is carried out by sowing on...*

A. medium type GAM;

B. yolk-salt agar;

C. Cedium Blaurocca;

D. on a medium with glycerin.

Topic 8. «Methods of microbiological control of drugs (ending)».

1. *Infection of medicinal plants with microorganisms excludes their subsequent use by the pharmaceutical industry. The invasive properties of phytopathogenic microorganisms are due to the following enzymes:*

A. isomerase;

B. oxidoreductase;

C. hydrolytic;

D. lyase;

E. transferase.

2. *What is the name of the culture media that are used for the cultivation of certain types of microorganisms that do not multiply on universal media?*

A. special;

B. differential;

C. synthetic;

D. basic;

3. *Determination of pathogenic Pseudomonas aeruginosa is carried out by sowing on...*

A. yolk salt agar;

B. on Wednesday with glycerin;

C. Wednesday Blaurocca;

D. medium type GAM.

4. *What nutrient media are used to determine the enzymatic properties of microorganisms?*

A. special;

B. differential diagnostic;

C. basic;

D. selective;

E. synthetic.

5. *Studies of collected medicinal plants have shown their significant seeding with various bacteria. Should the method be used to isolate pure cultures of these bacteria?*

A. phase contrast microscopy;

B. centrifugation in a density gradient;

C. contamination of laboratory animals;

D. sowing on solid nutrient medium;

E. using filters with pores of a certain diameter.

6. *One of the sources of contamination of medicines by microorganisms can be laboratory glassware. What method is appropriate to use to sterilize it?*

A. pasteurization;

B. tyndalization;

C. dry heat;

D. drying;

E. boiling.

7. *A set of measures aimed at preventing the penetration of microorganisms into the wound and into the body as a whole...*

A. asepsis;

B. disinfection;

C. Disinfection;

D. pest control;

E. canning.

8. *The industrial decontamination method is called...*

A. HPLC;

B. ionizing radiation;

C. liquid chromatography;

D. aseptic method;

E. thermal method for increasing the microbial purity of non-sterile drugs.

9. *The presence in sterile drugs of decomposition products of bacteria (lipopolysaccharides) is called...*

A. asepsis;

B. disinfection;

C. Disinfection;

D. pyrogenicity;

E. validation.

10. *The reason for the pyrogenicity of drugs is ...*

A. violation of asepsis;

C. all of the above;

C. increase in the time between preparation of the solution and sterilization;

D. violation of asepsis of the technological process;

E. microbial contamination of distilled water.

11. *Sterilization methods used for the preparation of medicines under aseptic conditions can be divided into physical, mechanical, and chemical. Specify the chemical sterilization method:*

A. dry heat sterilization;

B. radiation sterilization;

C. sterilization by steam under pressure;

D. UV sterilization;

E. adding preservatives.

12. *The production of sterile medicines is carried out in the premises:*

A. with purity class C;

B. with purity class B;

C. with purity class D;

D. for staff;

E. for finished products.

13. *Select the method by which pyrogenic substances are removed during the factory production of parenteral medicines:*

A. filtration;

B. centrifugation;

C. heat treatment at 120 oC;

D. ultrafiltration;

E. upholding.

14. *According to SPUs, sterile medicinal products intended for introduction into the human or animal body by injection, infusion or implantation are called:*

A. rectal;

B. vaginal;

C. oral;

D. parenteral;

E. sublingual.

15. Sterilization of auxiliary materials is carried out by autoclaving at a temperature of 120 oC during:

A. 45 min;

B. 1 hour;

C. 15 min;

D. 30 min

E. 2 hours.

Topic 9. «Pre-clinical testing of medicines. Choice of assessment methods».

1. *The fundamental elements of a quality assurance system that are internationally recognized is the system of good practices. The principles and rules related to the organizational process and the conditions under which preclinical safety studies for human health and the environment are planned, performed, monitored, documented, reported and archived are ... A. good pharmacy practice;*

B. good Manufacturing Practice;

C. good clinical practice;

D. good distribution practice;

E. good Laboratory Practice.

2. *At the international level, drug standardization carries out:*

A. European Union (EU);

B. Drug Administration (FDA);

C. International Federation of Pharmaceutical Manufacturers Associations (IFPMA);

D. World Health Organization (WHO)

E. International Pharmaceutical Association.

3. *Animals, plants, microorganisms, as well as cellular, subcellular, chemical or physical systems or their combinations used in tests are called...*

A. sample;

B. customer;

C. test system;

D. sample

E. monitoring.

4. *Ethical principles for preclinical research are described and endorsed by principle or concept...*

A. GCP principles;

B. GLP principle;

C. «2R»;

D. GMP principles;

E. «3R».

5. *The stage of drug development, which includes a set of research procedures and operations to determine the harmlessness and specific activity in order to obtain permission for their clinical trials, is called...*

A. the system of rules for Good Clinical Practice (GCP);

B. preclinical studies of drugs;

C. System of Good Laboratory Practice (GLP) Rules;

D. standard operating procedure (SOP);

E. clinical trials.

6. *The principles of Good Laboratory Practice (GLP) have been approved by the OECD Council in...*

A. 1983;

B. 1996;

C. 1999;

D. 1981;

E. 1985.

7. *The person responsible for the entire testing process is called..*

A. responsible executive;

V. chief researcher;

C. customer;

D. test auditor;

E. test system.

8. *The main responsibility of the head of the institution is...*

A. introduction of research audit;

B. protection of the territory where the research is carried out;

C. monitoring compliance with the GCP principles;

D. monitoring compliance with GLP principles;

E. providing qualified personnel with appropriate means, equipment and materials.

9. *A limited amount or batch of an investigated substance or a comparison substance obtained during a certain production cycle by a method that provides for compliance with the identity, and accordingly affects is called...*

A. research audit;

B. network schedule;

C. series;

D. standard operating procedure;

E. monitoring compliance with GLP principles.

10. *The governing body responsible for monitoring the compliance of institutions (laboratories) with GLP principles in its territory, as well as performing other functions related to compliance with GLP principles is called...*

A. National Designated Body for GLP Compliance Monitoring;

B. National GCP Compliance Monitoring Program;

C. Laboratory inspection;

D. quality control service;

E. standard operating procedure.

11. *A detailed scheme established by each individual state in order to monitor the compliance with the GLP principles of institutions (laboratories) located in its territory through inspections and verification of research...*

A. national program for monitoring compliance with the GCP principles;

B. quality control service;

C. Laboratory inspection;

D. National Designated Body for GLP Compliance Monitoring;

E. standard operating procedure

12. *Any agent that is used to mix, disperse, dissolve a test substance or reference drug in order to facilitate the conditions for their introduction into the test system is called...*

A. test system;

B. carrier (solvent)

C. sample;

D. sample

E. series.

13. Select the organization that oversees the proper functioning of the certification system in the European Union ...

A. World Health Organization;

B. European Directorate for the Quality of Medicines;

C. European Organization for Testing and Certification;

D. headquarters of the European Pharmacopoeia;

E. European Parliament.

14. *Choose a term that describes any substance or mixture of substances intended for use in the manufacture of a medicinal product and in this case, the use becomes its active ingredient...*

A. admissible impurity;

B. stabilizer;

C. intermediate product of the drug production

D. excipients;

E. active substance.

15. *At what stage of the life cycle of a medicinal product is its quality established and confirmed*?

A. transfer of technology and further industrial production of the product;

B. pharmaceutical development;

With only industrial production of the product;

D. discontinued product release;

E. all of the above.

Topic 10. «The main phases of clinical trials of new drugs».

1. *The fundamental elements of a quality assurance system that are internationally recognized is the system of good practices. The principles and rules for planning, conducting, performing, monitoring, auditing and documenting clinical trials of medicinal products, as well as processing and presenting their results are...*

A. good pharmacy practice;

B. Good Manufacturing Practice;

C. good distribution practice;

D. good clinical practice;

E. Good Regulatory Practice.

2. *Select the organization that oversees the proper functioning of the certification system in the European Union...*

A. European Organization for Testing and Certification;

B. World Health Organization;

C. the European Directorate for the Quality of Medicines;

D. headquarters of the European Pharmacopoeia;

E. European Parliament.

3. *At what stage of the life cycle of a medicinal product is its quality established and confirmed?*

A. all of the above;

B. technology transfer and further industrial production of the product;

C. only industrial production of the product;

D. discontinued product release;

E. pharmaceutical development.

4. *Which of the normative documents contains information about medicines allowed for production and use in medical practice?*

A. Technological regulations for the manufacture of a medicinal product

B. State Pharmacopoeia of Ukraine;

C. Pharmacopoeia monograph;

D. State Register of Medicines of Ukraine;

E. State Compendium.

5. *The phase, which is carried out on 20-80 healthy volunteers, of course, young men, in order to establish a dose range, within its limits, the test substance is well tolerated with a single or repeated administration is called....*

A. Phase 0;

B. III phase;

C. Phase II;

D. IV phase.

E. Phase I.

6. *Research work designed to identify or confirm clinical, pharmacokinetic, pharmacodynamic and / or other effects, study the absorption, distribution, metabolism and excretion of one or more drugs and / or identify adverse reactions to one or more drugs for the purpose assessment of its (their) safety and / or effectiveness is called...*

A. placebo;

B. experiment;

C. clinical trials;

D. preclinical studies;

E. observation.

7. *The method of empirical research, based on the active and purposeful intervention of the subject in the process of scientific cognition of phenomena and objects of reality by creating conditions that are controlled and controlled, which make it possible to establish certain qualities and regular connections in the object being investigated, and to reproduce them repeatedly is called…*

A. experiment;

B. clinical trials;

C. placebo;

D. preclinical studies;

E. observations.

8. *Testing of a medicinal product, which is carried out after its registration and entering the market, in order to determine the therapeutic value of the medicinal product, the strategy for its further use, as well as to obtain additional information about the spectrum and frequency of adverse reactions and interactions with other medicinal products is called.*

A. preclinical studies;

B. placebo;

C. experiment;

D. phase 4 clinical trial;

E. phase 2 clinical trial.

9. *The procedure for a comprehensive study of the component composition of a medicinal product (medicinal and auxiliary substances), the choice of a dosage form, optimization of the technological process, packaging, as well as the justification of quality indicators and development of the specification of a medicinal product represents the following stage of the life cycle of a medicinal product:*

A. registration;

B. preclinical studies;

C. laboratory research;

D. distribution;

E. pharmaceutical development.

10. *To establish or confirm the effectiveness and harmlessness (safety) of drugs, carry out:*

A. toxicological studies;

B. clinical research;

C. biochemical research;

D. preclinical studies;

E. pharmacological studies.

11. *Give a complete definition of the term «Medicines».*

A. These are substances of natural or synthetic origin used to prevent pregnancy, treat human diseases or change the state and function of the body;

B. are substances of natural or synthetic origin used for the prevention, diagnosis and treatment of human diseases or changes in the state and functions of the body;

C. any substance or combination of substances (one or more APIs and excipients), has properties and is intended for the treatment or prevention of diseases in humans, any substance or combination of substances (one or more APIs and excipients) that can be designed to prevent pregnancy, restoration, correction or change of physiological functions in a person by carrying out pharmacological, immunological or metabolic actions or to establish a medical diagnosis;

D. these are substances of natural, synthetic or biotechnological origin used for the prevention of pregnancy, prevention, diagnosis and treatment of human diseases or changes in the state and functions of the body;

E. are substances or mixtures thereof of natural, synthetic or biotechnological origin, used to prevent pregnancy, prevent, diagnose and treat human diseases or change the state and functions of the body.

12. *What is a generic drug?*

A. medicinal product, the term of the patent protection of which for the active substance has expired and this active substance is identical to the active substance of the original medicinal product, and the excipients and production process may differ;

B. a drug that is owned only by the company that developed it or by the company that held the first marketing license;

C. the medicinal product contains an active substance, excipients and production process of which differ from the original medicinal product

D. these are substances of natural, synthetic or biotechnological origin used for the prevention of pregnancy, prevention, diagnosis and treatment of human diseases or changes in the state and functions of the body;

E. medicinal product whose active substance is a patent, until the expiration of which no other pharmaceutical company has the right to synthesize and use this active substance for commercial and non-commercial needs.

13. *State registration of medicines in Ukraine is carried out using...*

A. procedure. with the help of which the Ministry of Health of Ukraine analyzes the quality of the medicinal product;

B. Pharmacopoeia Monograph;

C. the procedure by which the Ministry of Health of Ukraine allows the import of a drug into the territory of Ukraine;

D. the procedure by which the Ministry of Health of Ukraine confirms the effectiveness and safety of drugs and allows its medical use in Ukraine;

E. providing quality certificate

14. *The standard for planning, conducting, monitoring, auditing and documenting clinical trials, as well as processing and presenting their results is called...*

A. GMP;

B. FS;

C. GCP;

D. GLP;

E. HFC.

15. *A document describing the goals, objectives, scheme, methodology, statistical aspects and organization of the test is called...*

A. all of the above;

B. informational consent;

C. audit tests;

D. Investigator's brochure;

E. clinical trial protocol.

16. A trial in which a drug, the efficacy and safety of which has not yet been fully studied, is compared with a drug whose efficacy and safety are well known (comparator drug) is called ...

A. a randomized trial;

B. controlled test;

C. a pilot test;

D. parallel studies;

E. prospective trial.