20/1. The following parameters can be established based on the blood concentration/time curve:

A. Latency time  
B. Therapeutic field  
C. pH of the drug solution  
D. Minimum effective concentration  
E. Maximum safety concentration

20/2. Substituting a drug with another is not recommended in the following cases:

A. When the drug substance has a narrow therapeutic index  
B. Poor drug absorption  
C. For drug substances that are stable in gastrointestinal tract  
D. For drug substances with physical and chemical characteristics that prevent rapid dissolution  
E. For drug substances that undergo an important pre-systemic hepatic biotransformation

20/3. Drug-specific factors that influence bioavailability are:

A. Dissolution speed  
B. Solubility  
C. Manufacturing procedure  
D. Distribution coefficient  
E. Food

20/4. The following pharmaceutical forms are considered biopharmaceutically critical:

A. Oral suspensions  
B. Parenteral suspensions  
C. Retardation forms  
D. Solid preparations for oral use with hard soluble substances  
E. Solid preparations for oral use with slightly soluble substances

20/5. The following assertions regarding polymorphs are TRUE:

A. They are obtained by modifying the preparation conditions  
B. The polymorphs of the same substance have an identical chemical structure, but different physical properties  
C. The polymorphs of the same substance have an identical chemical structure and identical physical properties  
D. From the polymorphs of the same drug substance, in certain conditions of temperature and pressure, there are several stable forms and one or more meta-stable forms  
E. From the polymorphs of the same drug substance, in certain conditions of temperature and pressure, there is a stable form and one or more meta-stable forms

20/6. Bioavailability can be influenced by food through the following mechanisms:

A. Reducing the stomach motility  
B. Decreasing the rate of gastric emptying  
C. Their validity term  
D. Food type  
E. Increasing the drug maintenance period in the stomach

20/7. *The “first-pass” effect can be avoided by:

A. Changing the active drug  
B. Changing the administered pharmaceutical form  
C. Changing the administration route  
D. Changing the drug substance absorption  
E. Changing the drug substance elimination
20/8. The formulation determines:

A. The drug qualitative composition
B. The drug quantitative composition
C. The exact quantities for drug substances only
D. The exact quantities for auxiliary substances only
E. The exact quantities of each component, for both drug substances and for the auxiliary ones

20/9. In formulating a new drug, the following factors interfere:

A. Drug substance
B. Administration path
C. Food type
D. Pharmaceutical form
E. Auxiliary substances

20/10. In formulating a drug, the choice of the administration path depends on:

A. Bioavailability of drug substance
B. Treatment duration
C. Treatment at home
D. Active substance dosage method
E. Number of doses per day

20/11. Optimizing the absorption of the drug substance can be achieved by:

A. Reducing the particles’ size
B. Increasing the crystal energy
C. Increasing the polar character
D. Using meta-stable polymorph forms
E. Pro-drugs synthesis

20/12. The factors influencing the dissolution speed, which are revealed by Noyes-Whitney equation, are:

A. Diffusion coefficient
B. Thickness of diffusion layer
C. Hepatic clearance
D. Concentration gradient
E. Renal clearance

20/13. Pharmaceutical-technological factors that influence the bioavailability are:

A. Food
B. Pharmaceutical form
C. Age
D. Auxiliary substances
E. Manufacturing technology

20/14. The physiological factors that influence the bioavailability in oral absorption are:

A. Quantity and composition of gastric juices
B. Motility of gastrointestinal tract
C. Solubility and dissolution rate
D. Auxiliary substances
E. Bacterial flora
20/15. Viscosity agents influence bioavailability by:
A. Decreasing the stomach emptying rate
B. Increasing the intestinal motility
C. Decreasing the dissolution rate of the drug substance
D. Increasing the stomach emptying rate
E. Increasing the speed of the molecule of dissolved substance towards the absorption membranes

20/16. The effect of a surfactant upon the bioavailability depends on:
A. The type of the biological membrane through which the absorption takes place
B. The concentration of the surfactant
C. The nature of the drug substance
D. The area under the curve
E. The physical and chemical characteristics of the surfactant

20/17. The granulation process influences the transfer of the drug substance from tablets through:
A. Granulation period
B. Used granulation method
C. Particle size
D. Conditioning recipient
E. Amount of used granulation liquid

20/18. Bioavailability is characterized by:
A. Area under the curve
B. Rheological properties of the drug substance
C. Physical and chemical properties of auxiliary substances
D. The absorption rate of the drug substance
E. The relative quantity of absorbed drug substance

20/19. The chemical equivalence presumess:
A. The same drug substance
B. Different administration routes
C. Identical doses of the same drug substance
D. Different doses of the same drug substance
E. The same administration route

20/20*. Absolute bioavailability represents:
A. A pharmaco-technical parameter
B. \((S1/S2)\) Ratio between the blood concentration of the drug substance obtained with the tested drug (S1) and the blood concentration of the drug substance after i.v. administration (S2).
C. A pharmacokinetic parameter
D. A maximum plasmatic concentration
E. A physical-chemical parameter

20/21. For the drug substances that are slightly soluble in water, the bioavailability is influenced by:
A. Absorption rate
B. Conditioning recipient
C. The absorption grade through biological mucous membrane
D. Dosage method
E. The rate of drug substance bio-transformation
20/22*. In case of the substances that are sparingly soluble in water, bioavailability is influenced especially by:

A. Storage method  
B. Dosage method  
C. Dissolution rate  
D. One-compartment pharmacokinetic model  
E. Bi-compartment pharmacokinetic model

20/23. Based on the blood concentration / time curve, the following important parameters can be established for the bioavailability studies:

A. The area under the curve  
B. The minimum effective concentration  
C. The drug mechanism of action  
D. The highest safety concentration  
E. The therapeutic field

20/24*. The latency time represents:

A. The time in which the concentration of the drug substance in plasma exceeds the minimum effective value  
B. The time necessary for the drug substance to reach the maximum concentration level  
C. The time necessary for the minimum effective concentration of the drug substance to occur in blood  
D. The difference between the minimum effective concentration and the peak of the concentration  
E. The maximum capacity reached by the drug substance

20/25. In order to substitute a drug with another one, this one must:

A. Contain the same drug substance  
B. Be bioequivalent  
C. Contain different drug substances  
D. Contain the same drug substance and be bioequivalent  
E. Contain drug substances with narrow therapeutic index

21/1. The packaging of pharmaceutical dosage forms:

A. provides final appearance of the dosage form  
B. is a supplementary preparation step  
C. consists of enclosing the dosage form in a package of various shape  
D. consists of enclosing the dosage form in a cardboard package  
E. is non-separable from the preparation step

21/2. Additional packaging materials may be:

A. closures  
B. caps  
C. closure liners  
D. aluminum tubes  
E. dropper syringes
21/3. Packaging of the dosage forms is done by means of:
A. creating containers
B. creating applicators
C. creating cardboard packages
D. creating dropper tubes
E. creating dropper syringes

21/4. The role in identification/information of a container means:
A. providing lack of permeability to environmental agents
B. providing easy identification of the medication
C. providing opening and closing
D. providing physical-chemical protection
E. providing dose-fractionation options

21/5. Glass as a packaging material:
A. is an organic fused macromolecule
B. crystallizes upon cooling
C. is a mixture of glass-forming oxides
D. contains melting oxides
E. contains iron derivatives, which provide blue colour

21/6. Glass as a packaging material:
A. may pass from amorphous to crystalline state
B. contains a matrix composed out of silicone and oxygen ions
C. contains a matrix composed out of potassium, sodium and calcium ions
D. contains melting oxides that increase the melting point
E. cannot be sterilized

21/7. The mechanical properties of pharmaceutical glass are:
A. resistance
B. transparency
C. brittleness upon heating
D. stability against aqueous acid hydrolysis
E. stability against bases

21/8. Improving glass properties may be done by:
A. silicone treatment
B. inducing surface hydrophobicity by treatment with a polyvinyl alcohol solution
C. dry treatment with silicone oil solution
D. treatment with vitrification oxides (aluminum oxide)
E. wet treatment with silicone emulsion
21/9. Preparations for injection may be packed in:

A. type I borosilicate glass containers
B. thermo resistant plastomers (phenoplasts)
C. type I soda-lime-silica glass containers
D. type III, soda-lime-silica glass containers
E. polyethylene containers

21/10. Thermoforming packaging:

A. provides protection against light and moisture
B. uses only plastic materials (PVC, PP)
C. has multiple advantages compared to the Blister technology
D. is used by the pharmaceutical industry for solid dosage forms
E. is incompatible with moisture-sensitive drugs

21/11. The following statements regarding the Bottelpack packaging system are true:

A. is used for packaging liquid products, followed by sterilization
B. the containers are obtained by polymer extrusion
C. filling and sealing of the containers consist of one unit operation of the manufacturing cycle.
D. is a packaging system for multidose and single dose products
E. is a packaging system only for single dose dosage forms

21/12. Polyethylene containers possess the following properties:

A. are resistant to syneresis
B. may be used for packaging of ethanol
C. may be used for packaging of acetone
D. may be used for packaging of ether
E. have very good chemical resistance

21/13. Polypropylene has the following disadvantages:

A. UV-sensitive
B. is sensitive to cracking under tension
C. difficult thermoforming
D. impossible to be sterilized by chemical methods
E. low chemical resistance

21/14. Polyethylenes have the following disadvantages:

A. weak thermal behavior
B. UV-sensitivity
C. lack of chemical inertness
D. low resistance to shocks
E. absence of dielectric properties
21/15. Vinyl polichloride and its derivatives have as advantages:
A. resistance to acids
B. compatibility with esters and ketones
C. low permeability to gases
D. optimal rigidity
E. lack of carcinogenic action

21/16. The cellulose films used in pharmaceutical packaging have the following advantages:
A. plasticity, due to various treatments
B. can be easily colored and imprinted
C. can be sealed at temperatures below 100 °C
D. can be sealed under pressure
E. can be combined with polyethylene

21/17. The quality of natural rubber as a packaging material can be improved through:
A. addition of plasticizers
B. addition of sulphur
C. addition of phenol derivatives as vulcanizing agents
D. addition of fillers
E. addition of caolin as a plasticizer

21/18. Aluminum foils used as packaging materials have the following properties:
A. low mass
B. lack of permeability to gases
C. resistance to oxidation
D. resistance to hydrolysis
E. opacity

21/19. Synthetic rubbers as packaging materials:
A. lack permeability to gases
B. are permeable to water vapours
C. are resistant to syneresis
D. have low resistance to solvents
E. have high resistance to solvents

21/20. Single dose packaging containers have the following properties:
A. taking out the content is done without damaging the closing system
B. can be ophtadose containers
C. the content is stable for 24 hours after opening
D. cannot be used for packaging of nasal drops
E. can be used for packaging of preparations for injections
21/21. The *clic-lock* closure system for containers is specific to:

A. *ophthadose* containers
B. glass containers
C. plastomer containers
D. vials
E. containers with effervescent tablets

21/22. The multidose containers with individually-packed units:

A. avoid administration errors  
B. have high contamination risk  
C. avoid problems related to identification of medication  
D. may be plastic-made  
E. cannot be aluminum-made

21/23. The leaflet of a pharmaceutical product has the following data:

A. batch number  
B. instructions for administration  
C. therapeutic indications  
D. storage conditions  
E. manufacturing date

21/24. Paper and paper sachets for packaging of sterile products have the following properties:

A. permeability to the sterilizing agent  
B. permeability to water vapours  
C. incompatibility with ionized radiations  
D. resistance to dry-heat sterilization  
E. are a microbiological barrier

21/25. Silicones used for packaging of pharmaceutical products may be:

A. polysiloxanes  
B. elastomers  
C. oils  
D. polyesters  
E. polyurethanes

22/1. The 10th RoPh validates the following solvents for the preparation of solutions:

A. glycerol  
B. propylene glycol  
C. alcohol  
D. paraffin oil  
E. sunflower oil

22/2 * . According to FR X, the following statements are true for the preparation of solutions:

A. The dissolution order for active substances is solely based on their properties.  
B. After dissolution, the solutions must be filtered.  
C. The volatile substances are added at the end.
D. Filling to the specific weight is performed either w/w or w/v.
E. When the solvent is not specified, neutralized sunflower oil is used.

22/3. According to the 10th RoPh, the codeine syrup
A. is kept at Venena.
B is prepared by dissolving 0.2 g codeine phosphate in simple syrup.
C. is a viscous liquid with specific odor and sweet taste.
D. is photosensitive.
E. has a relative density > 1.

22/4. According to the 10th RoPh, in preparing syrups the following auxiliary substances can be used:
A. antioxidants
B. viscosity-enhancing agents
C. pH-adjusting agents
D. taste and odor adjusting agents
E. antimicrobial preservatives

22/5. Cosolvation is a method of increasing solubility which
A. is applied to the dissolution in water of weak electrolytes and substances with polar molecules.
B may be applied to solubilize volatile compounds.
C. involves the addition of a second water-miscible solvent.
D is based on the reduction of the solute/solvent interfacial tension.
E. does not require knowledge of the dielectric constant of the solvents used.

22/6. Which of the following statements regarding the dissolution of a solid in a liquid are true?
A. The solute diffusion coefficient is directly proportional to temperature and inversely proportional to viscosity.
B. The increase of solute surface area is inversely proportional to particle diameter reduction.
C. The dissolution process is not influenced by the porosity of the solid substance.
D. Three liquid areas form around the particles of solvent.
E. The diffusion process by forced convection is based on the difference in density between solute and solvent.

22/7. Filter materials used for filtering solutions may be made of
A. 10 micrometers-thick textile fibers.
B. cellulose fibers assembled in the form of sheets or discs.
C. layered filters that exclusively perform a depth filtration.
D. plastomers used for clarifying filtration.
E. fritted glass.

22/8. The following statements on anhydrous solvents used to prepare solutions for oral use are true:
A. Alcohol, glycerol, isopropyl alcohol and vegetable oils are the most commonly used.
B. The conditioning stage is facilitated by high density.
C. They provide physicochemical and microbiological stability to products.
D. High viscosity is a major disadvantage.
E. They are good solvents for a wide range of both water-soluble and water-insoluble substances.

22/9. Glycerol used as a solvent for the preparation of solutions is
A. a polyol formalized by the 10th RoPh.
B. miscible with water, alcohol and fatty oils.
C. hygroscopic and deliquescent.
D. a good solvent for sugars and organic salts.
E. incompatible with oxidizing agents.

22/10. Propylene glycol used as a solvent in the preparation of solutions is
A. recommended for dissolving water-insoluble substances.
B. contraindicated in preparations for internal use.
C. used in preparations for external use.
D. well tolerated on the auricular, nasal and ocular mucosa.
E. incompatible with nipa-esters.

22/11. Which of the following statements regarding castor oil are true?
A. It is miscible with alcohol.
B. It has a low content in ricinolein.
C. It is a vehicle reserved for lipophilic substances.
D. Administered internally, it has a purgative action.
E. It exhibits siccative properties.

22/12. Sorbitol used as a sweetener is a substance
A. which is efflorescent and has a sweet taste.
B. which replaces sugar in diabetic preparations.
C. associated with sugar to prevent crystallization.
D. which is insoluble in chloroform.
E. which may be administered in solutions with 70% alcohol.

22/13. The solvents used in the preparation of syrups include:
A. water
B. extractive aqueous solutions
C. hydroalcoholic extract solutions
D. propylene glycol
E. aromatic waters

22/14. The preparation of syrups by hot dissolution presents the following disadvantages:
A. high risk of microbiological contamination
B. formation of reducing sugars
C. risk of sugar caramelization
D. favoring syrup alteration by fermentation
E. resulting opalescent syrups

22/15. The following can be clarifying agents for syrups:
A. 0.1% filter paper pulp
B. 10% activated carbon
C. 10% talc
D. mixtures of polymers with absorbent properties
E. Magnesium carbonate

22/16. Carbonated soft drinks are
A. aqueous solutions with a well-determined carbon dioxide content.
B. aqueous solutions prepared by dissolving sodium hydrogen carbonate and an organic acid in water.
C. preparations conditioned in common glass or plastomer containers.
D. aqueous solutions filtered before neutralization.
E. solutions with a shelf life of 7 - 10 days.

22/17. Oral solutions are
A. prepared with the solvents used in the preparation of oral solutions.
B. solutions presenting a specific primary conditioning.
C. mixtures of tinctures administered in drops.
D. solutions which do not require antimicrobial preservatives.
E. conditioned solely in vials.

22/18. Vials with two capillaries used for conditioning oral solutions provide
A. the possibility of conditioning under inert gas.
B. the possibility of conditioning under vacuum.
C. easy discharge of the liquid.
D. perfect proofness against external agents.
E. easy opening without the risk glass fragmentation.

22/19. Aromatic waters are
A. officinal solution.
B. aqueous or hydroalcoholic solutions of essential oils.
C. solution for external use.
D. solutions for internal use.
E. solutions with high physicochemical stability

22/20. Volatile oils contained in aromatic water are
A. mixtures of lipophilic substances.
B. essential oils.
C. mixtures of hydrocarbons.
D. derived from plants.
E. not exposed to oxidative degradation processes.

22/21. According to the 10th RoPh, the concentrated solution of hydrogen peroxide
A. contains at least 95% hydrogen peroxide.
B. decomposes energetically in contact with organic substances.
C. is not miscible with alcohol.
D. may contain a suitable stabilizer.
E. is kept at Separanda.

22/22. The process for the preparation of aromatic waters by hydrodistillation involves the following stages:
A. wetting of plant products
B. entrainment with water vapor
C. clarification of the aromatic water
D. filtering
E. conditioning

22/23. In preparing the aromatic water, the ratio vegetable product: solvent can be
A. 1: 1.
B. 1: 3.
C. 1: 5.
22/24. Which of the following are officinal solutions?

A. the bromhexine hydrochloride solution
B. the diluted solution of hydrogen peroxide
C. the effervescent solution
D. the epinephrine solution
E. the calcium hydroxide solution

22/25 *. Which of the following are officinal alcoholic solutions?

A. mentholated alcohol
B. alcohol iodate
C. the alcoholic solution of iodurated iodine
D. the alcoholic solution of glyceryl trinitrate
E. camphorated alcohol

23/1 *. Are not parenteral preparations:

A. Sterile preparations
B. Preparations for a local effect
C. Preparations for injection
D. Preparations for infusion
E. Preparations for implantation

23/2 *. From parenteral preparations DO NOT belong:

A. Implants
B. Sterile preparations for irrigation
C. Injections and infusions
D. Concentrates for injections and infusions
E. Powders for injections or infusions

23/3. Hot air sterilization apply to:

A. Thermosensitive materials (glass, metal)
B. Thermosensitive substances (sodium chloride)
C. Oils and fat
D. Transparent plastomer containers
E. Opaque plastomer containers

23/4. Are used the following methods of sterilization by moist heat:

A. Pressure steam sterilization
B. Continuous pressure steam sterilization
C. Gas Sterilization
D. Sterilization by repeated heating
E. Sterilization by heating to 100 ° C

23/5. The sterilizing temperature and time in the drying oven:

A. 200 ° C, 20 minutes
B. 180 ° C, 30 minutes
C. 170 ° C, 1 hour
23/6. The temperature and time of sterilization with steam under pressure are:
A. 134 °C, 3 minutes
B. 128 °C, 10 min
C. 121 °C, 15 minutes
D. 100 °C, 60 minutes
E. 80 °C, 2 hours

23/7. Moist heat sterilization is performed in:
A. Autoclaves with air outlet device placed on the top
B. Ovens Pasteur
C. Sterilizers Poupinel
D. Autoclave equipped with a drain valve at the bottom
E. Autoclave equipped with vacuum pump

23/8. Factors that influence the effectiveness of sterilization with ethylene oxide are:
A. Humidity
B. Pressure
C. Light
D. Number and kind of germs destroyed
E. Concentration in the gas

23/9 *. The filter sterilizing micro-organisms are:
A. Removed
B. Destroyed
C. Attenuated
D. Coagulated
E. Inactivated

23/10. The sterilization methods provided by 10th RoPh are:
A. Sterilization with ionizing radiation
B. Sterilization with steam under pressure
C. Dry heat sterilization
D. Filter sterilization
E. Gas Sterilization

23/11. The main routes of drug injections are:
A. Intravenous
B. Intramuscular
C. Subcutaneous
D. Intracardiac
E. Intraarticular

23/12. Not may be added antimicrobial preservatives:
A. Injectable solutions used in the higher volume of 10 ml
B. Subcutaneous, intramuscular, intravenous
C. Injections administered intrathecal, intracisternally and epidural
D. Aseptic preparations
E. Tindalizate preparations.
23/13. What type of glass is NOT used for injections:

A. Normal sodium silicate glass  
B. Boro-silicate glass  
C. Sodico-calcium silicate glass surface treated  
D. Sodico-calcium silicate glass with moderate hydrolytic resistance  
E. Sodico-calcium glass with low hydrolytic resistance

23/14. Natural non-thermal sterilization methods are:

A. UV radiation  
B. Aseptic process  
C. Sterilizing filter  
D. Ionizing radiation  
E. Gas sterilization

23/15. Infusion solutions are:

A. Sterile and pyrogen-free isotonic aqueous solutions  
B. Emulsions U / A sterile and non-pyrogenic  
C. Sterile and non-pyrogenic aqueous suspension  
D. Sterile and non-pyrogenic lipophilic solutions  
E. Preparations to be administered intravenously in volumes of 100 ml or more

23/16. Sterilization processes which can be applied after the final conditioning of the injection preparations are:

A. Filter sterilization  
B. Heat sterilization  
C. Gas sterilization  
D. Radiation sterilization  
E. Aseptic preparation

23/17. Sterilization by gaseous substances:

A. Process is formalized by FR X  
B. Allow sterilization at lower temperatures  
C. Is used for thermoset materials  
D. Doses used are toxic to macro  
E. Sterilized solid, penetrating through the capillary network

23/18. Sterilizing filtration occurs through mechanisms:

A. Screening effect  
B. Adsorption effect  
C. The effect of the osmosis  
D. Diffusion effect  
E. Settling effect

23/19 *. Endotoxins have the following properties EXCLUDING:

A. Resistant to sterilization by autoclaving  
B. Can be destroyed by dry heat at 180-200  
C. Do not pass through most of the filters used  
D. Have pyrogenicity  
E. Cause leukopenia
23/20. Radio sterilization process is done:

A. Gamma radiation  
B. Negative beta radiation  
C. Infrared radiation  
D. Ultrasound  
E. Ultraviolet radiation

23/21. The methods of pyrogens destruction by inactivating endotoxins are:

A. Acid hydrolysis  
B. Alkaline hydrolysis  
C. Moist heat  
D. Dry heat  
E. Alkylation

23/22. Anhydrous solvents for injection purposes miscible with water are:

A. Benzyl benzoate  
B. Alcohol  
C. Glycerol  
D. Propylene glycol  
E. Dimethylacetamide

23/23. Reducing antioxidants to be used in parenteral formulations are the following:

A. Sodium bisulfite  
B. Sodium metabisulfite  
C. Tartaric acid  
D. Phosphoric acid  
E. Ascorbic acid

23/24. The buffers included in the formulation of injectable solutions are:

A. Acetic acid-sodium acetate  
B. Citric acid-trisodium citrate  
C. Monosodium phosphate-disodium phosphate  
D. Boric acid-sodium borate  
E. Monosodium carbonate-disodium carbonate

23/25. Anhydrous solvents water immiscible used for parenteral preparations are:

A. Sunflower oil, neutralized and sterilized  
B. Glycofurol  
C. Dimethylacetamide  
D. Liquid paraffin  
E. Ethyl oleate

24/1. Categories of ophthalmic preparations official examples in the Supplement 2004:

A. Eye drops  
B. Solutions for eye bath  
C. Semisolid ophthalmic preparations  
D. Contact lenses  
E. Ophthalmic implants
24/2. Conditioning containers for eye drops should NOT be:

A. Greater capacity of 10 ml  
B. Sealed  
C. Equipped with drip system  
D. Single dose  
E. Multidose

24/3. In practice for isotonizing eye drops are used:

O. De Vries Formula  
B. Freezing point  
C. The number of Sprowl  
D. Equivalents of sodium  
E. Clark's Formula

24/4. Tensioactive agents have the following effects:

A. they lower the surface tension  
B. they decrease epithelial barrier resistance  
C. they decrease the absorption of the drug substance  
D. they increase the absorption of the drug substance  
E. they increase the solubility of the drug substance

24/5. Advantages of ophthalmic drugs include:

A. localization of drug effects in the eye  
B. direct and rapid action  
C. high therapeutic concentration in the ocular area  
D. fast and easy, non traumatic delivery  
E. efficient systemic absorption

24/6. Filtration sterilizing for ophthalmic solutions:

A. Use membrane filters with variable sizes and porosity  
B. Use materials that retain microorganisms and spores  
C. Use materials that destroy microorganisms and spores  
D. Operations are carried out in an aseptic way  
E. Use the filters Millipore, Sartorius

24/7. The size of solid particles in ophthalmic suspensions is:

A. 25 µm (90 %)  
B. 100 µm  
C. 125 µm  
D. 150 µm  
E. 180 µm

24/8. Benzalkonium chloride used in eye drops is:

A. a preservative agent  
B. active at high concentrations of 1-2 %  
C. a quaternary ammonium salt  
D. characterized by increased activity at pH = 8  
E. characterized by decreased activity at acidic pH
24/9. Methylcellulose is an auxiliary substance for eye drops that has a role of:

A. viscosifying agent
B. delaying penetration through the cornea
C. increasing time of contact with the eye’s surface
D. osmotic agent
E. isohydric agent

24/10. Povidone is an auxiliary substance for eye drops that has a role of:

A. viscosifying agent
B. solubilizing drug substances
C. prolonging the action of eye drops
D. giving the solution a slightly acidic pH
E. isotonizing agent

24/11. Ophthalmic inserts:

A. are sterile solid or semisolid preparations
B. have an appropriate size and shape
C. are applied into the conjunctival sac
D. have a systemic effect
E. have a local effect

24/12. The rate of absorption of drug substances is influenced by:

A. epithelial lesions that are accidental or caused by substances
B. conjunctival irritation
C. presence of foreign body
D. attachment to proteins in tears or in the cornea
E. body temperature

24/13. For eye drops, the Xth edition of Romanian Pharmacopoeia allows the use of the following preservatives:

A. phenylmercuric borate
B. nipagin
C. chlorobutanol
D. benzalkonium chloride
E. chlorhexidine diacetate

24/14. The preservatives used in eye drops are:

A. Bacteriological active
B. with good local tolerance
C. use during operations on eyes
D. used to colirele single dose
E. eye drops concentrations ensure self sterilization

24/15*. Which of the following statements about polyvinyl alcohol is false:

A. It is soluble in cold water
B. It is soluble in warm water
C. It is a nonionic synthetic polymer
D. It can be sterilized by autoclaving
E. It provides low viscosity solutions
24/16*. Eye drop viscosity should not exceed the value of:

A. 40-50 mPa.s  
B. 80 mPa.s  
C. 100 mPa.s  
D. 500 mPa.s  
E. 1000 mPa.s

24/17* The following tensioactive agents are used for eye drops:

A. polysorbates  
B. sodium soap  
C. lecithin  
D. Bromocet  
E. Tego-Betain

24/18. Ophthalmic ointments:

A. prolong the action  
B. contain lipophilic excipients, such as: petroleum jelly, paraffin, liquid paraffin  
C. can be w/o emulsions  
D. must be sterile  
E. do not fog the eye

24/19. According to the Xth edition of Romanian Pharmacopoeia, officinal eye drops are:

A. Eye drops with chloramphenicol  
B. Eye drops with resorcinol  
C. Eye drops with atropine sulfate  
D. Eye drops with pilocarpine nitrate  
E. Eye drops with silver nitrate

24/20*. Which of the following eye drops becomes isotonic:

A. hypotonic eye drops  
B. hypertonic eye drops  
C. suspension eye drops  
D. emulsion eye drops  
E. colloidal solutions

24/21. The vehicles used for eye drops are:

A. freshly boiled and cooled distilled water  
B. sterile isotonic buffered solutions  
C. neutralized and sterilized sunflower oil  
D. glycerol  
E. water for injections

24/22.* pH values tolerated by eyes are:

A. 7.5-9.5  
B. 4.5-5  
C. 5-6  
D. 6-7  
E. 5-6.5
24/23. Viscosifying agents used in eye drops must have the following properties:

A. to be soluble in water  
B. to form clear solutions  
C. to be chemically inert  
D. to be well tolerated  
E. to produce mydriasis

24/24. Eye drops delivered locally without intermediate support are:

A. multi-dose aqueous eye drops  
B. single-dose aqueous eye drops  
C. ophthalmic ointments  
D. solutions for contact lenses  
E. therapeutic lenses

24/25. Ophthalmic formulations with modified release are:

A. viscous aqueous eye drops  
B. oily eye drops  
C. ophthalmic ointments  
D. aqueous eye drops  
E. ophthalmic washes

25/1. In the Rhinoguttae monograph, the 10th RoPh provides the following determinations:

A. particle size  
B. pH  
C. sterility  
D. total weight per container  
E. stability

25/2 *. Nose drops with naphazoline contain the following buffer system:

A. sodium acetate/acetic acid  
B. trometamol  
C. disodium phosphate/monosodium phosphate  
D. sodium citrate/citric acid  
E. borax/boric acid

25/3. The 10th RoPh provides the following solvents for the preparation of nose drops:

A. vegetable oils  
B. sunflower oil  
C. isotonic aqueous solutions  
D. neutralized sunflower oil  
E. liquid paraffin

25/4. Extended-release nasal formulations can be

A. membrane systems.  
B. implants.  
C. bioadhesive pulverulent systems.  
D. nasal bioadhesive systems.  
E. reservoir systems.
25/5. The transnasal route of administration exhibits the following advantages:

A. large absorption surface area
B. prolonged effect due to slow absorption
C. avoidance of hepatic first-pass effect
D. reduced enzymatic activity
E. compliance in patients with poor deglutition

25/6. Nasal mucus contains the following enzymes:

A. collagenase
B. glucuronyl transferase
C. lysozyme
D. cytochrome P-450
E. amylase

25/7. Nasal mucus performs the following functions:

A. protection of nasal mucosa
B. hydration of mucosa by water retention
C. retention of substances in the nasal cavity
D. acting as a semipermeable network for lipophilic substances
E. intervention in the transport of heat

25/8. In the formulation stage of erines as solutions the following factors must be considered:

A. isotony
B. viscosity
C. sterility
D. isohydry
E. innocuity

25/9. In the preparation of nose drops, the following isotonizing agents can be used:

A. trometamol
B. glucose
C. boric acid
D. citric acid
E. sodium chloride

25/10. The hydrophilic solvents recommended for preparing erines are:

A. glucose solution 5%
B. sodium chloride solution 0.9%
C. distilled water
D. boric acid solution 3%
E. propylene glycol

25/11. Propylene glycol can be used in the preparation of erines in a concentration of:

A. 5%
B. 1%
C. 15%
D. 20%
E. 10%
25/12. In the preparation of nasal drops the following antimicrobial preservatives may be used:

A. benzalkonium chloride  
B. cetylpyridinium chloride  
C. phenylmercury borate  
D. thiomersal  
E. boric acid

25/13. The transnasal absorption of a drug substance depends on the following formulation factors:

A. pH  
B. osmotic pressure  
C. sterility  
D. viscosity  
E. dose

25/14. Transnasal absorption is influenced by the following physicochemical parameters of the drug substance:

A. molecular weight  
B. aggregation state  
C. partition coefficient  
D. application system  
E. tonicity

25/15 *. Particle transit time to the nasopharynx by means of mucociliary clearance is:

A. 5 min.  
B. 20 min.  
C. 60 min.  
D. 30 min.  
E. 120 min.

25/16. Nose Drops are preserved as follows:

A. in tight containers  
B. in containers with a drip system  
C. in cold storage  
D. in cool storage  
E. protected from light

25/17. The pH of nose drops with naphazoline should have the following values:

A. 6  
B. 6.5  
C. 7  
D. 5.5  
E. 7.5

25/18. The following pathological states increase mucociliary clearance:

A. allergic rhinitis  
B. atrophic rhinitis  
C. nasal polyps  
D. nasal septum deviation  
E. cystic fibrosis
25/19. The paralysis of ciliary motion occurs upon the administration of a solution with the following pH values:

A. 5  
B. 6  
C. 7.5  
D. 8.5  
E. 5.5

25/20. Nasal suspensions must contain solid particles with the following sizes:

A. 30 μm  
B. 50 μm  
C. 200 μm  
D. 10 μm  
E. 250 μm

25/21. The following pathological conditions increase nasal pH to the alkaline range:

A. inflammations  
B. acute rhinitis  
C. allergic rhinitis  
D. sinusitis  
E. pH is not influenced

25/22. The isotonization of a solution for nasal administration is performed by taking into account:

A. the active substance concentration  
B. the active substance molecular weight  
C. the molecular weight of the isotonizing agent  
D. the dissociation coefficient of the isotonizing agent  
E. the molar concentration of the isosmotic glucose solution

25/23. The nasal tissue mucus contains:

A. 95% water  
B. 5% electrolyte  
C. 2% electrolyte  
D. 99% water  
E. 1% electrolyte

25/24. Nasal preparations with a local action may contain the following drug substances:

A. anti-allergens  
B. hormones  
C. amino acids  
D. antihistamines  
E. inflammatory drugs

25/25. Nasal glands are composed of:

A. secreting cells  
B. goblet cells  
C. ciliated cells  
D. neurosecretory cells  
E. serous cells
26/1. Preparation of suspensions through precipitation method:
A. implies drug comminution up to an adequate dispersion grade
B. includes the pH change technique
C. implies micronization or atomization for obtaining suspended fine powders
D. requires specifications for the recrystallization conditions
E. can be applied for suspending phenobarbital

26/2. In the case of deflocculated suspensions:
A. the sediment is formed rapidly, due to individual settling of the particles
B. the solvation layer is diminished and can be removed, leading to a low packing degree of particles
C. the attraction forces are smaller than the repulsive forces, leading to caking
D. small particles stay suspended for a longer period of time
E. the supernatant is cloudy

26/3. Water solubility of slightly soluble drugs:
A. influences the stability of suspensions
B. doesn’t influence the stability of suspensions
C. is correlated with the floating phenomenon
D. is correlated with the crystal growth phenomenon
E. is correlated with the viscosity of the dispersion medium

26/4. Flocculating suspensions with tensioactive agents:
A. uses both ionic and nonionic tensioactive agents
B. is done according to the Schultze-Hardy equation
C. implies total coating of particles with a tensioactive layer
D. uses only nonionic tensioactive agents
E. implies particle interaction through weak bonding forces

26/5. Formulation of flocculated suspensions:
A. is applicable for parenteral medication
B. is applicable for ophthalmic medication
C. is not applicable for parenteral medication, given the risk of clogging the syringe needle
D. is advantageous due to easy redispersion prior to administration
E. is not applicable for ophthalmic medication

26/6. In the case of preparation of sterile suspensions:
A. sterilization of the finished product by autoclaving is always recommended
B. sterilization of the finished product by autoclaving is not recommended
C. sterilization of the finished product by sterile filtration is recommended
D. moist-heat sterilization of the finished product is recommended
E. sterile ingredients will be used
26/7. Povidone as a suspending agent:
A. is used in powder form
B. has a high-viscosity colloidal solution
C. has a low-viscosity colloidal solution
D. is generally combined with other suspending agents
E. is an anionic polymer

26/8. The floating phenomenon:
A. is specific to supersaturated solutions
B. occurs in case of same sign particle charge
C. can be prevented by the use of wetting agents
D. can be prevented by increasing particle solubility
E. is specific to hydrophobic powders

26/9. Dry suspensions:
A. must redisperse slowly in aqueous vehicle
B. often contain flocculating agents
C. often contain wetting agents
D. may contain as suspending agent xanthan gum
E. often contain preservatives, such as sodium propionate

26/10. The sedimentation volume - F:
A. is the ratio of the equilibrium volume of the total suspension to the volume of the sediment
B. is the ratio of the equilibrium volume of the sediment to the total suspension volume
C. in the case of an ideal suspension, it is < 1
D. in the case of an ideal suspension, it is > 1
E. in the case of an ideal suspension, it is equal to 1

26/11. Particle size reduction in a suspension:
A. leads to an increase of the settling rate
B. leads to a decrease of the settling rate
C. is recommended for deflocculated suspensions, up to a high degree of fineness
D. may be obtained through spray drying technique
E. poses industrial limitations for the jet mill micronizer

26/12. Hydrophilic polymers as ingredients for suspensions:
A. maybe protective colloids for deflocculated suspensions
B. may induce flocculation easily
C. are adsorbed on the surface of the particles, leading to a flocculated suspension
D. are adsorbed on the surface of the particles, leading to a deflocculated suspension
E. may create tixothropic systems, leading to suspensions with a sediment occupying almost all the volume of the preparation
26/13. The use of suspensions:
A. has the disadvantage of not masking the unpleasant taste of certain drugs
B. is adequate for parenteral administration as prolonged-release intravenous injections
C. is adequate for children, compared to solid oral dosage forms
D. is adequate for parenteral administration as prolonged-release intramuscular injections
E. has the disadvantage of enhanced hydrolysis of certain active drugs compared to medicated solutions

26/14. Factors influencing the particle behavior in a suspension are:
A. the crystalline structure
B. polimorphism
C. the apparent density of the powder bed
D. the angle of repose
E. the anhydrous or hydrated state

26/15. Flocculation of suspensions by the aid of electrolytes:
A. is done with an electrolyte having opposite-sign charges compared to the suspended particles
B. is done with an electrolyte having same-sign charges compared to the suspended particles
C. increasing ionic valence leads to lower flocculation capacity
D. increasing ionic valence leads to higher flocculation capacity
E. may use dipotassium phosphate

26/16. Peptized systems:
A. are deflocculated systems
B. are flocculated systems
C. have an enhanced kinetic stability
D. avoid particle sedimentation
E. possess same-sign charged particles

26/17. The caking phenomenon:
A. may occur in deflocculated systems
B. is reversible
C. is specific to emulsions and suspensions
D. is avoided in flocculated systems
E. is a phenomenon of chemical instability

26/18. According to the Romanian Pharmacopoeia, preparation of suspensions is done:
A. by precipitation, after bringing the solid drugs to a degree of fineness adequate to the purpose and route of administration
B. by dispersing the solid drugs in a liquid dispersion medium using an adequate technique, followed by adding the vehicle up to the required volume.
C. by stirring for 1-2 minutes.
D. by dispersing the solid drugs in a liquid dispersion medium using an adequate technique, followed by adding the vehicle up to the required mass.
E. by pH change method
26/19. The dilatant flow phenomenon:
A. occurs in diluted suspensions
B. implies increasing flow capacity with the shear stress
C. occurs in pastes
D. is a reverse behavior to the pseudoplastic flow
E. doesn’t occur in suspensions

26/20. According to the Romanian Pharmacopoeia, the suspensions:
A. must settle after 1-2 minutes
B. are fluid, opaque preparations, homogenous after sedimentation
C. may settle in time
D. may contain wetting agents
E. may contain colorants

26/21. The Romanian Pharmacopoeia specifies as quality control determinations for suspensions:
A. mass uniformity
B. analytical determination of the active drug
C. dissolution test
D. total mass per container
E. stability

26/22. Physical instability of suspensions occurs through:
A. changes in viscosity
B. aggregation
C. creaming
D. sedimentation
E. caking

26/23. The deflocculating agents for suspensions:
A. may lead also to flocculated particles, depending on the wetting agent used
B. maintain the suspended particles as individual entities
C. for oral suspensions, polyelectrolites are frequently used, due to their low toxicity
D. may be also nonionic polymers
E. may act by enthalpic stabilization

26/24. The following suspending agents are nonionic:
A. ethylcellulose
B. hydroxypropyl methylcellulose
C. carboxomers
D. tragacanth
E. acacia
26/25. The carbomers as suspending agents:
A. lead to basic dispersions
B. have a pH-dependent viscosity
C. have a temperature-dependent viscosity
D. are photosensitive
E. are used only in topical suspensions

27/1. The active substances from the surface dermatological products present the following effects, EXCEPT:
A. Absorption of ultraviolet radiations
B. Absorption of irritating compounds
C. Occlusion of corneum stratum
D. Absorption in order to obtain a systemic effect
E. Transfollicular absorption

27/2. According to Noyes-Whitney equation, the dissolution rate of the drug substance from the ointment base is influenced by the following factors:
A. Concentration of the drug substance in vehicle
B. Solubility of the drug substance in vehicle
C. Thickness of diffusion layer
D. Gravitational acceleration
E. Surface of drug substance particles

27/3. The drug substance dependant-factors that influence the percutaneous absorption are the following, EXCEPT:
A. Skin type
B. Chemical structure of the active substance
C. Presence of polymorph forms
D. Particle size
E. Excipient viscosity

27/4. The following affirmations regarding the cutaneous absorption promoters are TRUE:
A. They decrease the permeability of the drug substance through the corneum stratum
B. They temporarily decrease the barrier ability of the skin
C. They increase the permeability of the drug substance through the corneum stratum
D. They allow the loss of some components of the biological liquids
E. They reduce the interfacial tension

27/5. The following excipients used in formulating the dermatological preparations are sterols, EXCEPT:
A. Semi-synthetic lanoline
B. Stearyl alcohol
C. Cetyl alcohol
D. Colesterol
E. Wax bee

27/6. * According to FRX, ointment pH has the following value:
A. Lower than 4.5
B. Higher than 8.5
C. 4.5 – 6.5
D. 4.5 – 8.5
E. 4 – 7
27/7. According to FRX, the following affirmations regarding the ophthalmic ointments are TRUE:

A. They apply on the conjunctive mucous membrane  
B. They are liquid preparations  
C. They are sterile preparations  
D. They are semisolid preparations  
E. They are collyrium

27/8. Pastes:

A. They are ointments with a high content of solid insoluble substances (20-50%)  
B. They are ointments with a high content of solid insoluble substances (10-15%)  
C. The film created on the tegument is transparent  
D. They have skin protecting properties  
E. They have a solar filter effect

27/9. According to FRX, depending on the dispersion grade of the active substances, the ointments can be:

A. Suspensions  
B. Solutions  
C. Emulsions  
D. Pomades  
E. With several phases

27/10. The following definitions regarding the Vaseline as a base for ointment are TRUE:

A. it has got elevated tolerance  
B. it does not oxidize  
C. it is chemically inert  
D. it does not have occlusive properties  
E. it sterilized by dry heat

27/11. According to FRX, the following affirmations regarding the ointments are TRUE:

A. they are used with cosmetic purpose  
B. they are intended to skin application  
C. they are intended for mucous membrane application  
D. they are used therapeutically  
E. they are semi-solid pharmaceutical preparations

27/12. Hydrogels present the following characteristics:

A. Form a protecting film on the application site  
B. Have a good transfer capacity of the drug substance  
C. pH cannot be adjusted  
D. Are stable towards microorganisms  
E. Form xerogels

27/13. The absorption promoters used in ointment formulation must have the following conditions:

A. to be pharmacologically inert  
B. not to have immediate reaction  
C. to have easy metabolism in organism  
D. not to interact with active substances  
E. not to interact with other components of the formulation
TTSs have the following structural elements:

A. A permeable layer also called support material
B. A support layer for the active drug
C. A membrane to control the release speed of the active drug
D. An adhesive layer
E. The protection line or the release line

*According to FR X – Supplement 2004, the following affirmations regarding TTSs are real, EXCEPT:

A. They are flexible pharmaceutical preparations
B. They are applied on the damaged skin in order to release one or more active substances in general circulation
C. They contain one or more active substances
D. Are individually packed in sealed envelopes
E. They can have different dimensions

TTS has got the following advantages:

A. The drug substance is controllable release
B. The active substance metabolism is reduced by avoiding the liver
C. The drug substance enters directly in the systemic circulation
D. The drug substance can suffer degradations due to digestive fluids
E. They can substitute the oral route administration when this is impossible

Upon TTS formulation, the following characteristics must be required:

A. Adhesion
B. Biocompatibility
C. Impermeability
D. Resistance to environment
E. Detachment capacity

The absorption promoters included in TTS formulation must have the following properties:

A. To allow the release of the active substance from the transdermal system
B. To have a great penetration capacity
C. To act slowly
D. To uni-directionally alter the barrier property of the skin
E. To increase the percutaneous absorption of the active substance

According to FRX the ointments have the following characteristics:

A. Homogeneous aspect
B. White color
C. Homogeneity without agglomerations or drops
D. Color and odor characteristic to components
E. Odorless
27/20. *The following ophthalmic ointment is in FRX:

A. Ointment with hydrocortisone acetate
B. Phenylbutazone ointment
C. Clotrimazole ointment
D. Pilocarpine nitrate ointment
E. Pilocarpine hydrochloride ointment

27/21. According to FRX, the following affirmations regarding the emulsifier ointment are TRUE:

A. it contains liquid paraffin
B. it is an A/U ointment basis
C. it is an A/U ointment basis
D. it contains white vaseline
E. it contains cetyl stearyl alcohol emulsifier

27/22. According to FRX, the ophthalmic ointments are stored as follows:

A. In tight containers
B. In sterile containers
C. In well closed containers
D. Maximum 20 g ointment
E. Maximum 10 g ointment

27/23. According to FRX – Supplement 2004, the following affirmations regarding the semisolid preparations for cutaneous applications are REAL:

A. They are intended to local absorption of the active substances
B. They are intended to transdermal absorption of the active substances
C. They may contain antimicrobial preserving agent
D. They may contain agents to increase the viscosity
E. They may contain colorants

27/24. According to FRX, the ointment with Macrogol:

A. Is a lipophilic ointment base
B. is an A/U emulsion ointment base
C. is an U/A emulsion ointment base
D. contains Macrogol 400 and Macrogol 4000
E. is a hydro-soluble ointment base

27/25. According to FRX, the ointments applied on the following areas must be sterile:

A. Burns
B. Wounds
C. Pigmented skin
D. Scalp
E. Baby skin

28/1. According to FRX, the rectal suppositories may have the form:

A. Cylindrical
B. Conical
C. Cilindro-conical
D. Triangular
E. Torpedo
28/2. *According to FRX, the mass of the rectal suppositories for adults is:

A. 2-4 g  
B. 2-3 g  
C. 3-4 g  
D. 1-2g  
E. 5-12 g

28/3. The following suppositories are in FRX:

A. Glycerine suppositories
B. Metronidazole suppositories
C. Nystatine suppositories
D. Indometacin suppositories
E. Diclofenac sodium suppositories

28/4. According to FRX – Supplement 2004, the following affirmations regarding suppositories are TRUE:

A. They are solid mono-dose preparations  
B. They are semisolid mono-dose preparations  
C. They contain one or more active substances dissolved in an adequate basis  
D. They contain one or more active substances dispersed in an adequate basis  
E. They may contain anti-microbial agents and coloring agents authorized by the Competent Authority

28/5. According to FRX, at the quality control, Suppositoria monography included the following determinations:

A. Behavior at melting  
B. Behavior at dissolution  
C. Aspect  
D. Size of particles  
E. pH

28/6. The gelatinous mass used as a base for the suppository is prepared, according to FRX, by the following formula:

A. Gelatin : glycerol : distilled water = 2 g : 4 g : 10 g  
B. Gelatin : glycerol : distilled water = 4 g : 2 g : 10 g  
C. Gelatin : glycerol : distilled water = 2 g : 10 g : 4 g  
D. Glycerol : gelatin : distilled water = 2 g : 4 g : 10 g  
E. Gelatin : distilled water : glycerol = 2 g : 4 g : 10 g

28/7. The bases for suppositories must have the following conditions:

A. To melt at body temperature  
B. To dissolve in the rectal fluid  
C. To be able to be sterilized  
D. To have a large interval between the melting point and the solidification point  
E. To have a good display capacity on the rectal mucous membrane

28/8. Cacao butter has got the following advantages as suppository base:

A. Melting point close to body temperature  
B. Variations in chemical composition  
C. Can be sterilized  
D. Can be used to prepare suppositories by melting and moulding  
E. Can be used to prepare suppositories by manual moulding
28/9. Semi-synthetic glycerides, as suppository bases, are prepared from vegetal oils through the following procedures:

A. Direct hydrogenation of the oils
B. Inter-esterification procedure
C. Trans-esterification procedure
D. Re-esterification procedure
E. Melting the components

28/10. The disadvantages of semi-synthetic glycerides as suppository bases are the following:

A. Decreased viscosity in fluid state
B. Good emulsification capacity
C. Significant volume contraction
D. They brittle if cooled rapidly
E. Stability during storage

28/11. The following suppositories bases are hydro-soluble:

A. Glycerol-gelatin mass
B. Cacao butter
C. Polyethylene glycols
D. Estarinum mass
E. Glycerin masses and sodium soaps

28/12. The following affirmations regarding the glycerol-gelatin mass as suppository base are TRUE:

A. Good for melting and moulding method
B. Good for manual moulding method
C. Elastic suppositories are obtained
D. Solid drug substances can be dispersed
E. Miscible liquids can be dispersed

28/13. The disadvantages of the suppository bases with PEG are:

A. Induce growth of suspended crystals
B. Can dissolve drug substances that are sparingly soluble in water
C. Produce irritation of rectal mucous membrane
D. Cause discomfort
E. Do not need lubrication of the moulding forms

28/14. The bases of hydro-dispersible suppositories:

A. are characterized by their property to form emulsions
B. are characterized by the property to disperse in water
C. form emulsions of H/L type
D. form emulsions of L/H type
E. most of them have a lipophilic character

28/15. The following substances are used as rectal absorption promoters:

A. Tween 40
B. Tween 80
C. EDTA
D. Hyaluronidase
E. BHT
Suppositories are prepared through the following methods:

A. Melting and pressing  
B. Manual moulding  
C. Cold pressing  
D. Konig procedure  
E. Melting and moulding in forms

Powdering the suppositories by manual moulding is made with:

A. Starch  
B. Lactose  
C. Talc  
D. Bentonite  
E. Hyaluronidase

In suppository bases the following adjuvant substances can be associated:

A. Adjuvants to improve the dispersion of the drug substances  
B. Adjuvants to improve wettability  
C. Plastifiers  
D. Lubricants  
E. Colorants

When preparing the suppositories, the following substances are used as anti-oxidants:

A. Tocopherol  
B. Butylhydroxyanisol  
C. Parabens  
D. Butylhydroxytoluene  
E. Propyl gallate

The following substances are used as anti-microbial preservatives when preparing suppositories:

A. Hyaluronidase  
B. Sorbic acid  
C. Parabens  
D. Castor oil  
E. Tween 80

The following affirmations regarding the absorption of the drug substance from suppositories are true, EXCEPT:

A. the absorption of the substance at the level of inferior and medial hemorrhoidal veins avoids the first-pass metabolism  
B. the superior hemorrhoidal veins bring the drug substance through the portal vein in the liver  
C. the superior hemorrhoidal veins do not avoid the first-pass metabolism  
D. between inferior and superior hemorrhoidal veins there are many anastomoses  
E. the quantity of substance avoiding the first-pass barrier is of 100%
28/22. *In order to establish the excipient mass necessary for suppository preparation by melting, the following parameters must be known, EXCEPT:

A. the displacement factor of the drug substance  
B. the quantity of the drug substance for a suppository  
C. the solubility of the drug substance in excipient  
D. the capacity of the empty forms  
E. the desired number of suppositories

28/23. The surfactants act as promoters of the rectal absorption through the following mechanisms:

A. Increase of the wetting capacity  
B. Increase of the interfacial tension  
C. Solubilization of the lipids from the membrane  
D. Decrease of the wetting capacity  
E. Forming ion pairs

28/24. According to FRX, the storage of the suppositories is made:

A. In tight closed containers  
B. In well closed containers  
C. At 8-15 °C  
D. At maximum 25 °C  
E. At cold

28/25. When manually preparing the suppositories, the following plasticizers are added:

A. Lanoline 1g%  
B. Castor oil 10 g%  
C. Sunflower oil  
D. Castor oil 1g%  
E. Ethyl alcohol

29/1. As an excipient in tablet formulation, lactose:

A. may be a disintegrant by swelling in contact with water  
B. may be a filler, in anhydrous or hydrated form  
C. may react with amino-groups (the Maillard reaction)  
D. as anhydrous form has adequate cohesion properties as well as excellent flow  
E. can be agglomerated by spray drying to form a direct compression grade

29/2. Magnesium stearate:

A. is used as a glidant in the formulation of capsules and tablets  
B. is a soluble lubricant for effervescent tablets  
C. acts as a boundary lubricant, through adhesion of non-polar groups of the molecule to the metal die walls  
D. acts as a boundary lubricant, through adhesion of polar groups of the molecule to the metal die walls  
E. may delay the dissolution time of drug from tablets

29/3. Enteric-release polymers used for tablet film-coating are:

A. shellac  
B. cellulose acetyl phtalate  
C. calcium phosphate dihydrate
D. hydroxypropyl cellulose
E. co-polymers of metachrilic acid (Eudragit grades)

29/4. Sustained-release tablets:
A. provide initial immediate release of a drug dose, followed by the immediate release of a second dose after a period of time
B. provide initial immediate release of a drug dose, followed by the prolonged release of the remained dose
C. can maintain the drug concentration in the therapeutic range over a period of 24 hours
D. are not formulated with drugs with small therapeutic index
E. are preferred for the formulation of drugs with narrow therapeutic range, being easy to adjust

29/5. During the compression process:
A. the particles undergo plastic deformation
B. the particles don’t undergo plastic deformation, only fragmentation
C. new, clean surfaces are formed
D. adsorption of films on the particle surface increases particle bonding
E. in the ejection phase the tablet undergoes elastic recovery

29/6. Inside the Wurster coating chamber:
A. a spray nozzle is fitted on the upper side
B. a hydraulic nozzle is fitted in the base plate
C. two concentric chambers are fitted
D. the upward movement of tablet cores is controlled by the air stream
E. there are baffles that penetrate the tablet bed

29/7. Preparation of effervescent tablets:
A. can be done by granulation of the total mix with isopropyl alcohol
B. must be done in production areas having a relative humidity of max. 40 % at 25°C
C. can use citric acid monohydrate
D. requires dies and punches of approx. 20 mm
E. is not done by wet granulation

29/8. Hydrophilic matrix tablets:
A. are prepared by granulation of drugs and excipients with organic solvents
B. are prepared by spray-congealing
C. may contain polyacrylic acid
D. release the drug by diffusion
E. are prepared by direct compression

29/9. Nitroglycerin tablets:
A. may contain povidone as stabilizer
B. belong to the category of compressed lozenges
C. must disintegrate in not more than 5 minutes
D. have the risk of drug migration in the case of bulk containers
E. the drug is dissolved in a glicerinated gelatin mass (20:40:40)
29/10. The processed starch grades:

A. are also known by the name of Avicel
B. may be used in direct compression
C. undergo a volume change in water
D. may be superdisintegrants
E. may be used as binders (paste)

29/11. Hard gelatin capsules:

A. may contain mixtures of active drugs as powders or granules
B. may contain drug solutions or suspensions as heat-sensitive mixtures with high melting point
C. are obtained through the Scherer process
D. may have a residual moisture of 15 %
E. are not moisture-sensitive

29/12. Gastro-resistant (enteric) hard capsules may be obtained:

A. by coating with cellulose acetyl phthalate
B. by coating with hydroxypropyl methylcellulose
C. by capsule exposure to vapors of formaldehyde
D. by encapsulation of coated pellets
E. by coating with phenol salicylate

29/13. Povidone:

A. is used as a lubricant in tablet formulation
B. is a binder with good granulating properties, being used as a solution
C. may be used in colored tablets
D. is not used in colored tablets, because it doesn’t provide homogenous coloration
E. forms granules with slow disintegration

29/14. For the suspensions formulated in soft gelatin capsules:

A. suspending agents may be methylcellulose, hydroxypropyl methylcellulose
B. suspending agents may be beeswax, solid paraffin
C. a wetting agent is used, such as soy lecithin
D. smaller capsule sizes will be chosen in the case of encapsulation of dense liquids
E. the vehicle may be polyethylene glycol (PEG) 400.

29/15. Ingredients of the soft gelatin capsule wall may be:

A. sorbitol
B. sugar
C. titanium dioxide
D. magnesium stearate
E. colloidal silicon dioxide
29/16. Preparation of the empty shells for hard capsules implies:

A. forming gelatin ribbons of controlled thickness
B. dipping of pin bars in the warm gelatin solution
C. drying the capsule halves
D. joining the cap and body of the capsules
E. applying gelatin ribbons on a die roll

29/17. Hydroxypropyl methylcellulose as an excipient for hard gelatin capsules:

A. is ideal for the formulations with moisture-sensitive drugs
B. forms gel at temperatures lower than 60 °C
C. forms flexible capsules
D. forms gel with the aid of gel-forming agents
E. like gelatin, possesses chemically reactive groups

29/18. The sugar-coating process requires the following technological conditions:

A. an optimal convexity of the cores to be coated
B. a low mechanical resistance of the cores
C. a low friability of the cores
D. the use of double radius punches
E. the use of concave punches

29/19. Plasticizers as excipients for tablet coating:

A. act by increasing the glass transition temperature (Tg) of the polymers
B. act by reducing the glass transition temperature (Tg) of the polymers
C. may increase polymer permeability
D. decrease the film-elongation effect
E. may be co-polymers of methacrylate amino-esters (Eudragit grades)

29/20. Colloidal silicone dioxide:

A. is a glidant, for which the Romanian Pharmacopoeia sets a proportion in tablet formulation of not more than 10%
B. is a lubricant, without specific limitations imposed by the Romanian Pharmacopoeia.
C. is a lubricant, for which the Romanian Pharmacopoeia sets a proportion in capsule formulation of not more than 1%
D. is a glidant, for which the Romanian Pharmacopoeia sets a proportion in capsule formulation of not more than 10%
E. is a glidant, for which the Romanian Pharmacopoeia sets a proportion in tablet formulation of not more than 3%

29/21. The Rom. Pharm. has the following specifications for the capsule content:

A. active drugs dispersed as pastes
B. solid active drugs dissolved as solutions
C. mixtures of active drugs as pellets
D. mixtures of active drugs as powders
E. mixtures of active drugs as granules
29/22. According to the Romanian Pharmacopoeia, coated tablets:

A. may present spots or colored particles on their surface, which must be homogenously dispersed
B. may present on one or both sides markings or break-marks.
C. have continuous, flat or convex surface.
D. are white or colored
E. have intact edges

29/23. According to the Romanian Pharmacopoeia, the following statements are true regarding sugar-coated tablets:

A. belong to the category named compressi obducti
B. have a flat or convex surface
C. the total mass of the coating layer must not exceed the core mass
D. may present on one or both sides markings or break-marks.
E. are also called film-coated tablets

29/24. According to the Romanian Pharmacopoeia the following statements are true for the gastro-resistant film-coated tablets:

A. they must disintegrate in pepsin-acid solution (R) in not more than 1 hour, unless otherwise specified
B. they must disintegrate in pancreatin-alkaline solution (R) in not more than 2 hours, unless otherwise specified
C. have a continuous, usually glossy surface
D. the prolonged-release ones may present spots or colored particles on their surface, which must be homogenously dispersed
E. they must disintegrate in pancreatin-alkaline solution (R) in not more than 1 hour, unless otherwise specified

29/25. The Romanian Pharmacopoeia specifies the following administration routes for capsules:

A. rectal route
B. oral route, with prior dispersion/dissolution in water
C. vaginal route
D. by implantation
E. oral route