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The South African Pharmacy Council

PROFESSIONAL EXAMINATION OF COUNCIL IN TERMS OF THE PHARMACY ACT, 1974 (ACT 53 OF 1974)

APPLIED PHARMACEUTICS AND PHARMACEUTICAL CHEMISTRY EXAMINATION

2020 PRACTICE PAPER

TIME ALLOWED:	Three (3) hours
MAXIMUM MARKS:	50
PASS MARK:	25

APPLIED PHARMACEUTICS: SECTION B

EXAMINER:	Prof PH Demana
MODERATOR:	Prof T Govender
NO. OF PAGES:	11

CANDIDATES PLEASE NOTE:

(a) Ensure that you have the correct question paper for your examination.
(b) Ensure that all your details as requested on the cover page are filled in correctly.
(c) There is 15 minutes reading time for this paper.
(d) Do not commence writing until you are told to do so.
(e) The marks allocated to each question must be borne in mind when answering.
(f) All multiple choice questions are worth one mark.
(g) There is no negative marking for incorrect answers.
(h) There is only one correct answer per multiple choice question, therefore select only one option per question.
(i) Questions can be answered in any given order within the given time.
(j) All questions must be answered.
(k) **Section A: Pharmaceutical Chemistry** and **Section B Pharmaceutics** *Mark the answers for each question clearly.* Please ensure that all your details as requested on the cover page are filled in correctly.

Surname: ----------

First names: ----------

P Number: ----------

ID/Passport number: ----------

Date: ----------

Question	Marks awarded		Final Mark
	Examiner	Moderator	
Total			
Examiner		Moderator	

1. Dose dumping is a problem that is associated with the formulation of:

   (a) Effervescent tablets
   (b) Soft gelatin capsules
   (c) Emulsions
   (d) Controlled release drug products

2. Polymorphism refers to one of the following:

   (a) Two forms of a crystalline solid that differ in unit cell structure
   (b) Two forms of a crystalline solid that differ in the number of unit cells assembled in each dimension
   (c) Two forms of a solid such that one is crystalline and the other is amorphous
   (d) Two forms of a crystalline solid that differ in the solvent molecule entrapped in the crystal lattice

3. Picking is a common processing problem encountered in the manufacturing of tablets. This is mainly attributed to:

   (a) Tablet material adhering to the die wall
   (b) Unequal distribution of colour on a tablet
   (c) Tablet material adhering to the punch surface
   (d) Separation of a tablet into two or more distinct layers

4. Choose the appropriate semisolid preparation for application on dry & scaly skin where emollient properties of the preparation are beneficial:

   (a) Gels
   (b) Ointments
   (c) Paste
   (d) Cream

5. Which of the following is correct for drugs that belong to Class III of the Biopharmaceutical Classification System?

   (a) High solubility and High permeability
   (b) High solubility and Low permeability
   (c) Low solubility and High permeability
   (d) Low solubility and Low permeability

6. What kind of substances cannot permeate membranes by passive diffusion?

   (a) Lipid-soluble substances
   (b) Non-ionized substances
   (c) Hydrophobic substances
   (d) Hydrophilic substances

7. Which of the following statements relating to nasal drug delivery systems is TRUE?

   (a) In the design, it is not necessary to take into account the lack of metabolic ability of the nasal mucous membranes

(b) Mucoadhesive polymers are applied in nasal preparations to keep the nasal mucous membranes wet
(c) The optimal pH of the administered preparations is between 3 to 8
(d) Surfactants applied in the preparations increase the permeability

8. Cake formation is a characteristic feature of one of the following:

(a) Flocculated suspension
(b) Deflocculated suspension
(c) Thixotropic suspension
(d) Structured suspension

9. A surfactant with a Hydrophile-Lipophile Balance (HLB) value of 18 is expected to function as a:

(a) Anti-foaming agent
(b) Water in oil (w/o) emulsifier
(c) Oil in water (o/w) emulsifier
(d) Solubility enhancer

10. What biological tests can be undertaken to confirm product quality of a recently formulated cough mixture?

(a) Antibiotic susceptibility testing
(b) Air sampling
(c) Sterility tests
(d) Preservative efficacy testing

11. Which of the following devices is used to increase the efficiency of drug delivery via aerosols?

(a) Tube spacers
(b) Metered valves
(c) Actuator
(d) Pressure valve

12. In control of microbial contamination and the preservation of medicines, it is important to consider the following:

(a) Small pockets of water in oil-based products or condensates in syrups can allow microbial growth
(b) Synthetic materials are normally heavily contaminated with microorganisms, with the species present reflecting the source of the material
(c) If the material is thermolabile, sterilisation methods such as autoclaving is used to sterilise the material
(d) Gamma irradiation has a low penetrative power and low killing efficiency

13. In the tablet coating process, inadequate spreading of coating solution before drying causes:

(a) Orange peel effect

(b) Mottling
(c) Blistering effect
(d) Logo bridging

14. Which of the following dispersions does not have a liquid continuous phase?

(a) Nanosuspension
(b) Microemulsion
(c) Gel
(d) Foam

15. Which of the following is a physical penetration enhancer that is dependent on drug concentration, applied current and pH for enhancing transdermal drug delivery?

(a) Phonophoresis
(b) Iontophoresis
(c) Microneedles
(d) Ultrasound

16. During the preparation of solutions, the following approach can be used to improve the aqueous solubility of a particular drug:

(a) Addition of a water miscible solvent in which the non-polar compound is soluble
(b) Increasing the pH of the solution when the drug is a weak base
(c) Reaction of an insoluble drug and soluble material to form a soluble intermolecular non-reversible complex
(d) Increasing the particle size of a poorly soluble drug

17. The use of petrolatum-like bases in the formulation of semi solid dosage forms makes them:

(a) Occlusive
(b) Greasy
(c) Water washable
(d) Occlusive and greasy

18. Increasing the surfactant concentration above the critical micellar concentration will result in:

(a) An increase in surface tension
(b) A decrease in surface tension
(c) No change in surface tension
(d) All of the above

19. What is the main result of adding surfactants into a liquid composed of two immiscible phases such as oil and water?

(a) Reduction in the interfacial tension between the phases
(b) Increase in the interfacial tension between the phases
(c) Catalysation of a chemical reaction between the phases
(d) None of the above

20. In the preparation of cold creams, which of the following is MOST preferred?

(a) Absorption bases
(b) Water removable bases
(c) Hydrocarbon bases
(d) Water soluble bases

21. Bioavailability is best defined as:

(a) The measurement of the extent of drug absorption at site of action
(b) The rate and extent to which an active ingredient is delivered from a pharmaceutical form into the systemic circulation
(c) The fraction of the total amount of drug eliminated from the systemic circulation
(d) The transfer of total dose of drug from site of administration into the body

22. When compounding an oil-in-water emulsion that contains a flavouring agent, the flavouring agent should be in the:

(a) Continuous phase
(b) Dispersed phase
(c) Emulsifier
(d) Any of the above

23. Which of the following statement is TRUE with regard to elimination of a drug in the body?

(a) Tubular reabsorption is an active process
(b) Protein-bound drugs are not subjected to glomerular filtration
(c) A drug that is completely reabsorbed has a clearance rate of not more than 120 ml/min
(d) Elimination rate is increased when ATP is used

24. The isoelectric point of an amphoteric molecule is:

(a) The pH at which the substance has the lowest aqueous solubility
(b) The pH at which the substance has the lowest lipophilicity
(c) The pH at which the substance has the highest lipophilicity
(d) The pH at which the substance has the highest aqueous solubility

25. The distribution of drugs into the central nervous system (brain) usually depends on:

(a) Lipid diffusion
(b) Active transport
(c) Facilitated transport
(d) Receptor-mediated endocytosis

26. Which of the following relating to concept of biopharmaceutics is TRUE?

(a) Gastric emptying is the rate limiting step for oral absorption of drug from its solution form in the gastrointestinal tract
(b) The effects of a drug often correlate better with its administered dose than with its measured plasma concentration

(c) The bioavailability of a drug administered in the same dosage form by different routes is usually the same
(d) The key biopharmaceutical properties of a drug cannot be quantified to provide direction for the drug's bioavailability

27. How does the increase in viscosity of the suspending medium affect the rate of sedimentation when assuming the density of the particles is greater than that of the suspending medium?

(a) Sedimentation rate will not change
(b) Sedimentation rate will be slower
(c) Sedimentation rate will be faster
(d) No particle sedimentation will take place

28. Capping of a tablet can be reduced by:

(a) Pre-compression
(b) Reducing the final compression rate
(c) Using flat punches
(d) All of the above

29. Which of the following statements applies to heat sterilisation is TRUE?

(a) Sterilisation using dry heat is generally less efficient than moist heat
(b) Conduction is the main type of heat transfer in dry heat sterilisation
(c) Moist heat sterilisation relies only on the combination of steam and temperature
(d) For dry heat sterilisation, the temperature of 170°C for not less than 30 minutes is recommend in the BP

30. Which of the technologies listed below is a valuable method for mass-producing drugs and other useful proteins?

(a) Recombinant DNA technology
(b) Transgenic technology
(c) Biotechnology
(d) Gene targeting

31. Which of the following constituents may be suitable as base constituents for rectal dosage forms?

(a) Theobroma Oil
(b) Macrogols
(c) Glycero-gelatin
(d) Any of the above

32. Which of the following statements with regard to microencapsulation is TRUE?

(a) The material to be microencapsulated must be solid in nature
(b) The air suspension coating technique enables encapsulation and drying of particles in one piece of equipment

(c) Step 1 of the coacervation-phase separation process is the formation of three miscible chemical phases
(d) In the spray-congealing process, coating solidification is achieved by rapid evaporation of the solvent in which the coating material is dissolved

33. The procedure which is used to prove that the various production procedures, equipment and materials will produce accurate results is known as:

(a) GMP
(b) Quality Control
(c) Quality assurance
(d) Validation

34. A basic requirement for Good Manufacturing Practice is:

(a) Critical steps in the process are video recorded
(b) Operators are trained to carry out procedures correctly
(c) The recall system can identify the patient who took the medicine
(d) All of the above

35. What mass of salicylic acid is required to prepare 30 g of a 2% $^{w}/_{w}$ salicylic acid in aqueous cream?

(a) 0.2 g
(b) 0.6 g
(c) 1.0 g
(d) 2.0 g

36. A patient is being given chloramphenicol eye drops 0.5% for an eye infection. How much is contained in 5 ml?

(a) 500 mg
(b) 250 mg
(c) 100 mg
(d) 25 mg

37. How much millimeters of a 1:400 $^{w}/_{v}$ solution of Benzalkonium chloride solution can be made from 250 ml of a 2% solution?

(a) 25 ml
(b) 40 ml
(c) 312.5 ml
(d) 2000 ml

38. Calculate the volume in milliliters of a 0.2% solution of an antigen that must be used to prepare 4 ml of a solution containing 0.4 mg/ml of the antigen.

(a) 0.8 ml
(b) 1.0 ml
(c) 1.6 ml
(d) 2.0 ml

39. How many milligrams of hydrocortisone are needed to compound the following formulation?

Hydrocortisone	3.5% $^{w}/_{w}$
Ointment base	30 g

(a) 0.8271 mg
(b) 827.1 mg
(c) 1050 mg
(d) 1088 mg

40. A prescriber wants to know the amount of 15% $^{w}/_{v}$ KCl ampoules to add to a 500 ml infusion bag containing 5% $^{w}/_{v}$ dextrose in order to make a 0.3% $^{w}/_{v}$ KCl solution.

(a) 2.0 ml
(b) 2.6 ml
(c) 9.6 ml
(d) 10.2 ml

41. Calculate the amount of mannitol (in grams) required to prepare 85 ml solution with a concentration of 21.00% $^{w}/_{v}$.

(a) 17.85 g
(b) 24.71 g
(c) 36.24 g
(d) 48.31 g

42. What is the volume of a solution that contains 17.5 g of dextrose if the concentration of the solution is 20.59% $^{w}/_{v}$?

(a) 36.03 ml
(b) 44.56 ml
(c) 63.72 ml
(d) 84.99 ml

43. How many grams of sodium chloride should be used to make 468.75 ml of a 25% $^{w}/_{w}$ solution (density = 1.28 g/ml)?

(a) 75 g
(b) 150 g
(c) 37.5 g
(d) 200 g

44. An antiseptic solution contains 0.75% $^{w}/_{v}$ phenol BP. What is the volume of the solution that contains 30 mg phenol?

(a) 8 ml
(b) 16 ml
(c) 2 ml
(d) 4 ml

45. How much of a 15% $^{w}/_{w}$ zinc oxide is required to be mixed with 200 g of 10% $^{w}/_{w}$ Zinc Oxide powder in order to prepare a powder containing 12% $^{w}/_{w}$ Zinc Oxide?

(a) 56.8 g
(b) 133.3 g
(c) 147.2 g
(d) 187.5 g

46. You are required to make 0.6 litres of a 0.5% solution from a stock solution of 2%. By how much should it be diluted in millilitres?

(a) 150 ml
(b) 280 ml
(c) 450 ml
(d) 620 ml

47. How many millilitres of a 2% stock solution of potassium permanganate should be used in compounding the following prescription?

(a) 5.00 ml
(b) 2.50 ml
(c) 3.75 ml
(d) 1.25 ml

48. Drug X has a half-life of 2 hours. When this drug is administered by IV injection, the concentration in the plasma was found to be 116 µg/ml immediately after administration. Calculate drug levels in µg/ml 8 hours.

(a) 2.63 µg/ml
(b) 7.25 µg/ml
(c) 14.50 µg/ml
(d) 21.00 µg/ml

49. Below is a formula for a Cough Syrup.

Guaifenesin	100.00 mg
Sodium Carboxymethyl Cellulose	39.520 mg
Sodium Saccharin	7.62 mg
Methyl hydroxybenzoate	2.490 mg
Glycerine	20.00 mg
Extract of Liquorice	0.125 ml
Water Purified to	5.00 ml

How many milliliters of glycerine (density = 1.258 g/ml) would be required to produce 1500 litres of Cough Syrup?

(a) 2.2 ml
(b) 4.8 ml
(c) 9.4 ml
(d) 10.0 ml

50. Below is a formula for a Cough Syrup.

Guaifenesin	100.00 mg
Sodium Carboxymethyl Cellulose	39.520 mg
Sodium Saccharin	7.62 mg
Methyl hydroxybenzoate	2.490 mg
Glycerine	20.00 mg
Extract of Liquorice	0.125 ml
Water Purified to	5.00 ml

A total of 1500 litres is required. The product is packed in 100 ml bottles. 14728 bottles are packed. The percentage yield is as follows:

(a) 96.8%
(b) 98.2%
(c) 99.4%
(d) 97.0%