KATHMANDU UNIVERSITY
End Semester Examination [C]
May/June, 2019

Marks scored:

Level : B. Pharm.
Year : IV

Course : PHAR 404
Semester: I

Exam Roll No. :

Time: 30 mins.

F. M. : 20

Registration No.:

Date 03 JUN 2019

SECTION "A"
[20Q. × 1= 20 marks]

I. Check (√) the correct answer of the following multiple-choice questions:

1. Which of these statements is true?
   a. All candidate drug substances can be developed into drug products
   b. It can cost nearly $2 billion to develop and launch a medicine
   c. All drug products that reach the market are blockbusters
   d. Drug companies have patent protection from the moment the drug product is launched

2. A concentration of 2% w/v is equivalent to .....
   a. 2M b. 2g/L c. 0.2g/L d. 20g/L

3. Regarding weakly basic drug molecules, which of the following statement is true?
   a. The solubility of weak bases increases as the pH is decreased.
   b. The solubility of weak bases increases as the pH is increased.
   c. The solubility of weak bases in pharmaceutical formulations are not affected by the presence of counterions.
   d. All weakly basic therapeutic agents exhibit an isoelectric point.

4. Regarding pharmaceutical elixirs, which of the following statements are true?
   a. Preservatives are required in all elixir formulations.
   b. Elixirs generally require the addition of sweetening agents.
   c. Elixirs generally contain < 10% alcohol USP.
   d. Colours are required for all elixir formulations.

5. Concerning the use of pharmaceutical suspensions designed for oral administration, which of the following statement is true?
   a. Suspensions for oral administration are primarily used for administration to adult.
   b. Many antacid formulations are suspensions.
   c. Drugs with high aqueous solubility are frequently formulated as suspensions designed for oral administration.
   d. Pharmaceutical suspensions designed for oral administration must be coloured.

6. Concerning the use of oil in water emulsions, which of the following statements are true?
   a. Oil in water emulsions may be used for the oral administration of therapeutic agents.
   b. Oil in water emulsions is only formulated for topical administration.
   c. Drugs with high aqueous solubility are frequently formulated as oil in water emulsions.
   d. Oil in water emulsions designed for oral administration must be coloured.

7. Regarding the role of surfactants in pharmaceutical suspensions for oral administration, which of the following statements are true?
   a. Surfactants increase the water contact angle of dispersed drug particles.
   b. Surfactants promote flocculation.
   c. Surfactants with low HLB are used to stabilise oral suspensions designed for oral administrations.
   d. Surfactants increase the viscosity of the continuous phase of pharmaceutical suspensions.

8. Concerning direct compression as a method for tablet manufacture, which of the following statements are true?
   a. It is a complex process, involving a more number of unit operations in comparison to wet granulation.
   b. The morphology of particles is not important in direct compression.
   c. Direct compression employs spray-dried excipients only.
   d. Coloured tablets may be easily produced by direct compression.

9. Regarding the various types of tablets, which of the following statement is false?
   a. Enteric-coated tablets release the therapeutic agent within the small intestine but not in the stomach.
   b. Effervescent tablets are used to enhance the dissolution rate and hence absorption rate of poorly soluble drugs.
   c. Sugar-coated tablets are employed to reduce drug degradation within the stomach.
   d. Film-coated tablets may be used to target drug release to the colon.

10. Regarding capsules, which of the following statement is False?
   a. Capsules are more straightforward to manufacture than tablets.
   b. Capsules may be formulated to increase the bioavailability of poorly soluble drugs.
   c. Capsules may be coloured to aid identification.
   d. The stability of therapeutic agents when formulated as capsules is always greater than that of tablets.

11. Concerning hard gelatin capsules, which of the following statements are true?
   a. Gelatin is a polysaccharide that is derived from animal sources.
   b. There are three types of gelatin, each exhibiting different isoelectric points.
   c. The grade of gelatin is defined by the bloom strength.
   d. Gelatin is freely soluble in water at room temperature.

12. Concerning film coatings, which of the following statement is true?
   a. Film coatings may enhance the dissolution rate of therapeutic agents in the gastrointestinal tract.
   b. Enteric film coatings should dissolve in the stomach.
   c. Aqueous film coatings, e.g. hydroxypropylcellulose, may be employed to target drug release at the colon.
   d. Film coatings may be employed to mask the taste of unpalatable therapeutic agents.

13. Concerning respiratory drug delivery, which of the following statements are true?
   a. Delivery of therapeutic agents to the respiratory tract is performed primarily for the treatment of local conditions, e.g. asthma, infection.
   b. The treatment of asthma involves the deposition of the therapeutic agent at the alveoli.
   c. Systemic absorption of certain therapeutic agents does not occur following respiratory delivery.
   d. Respiratory drug delivery is associated with a slow onset of drug action.

14. Concerning the formulation and use of metered-dose inhalers, which of the following statement is true?
    a. Oxidation of drugs is minimised.
    b. Metered-dose inhalers are usually formulated to ensure that the drug is soluble within the propellant system.
    c. Metered-dose inhalers require the inclusion of a preservative.
    d. Metered-dose inhalers may be easily formulated to contain water.

15. With respect to ointments, which of the following is false?
    a. The bases of hydrocarbon ointments are typically derived from petroleum.
    b. Hydrophobic ointment bases are suitable for exuding lesions.
    c. An ointment may be formed by fusion of silicone oil and a wax.
    d. Drug solubility in an ointment base may be modified by the inclusion of a co-solvent such as propylene glycol.

16. With respect to paste formulations, which of the following is true?
    a. Pastes contain low drug loadings.
    b. Pastes may not be applied to exuding wounds.
    c. Pastes are opaque and therefore used as sunblock formulations.
    d. Pastes are cosmetically acceptable formulations.

17. With respect to pharmaceutical lotions, which of the following are true?
    a. Pharmaceutical lotions may be formulated as solutions or suspensions, with solutions being preferred.
    b. Pharmaceutical lotions are typically used for the treatment of local conditions.
    c. Pharmaceutical lotions are principally non-aqueous formulations.
    d. Pharmaceutical lotions do not require the inclusion of preservatives.

18. The most preferred dosage form for veterinary purpose is.....
    a. Paste or gel b. tablet c Liquid d. capsule

19. Activities carry by company to design and produce a differentiated container for particular product is classified as .....
    a. Guaranties b. warranties c. labeling d. Packaging

20. Constituents of primary packaging moving towards product is known as .....
    a. Diffusion b. Permeation c. Dissolution d. Leaching

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Note: Check (√) the number of each question you have answered in the front page of main answer book (of Sections B, C and D).

SECTION "B"

[5Q. × 3 = 15 marks]

II. Answer *ANY FIVE* questions.

1. What are the roles of pKa, Polymorphism and partition coefficient in Preformulation studies?
2. What are the main types of tablet defects? Describe them with reasons and remedies.
3. Mention the rationales of 'tablet coating'.
4. What are the reasons both 'soft' as well as hard gelatine capsules are existed in the market?
5. Describe the methods of manufacture of Metered Dose Inhalers?
6. What are the bases for ointments?
7. Describe the types of pharmaceutical packaging materials? With examples of each.

SECTION "C"

[5Q. × 5 = 25 marks]

III. Answer *ANY FIVE* questions.

8. What are the Excipients used in the manufacture of tablets? Mention them with example.
9. Describe the tablet manufacturing methods.
10. What are the advantages and disadvantages of 'Soft gelatin capsules'?
11. Why different types of impellers are required for oral liquid preparations?
12. Mention the problems of 'Suspension' and 'Emulsion'. Mention their causes and remedies.
13. What are the challenges and eases in veterinary dosage forms in comparison with dosage forms for human consumption?
14. Describe the evaluation parameters of Semi-solids.

SECTION "D"

[2Q. × 7.5 = 15 marks]

IV. Answer *ANY TWO* questions.

15. Describe the behavior of solids during drying with diagram. Mention the dryers used in pharmaceutical industries.
16. Describe the hard gelatin manufacturing process. Mention its storage condition.
17. Define 'Ideal Mixing'. What are the objectives of mixing? Describe the mixing mechanisms. What are mixing equipments?