T. Y. B. Pharm
12/03/25.
Sem-V
Semester Exam

(3 hours) (Total Marks:75)

ATKT

N.B.: 1. All questions are compulsory.
2. Draw neat and well labeled diagrams wherever necessary.
3. Figure to the right indicate full marks.

Q.1. Multiple Choice Questions (MCQs) **(20)**
All questions are compulsory

1. Coil/ Cwater gives an estimate of drug's _____
   a) Partition Coefficient
   b) pKa
   c) Polymorphism
   d) pH

2. As per BCS, a drug substance is classified as highly soluble if
   a) The highest dose is completely soluble in 500 mL or less of aqueous media
   b) The lowest dose is completely soluble in 250 mL or less of aqueous media
   c) The highest dose is completely soluble in 250 mL or less of aqueous media
   d) The lowest dose is completely soluble in 500 mL or less of aqueous media

3. Which of the following forms is associated with high thermodynamic energy
   a) Polymorphs
   b) Amorphous
   c) Crystalline
   d) Inclusion compounds

4. Cold filling apparatus for filling propellant employs the use of ____ in an insulated container
   a) Cullet
   b) Nitrous oxide
   c) Dry Ice
   d) CFC

5. Type II Soda Lime glass is
   a) Regular Soda Lime
   b) Type NP
   c) Treated Soda Lime
   d) General purpose Soda Lime

6. Moulding and flaming are the steps involved in the manufacturing of ____
   a) Shampoo
   b) Lipstick
   c) Nail polish
   d) Toothpaste

7. Beeswax is the major ingredient in.
   a) Hair dye
   b) Toothpaste
   c) Lipstick
   d) Cold cream

8. pH of tears is
   a) 7.4
   b) 8.4
   c) 6.4
   d) 5.4

9. _____ is commonly used as a sterilization method for aqueous parenteral formulations
   a) Moist heat sterilization
   b) Chemical sterilization
   c) Dry heat sterilization
   d) Radiation sterilization

10. Sterility test for parenterals is carried out under _____ conditions
   a) Clean
   b) Ambient
   c) Aseptic
   d) Cold

11. In LAL test, _____ react with LAL reagent to produce a firm gel within the incubation period.
   a) Endotoxins
   b) Radionuclides
   c) Xenobiotics
   d) Chemicals

12. The usual volume for an intramuscular route of administration is
   a) 0.5-3 mL
   b) 20 mL
   c) 15 mL
   d) 5-10 mL

13. Ingredient used post granulation only in the manufacturing of tablets
   a) Lubricant
   b) Binder
   c) Diluent
   d) Disintegrant

14. Diosna mixer granulator is used in _____ process
   a) Dry granulation
   b) Wet granulation
   c) Direct compression
   d) Slugging

15. _____ test is not done for coated tablets
   a) Disintegration
   b) Dissolution
   c) Friability
   d) Weight Variation

16. Hard Gelatin capsule should not contain more than ____ ppm of iron as impurity
    a) 15
    b) 20
    c) 10
    d) 30

17. Base adsorption parameter is important for
    a) Hard gelatin capsule
    b) Chewable tablets
    c) Soft gelatin capsule
    d) Sugar coated tablet

18. _____ is not a step in sugar coating process
    a) Seal coating
    b) Sub coating
    c) Polishing
    d) Marbling

19. Extrusion spheronization is a method to manufacture
    a) Injectable
    b) Eye ointment
    c) Pellets
    d) Soft gelatin capsule

20. Choose the major instability in emulsions.
    a) Creaming
    b) Phase separation
    c) Flocculation
    d) Caking

Q.2. Answer <u>any 2</u> questions. **(20)**

1. Define preformulation and classify the various tests involved in preformulation studies. Elaborate on any two chemical degradation pathways of a drug.
2. Draw the flowchart for wet granulation process with names of equipment at each step and elaborate on the use of Fluidized bed granulator dryer in this process.
3. Explain in detail about production facilities for parenterals along with plant layout.

Q.3. Answer <u>any 7</u> questions. **(35)**

1. Explain the goals and objectives of preformulation.
2. Write a short note on the principle and working of a metered dose inhaler.
3. Elaborate on plastic as a packaging material and various drug-plastic interactions.
4. Elaborate on Rotary die process of filling soft gelatin capsules.
5. Enlist the QC tests done on tablets and elaborate on Disintegration test for enteric coated tablets.
6. Write a note on any one manufacturing technique of pellets.
7. Explain preparation of eye drops in detail.
8. Write a note on formulation components of shampoos.
9. Explain in vivo pyrogen testing for parenteral preparations.

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