

8.A 2^3 Full Factorial design has ?
- 3 factors and 2 levels
 - 2 factors and 3 levels
 - 8 factors and 9 levels
 - 9 factors and 8 levels
9. Example of the penetration enhancer?
- Lactose
 - Dimethyl sulphoxide
 - Cellulose acetate phthalate
 - Crosscarmellose Sodium
10. Example of the super disintegrant?
- Sodium starch glycolate
 - Sodium metabisulfite
 - Lactose
 - Talc
11. Which of this cannot be used as solubilizer?
- Ethanol
 - Tween 80
 - Span 60
 - Crosscarmellose Sodium
12. A drug that belongs to BCS class IV has ?
- High solubility and Low permeability
 - High solubility and High permeability
 - Low solubility and High permeability
 - Low solubility and Low permeability
13. Correct sequence of the stages of new drug development is?
- Drug discovery- Preclinical studies-IND approval-Clinical studies-NDA-Post marketing phase
 - Preclinical studies- Drug discovery- IND approval- Clinical studies -NDA- Post marketing phase
 - Drug discovery- Preclinical studies- NDA -Clinical studies- IND approval -Post marketing phase
 - Drug discovery- Preclinical studies-IND approval-Clinical studies-Post marketing phase-NDA
14. Fast Flo® Lactose is used for.
- Wet granulation
 - Direct compression
 - Dry granulation
 - Coating of pallets

15. QBD is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based onQuality target product profile
- Sound science and quality management
 - Sound science and risk management
 - Risk management
 - Sound science and quantitative and qualitative risk management
16. Surfactant that dissolves in water to produce negative ions are called.
- Anionic surfactant
 - Non-ionic surfactant
 - Cationic surfactant
 - Synthetic surfactant
17. ...is a critical parameter that should be validated to get a tablet having desired quality attributes.
- Hardness
 - Dose
 - Weight variation
 - Mixing time
18. Suck back effect is observed in
- Eye Drops container
 - Ampoules
 - Glass bottle
 - Screw cap bottles
19. Quality characteristics of drug product that must ideally be achieved to ensure its quality, safety, and efficacy is called.
- Quality target product profile
 - Critical Quality attrition
 - Critical Material attributes
 - Critical process parameters
20. Bubble test is used as a quality control test for
- Sachet
 - Plastic container
 - Glass container
 - Blister pack

Q.II Answer Any Two of the Following $10 \times 2 = 20M$

- i. Discuss steps involved in large-scale manufacturing and Q.C testing of ophthalmic.
- ii. Explain significance of coating material in manufacturing of tablet? Discuss any two enteric coating polymers in detail?
- iii. Illustrate role of cyclodextrin in pharmaceutical development along with classification.

Q.III Answer Any Seven of the Following $5 \times 7 = 35M$

- A. Discuss factorial design
- B. Discuss the Q.C tests to be conducted for glass?
- C. Explain Aerosol excipients.
- D. Explain parenteral excipients
- E. Discuss stability evaluation protocol for pharmaceutical product as per ICH guidelines?
- F. Briefly, discuss plastic as packaging material for pharmaceutical dosage form?
- G. Discuss significance and role of surfactants and glycols in pharmaceutical formulations.
- H. Discuss various optimization techniques in pharmaceutical product development.
- I. Discuss the characteristics of ideal closures. Discuss pharmacopoeia testing of closures.
