11/10/24 Paper / Subject Code: 14233 / Pharmaceutical Product Development PPD V111 Marks: 75 Time: 3 hrs 1. Preformulation study involves all except? a. Solubility analysis b. Light sensitivity c. Drug Excipient interaction d. Evaluation of finished product glass is the first choice for preparations intended for parenteral administration? a. Type I b. Type II c. Type III d. NP 3. Avicel CE-15 is? a. Special grade of sodium carboxyl·methyl cellulose b. Physical mixture of hydroxyl propyl methyl cellulose and tragacanth c. Co-processed excipient of microcrystalline cellulose and guar gum d. Used in the enteric coating of tablets 4. ... is an example of suspending agent used in the development of pharmaceutical suspension? a. Tragacanth b. Cyclodextrin c. Talc d. Propylene glycol 5. Which activity is not a part of the preformulation study? a. Solubility analysis b. Bulk characterization c. Stability of API d. Finalization of commercial batches 6. The ICH guideline which related to light on Pharmaceutical Development is? a. Q4 b. Q8 c. Q10 d. 05 7. Which is not factorial design ...? a. Box hunter b. Plackett Burman c. Taguchi d. Box Behnken

64257

Page 1 of 4

Scanned with OKEN Scanner

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

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



## Paper / Subject Code: 14233 / Pharmaceutical Product Development

- O.II Answer Any Two of the Following  $10 \times 2 = 20M$
- j. 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 5×7= 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.
  - Discuss the characteristics of ideal closures. Discuss pharmacopoeia testing of closures.