

Time: 3 Hour

Marks: 75

Q.I Select the right option

20 M

1. Preformulation study involves all except?
 - a.Solubility analysis
 - b.Light sensitivity
 - c.Drug Excipient interaction
 - d.Evaluation of finished product

2. In type I glass, boric acid is added to?
 - a.Reduce cost
 - b.Reduce alkalinity
 - c.Increase wall thickness
 - d.Decrease water vapour permeability

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. Water wicking and swelling are the mechanism involved in?
 - a.Disintegration
 - b.Flowability
 - c.Granulation
 - d.Size Reduction

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 topics are divided into the following guideline except?
 - a.Safety guidelines
 - b.Efficacy guidelines
 - c.Quality guidelines
 - d.Stability guidelines

7. Which is not factorial design ..?
 - a.Box hunter
 - b.Plackett Burman
 - c.Taguchi
 - d.Box Behnken

56602

8.A 2^3 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. Crosscarmellose Sodium

10. The glucose subunits in cyclodextrins are linked by?

- a. B- (1,3) glycosidic bonds
- b. A-(1,7) glycosidic bonds
- c. A-(1,4) glycosidic bonds
- d. A-(1,4) amino bonds

11. Which of this cannot be used as solubilizer?

- a. Ethanol
- b. Tween 80
- c. Span 60
- d. Crosscarmellose Sodium

12. A drug that belongs to BCS class II 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. 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

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

- 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. Spray dried lactose is used for ...

- a. Direct compression
- b. Wet granulation
- c. Dry Granulation
- d. Coating capsule

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. Following test is done for Plastics

- a. Collapsibility test
- b. Hydrolytic Resistance Test
- c. Powdered glass test
- d. Fragmentation test

19. Suck back effect is observed in

- a. Eye Drops container
- b. Ampoules
- c. Glass bottle
- d. Screw cap bottles

20. Identify the correct property of thermoset plastics

- a. Highly recycled
- b. Less resistant against high temperature
- c. Can be remoulded or reshaped
- d. May softened when heated

Q.II Answer Any Two of the Following

20M

- i. What is pharmaceutical product development? Explain in detail the steps involved.
- 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

35M

- a) Discuss factorial design
- b) What are the different types of glass? Which test is done to differentiate glass?
- c) Briefly discuss aerosol excipients.
- d) Discuss stability evaluation protocol for pharmaceutical product as per ICH guidelines?
- e) Explain polymers used in novel drug delivery systems.
- f) Explain concept of QbD and its application in product development.
- g) Discuss significance and role of surfactants and glycols in pharmaceutical formulations.
- h) Discuss the characteristics of ideal closures. Discuss pharmacopoeia testing of closures.
- i) Discuss role of solvents and solubilizers.
