MPHARM SEM I (CBCS REVISED)

QUESTION BANK FOR PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

1. Example of a thermoplastic packaging material is

a) Polystyrene

b) Phenol formaldehyde

c) Urea formaldehyde

d) Melamine formaldehyde

2. Sorption is

a**)** the transmission of gases, vapors or liquids through plastic packaging material

b) removal of constituents from the packaging material by the drug product

c) **removal of constituents from the drug product by the packaging material**

d) chemical interaction with contents

3. Most expensive rubber as packaging material is

a) Butyl rubber

b) Nitrile rubber

c) Chloroprene rubber

d) Silicon rubbers

4. Fragmentation Tests are performed on following packaging material

a) Rubber closures

b) Metal tubes

c) Plastic bottles

d) Ampoules

5. Which amongst following is an example of primary packaging

a) Wrapper to contain primary pack

b) Box to contain primary pack

c) Labels, patient information leaflet

d) Ampoule, vial, infusion fluid container, dropper bottle

6. Glass is manufactured by all except one method

a) Blowing

b) pulling

c) casting

d) drawing

7. Degree of concern associated with route of administration is highest for

a) Injections

b) Topical solutions

c) Nasal aerosols

d) Topical sprays

8. Aseptic systems commercially sterilize the product

a) with the package

b) only

c) after packing

d) separately from the package

9. HTST stands for

a) high temperature short time

b) High throughput screen and testing

c) High temperature screen time

d) High temperature short test

10. Regulatory requirements for which GHTF class of medical devices are highest

a) A

b) D

c) B

d) C

11. Which of the following is NOT needed for an investigational new drug application?

a) Animal pharmacology and toxicology

b) Manufacturing information

c) Clinical protocols and Investigator Information

d) Phase III trial data

12. Which technique is the less common method used to protect the integrity of clinical trial results?

a) Single blinding

b) Double blinding

c) Randomization

d) Placebo and control groups

13. What is a synonym/description for the Phase 4 trials?

a) Post Marketing Surveillance

b) Pre-Marketing Surveillance

c) Pre-FDA Approval

d) Post FDA Approval

14. On which two criteria does the FDA classify NDAs?

a) Novelty of the active ingredient and time to market

b) Balance between safety and effectiveness

c) Novelty of the active ingredient and clinical improvement

d) Clinical improvement and effectiveness of product

15. What is the primary focus of Phase 3 Clinical testing?

a) How to manage costs.

b) The collection and analysis of highly specific efficacy end-point data.

c) The optimal range of effective dosage.

d) The analysis of data results from the small-subset target population.

16. Which is the primary goal/major milestone of preclinical development?

A. Filing an IND application with the FDA

B. Identifying the target population for the lead compound that is being developed

C. Aligning the development process with the strategic aims of the company

D. To determine anticipated revenue

17. What are the two greatest challenges for the Development team?

A. Managing risks and complying with FDA requirements

B. Improving time to market and decreasing toxicity

C. Accelerating time to market and managing risk

D. Complying with FDA requirements and improving efficacy

18. This is a minor detail, but to hit home the concept of how few drugs make it to market, please fill in the blanks (straight out of the book): For every _____ compounds that enter preclinical testing, only _____ go to clinical development, and only _____ win FDA approval.

a) 1,000, 100, 1

b) 250, 5, 1,

c) 1, 5, 250

d) 1, 100, 1,000

19. What is the approximate ratio of potential compounds the beginning of Development to number of products that ultimately get FDA approval?

a) 1:10

b) 1:100

c) 1:1,000

d) 1:10,000

20. On what does Phase 1 clinical testing test?

a) Animal subjects

b) Healthy human volunteers

c) Widespread differentiated population

d) **Large-scale tests in people with the target disease/population**

21. Which one of the following is NOT a physical property of drug substance being evaluated during preformulation studies?

a) Degradation profile

b) Solubility

c) Polymorphism

d) Crystalline or amorphous nature

22. What are NOT organoleptic properties of drugs?

a) Appearance

b) Colour

c) Odour

d) moisture content

23. Excipients are added to tablet dosage form to improve processability. An ideal excipient should have all these properties EXCEPT

a) Non-toxic

b) Physiologically active

c) Stable

d) Low cost

24. Which is the correct ICH guidelines for Stability studies?

a) ICH Q1

b) ICH Q3

c) ICH Q8

d) ICH Q10

25. Which is the correct stability study condition for refrigerated product?

a) 40±2°C and 75±5 % RH

b) 25±2°C and 60±5 % RH

c) 30±2°C and 85±5 % RH

d) 50±2°C and 75±5 % RH

26. Which is the correct stability zone for India?

a) Zone I

b) Zone II

c) Zone IVa

d) Zone IVb

27: Which one of the following is NOT true? Different polymorphs forms of a drug can have different:

a) Melting points

b) Molecular formulae

c) Solubilities

d) Crystal habits

28: Which one of the following is NOT true?

a) Drugs can be hydrophilic or hydrophobic

b) Hydrophobic drugs are easily wetted

c) Hydrophobic drugs have low solubility in water

d) Hydrophobic drugs dissolve slowly

29: Which one of the following is NOT true of crystalline solids?

a) They have long range order

b) They have short range order

c) They contain a random arrangement of constituents

d) They have sharp, well-defined melting points

30. Sieving method for determination of particle size uses a series of standard sieves calibrated by the……..

a) National Bureau of standards

b) IUPAC

c) ICH

d) EMEA

31. Which water is used for hand washing in change room of pharmaceutical manufacturing plant?

a) Potable water

b) Sterile water

c) Purified water

d) Soap water

32. Which of the following drying method is used in pharma industry for drying of soft gelatin capsule?

a) Vacuum drying

b) Truck drying

c) Fluid bed drying

d) Tumble drying

33. If all the processing equipment and machines are arranged according to the sequence of operations of a product the layout is known as

a) Product layout

b) Process layout

c) Fixed position layout

d) Combination layout

34. Which of the following investigations are performed during preformulation investigations of pharmaceuticals?

a) Solubility investigations

b) Melting point investigations

c) Stability investigations

d) Relative harmlessness investigations

35. Which of the following facility layout is best suited for the intermittent type of production, which is a method of manufacturing several different products using the same production line?

a) Product layout

b) Process layout

c) Fixed position layout

d) Cellular manufacturing layout

36. Which of the following is not a semisolid dosage form

a) Paste

b) Creams

c) Ointments

d) Suspensions

37. Class 10,000 is:

a) Particle count not to exceed a total of 10,000 particles per cubic foot of a size 5µ and larger

b) Particle count not to exceed a total of 10,000 particles per cubic foot of a size 0.5µ and smaller

c) Particle count not to exceed a total of 100,000 particles per cubic foot of a size 0.5µ and larger

d) Particle count not to exceed a total of 10,000 particles per cubic foot of a size 0.5µ and larger

38. The efficiency of HEPA filter is:

A) remove at least 99.97% of airborne particles 0.3 micrometers (µm) in diameter.

B) remove at least 100% of airborne particles 0.3 micrometers (µm) in diameter.

C) remove at least 99.97% of airborne particles 2 micrometers (µm) in diameter.

D) remove at least 97.99% of airborne particles 0.3 micrometers (µm) in diameter.

39. Which of the following is NOT the principle problem areas exists in plastic containers:

a) Leaching

b) Hardness

c) Permeation

d) Sorption

40. Powdered glass test challenges the leaching potential of:

a) Exterior structure of glass

b) Plastic containers

c) Interior structure of glass

d) Intact surface of glass

41. Process innovation refers to:

a) the development of a new service.

b) the development of a new product.

c) the implementation of a new or improved production method.

d) the development of new products or services.

42. Following establishment of a dominant design in the product life cycle, what would you expect to happen?

a) Emphasis on product innovation rather than process innovation.

b) Emphasis on process innovation rather than product innovation.

c) Competition to increase as new firms enter the industry.

d) Competition to decrease as more firms exit than enter the industry.

43. Which of the following is not a mode of international technology transfer?

a) joint ventures

b) licensing

c) patents

d) industrial espionage

44. Technological progress is a three-step process of

a) creation, pricing, and marketing

b) invention, innovation, and diffusion

c) manufacturing, venturing, and promotion

d) start-ups, imitation, and creative destruction

45. Guidelines for Technology Transfer and Pharmaceutical Quality Systems is

a) ICH Q1

b) ICH Q3

c) ICH Q8

d) ICH Q10

46. What potential advantages can be gained from involving overseas subsidiaries in R&D activities?

a) Local subsidiaries offer financial advantages such as lower land and labour costs.

b) Local subsidiaries offer access to local companies.

c) Local subsidiaries offer access to technical knowledge and skills.

d) Local subsidiaries offer financial advantages as well as access to local markets, technical knowledge and skills.

47. The fundamental challenge of knowledge transfer in multinational firms is:

a) transferring explicit knowledge across borders.

b) transferring tacit knowledge across borders.

c) creating tacit knowledge in overseas subsidiaries.

d) transferring tacit and explicit knowledge across borders.

48. Innovation can help to provide a temporary competitive advantage when:

a) barriers to entry are high.

b) barriers to imitation are low and intellectual property rights are difficult to enforce.

c) there are few other competitors.

d) barriers to entry are low.

49. Outsourcing of innovation globally is more likely where:

a) Innovations are autonomous

b) Innovations are systemic

c) Innovations are systemic or autonomous

d) Innovations are made by service sector firms

50. Established firms relative to new firms are better at:

a) all types of innovation.

b) innovation which is competence-enhancing.

c) innovation which is competence-destroying.

d) Innovation which is disruptive.