Quality Assurance F.Y. M.Ph
Sem - I 15/04/25

Time: 3 hrs **Marks: 75**

Q I Multiple Choice Questions **(20)**

1 Clinical studies of a new drug molecule is conducted in ----- phases.
- a 2
- b 3
- c 4
- d 6

2 Abbreviated New Drug Application is filed under which of the following section of Federal Drugs and Cosmetic Act?
- a 505 b1
- b 505 b2
- c 505 j
- d 505 a

3 X-ray diffraction technique is used to determine ------.
- a Melting point
- b Polymorphism
- c Water content
- d Assay

4 In case of generic drug application, following studies are conducted as part of product development except ------.
- a bioequivalence
- b dissolution
- c stability
- d Preclinical

5 In case of NDA the pharmaceutical company avails marketing exclusivity of _____ years.
- a 2
- b 3
- c 5
- d 4

6 Drugs having high solubility and high permeability are categorised in ---------- of BCS classification.
- a Class I
- b Class II
- c Class III
- d Class IV

7 Borosilicate glass is which type of glass?
- a Type I
- b Type II
- c Type III
- d Type IV

8 Which parameter is most crucial in evaluating the chemical stability of a drug during preformulation?
- a Particle size
- b Melting point
- c Degradation rate
- d pH of the solution

9 The pilot plant scale up activity is joint responsibility of -------- departments of pharmaceutical manufacturing industry.
- a Production and Research development
- b Q.A, Production, Q.C
- c R &D, Q.A, Production, Q.C and Engineering
- d R &D, Q.A, Q.C

10 An important process parameter during pilot plant scale up studies for aseptic filling and sealing operation of parenteral is -----
- a Laminar air flow speed
- b Area allocation
- c Type of glass used
- d Particulate count

11 Micronization of drug increases -----.
- a Dissolution rate
- b Density
- c Crystallinity
- d Porosity

12 BMR refers to ------.
- a Batch Marketing record
- b Batch Manufacturing record
- c Batch Manufacturing registration
- d Batch Marketing registration

13 Select suitable instrumental analytical technique for residual solvent analysis as part of preformulation studies of drug product development.
- a HPLC
- b UV spectroscopy
- c GC
- d DSC

14 Which one of the following test is performed for evaluation of closure?
- a Crushing Strength
- b Fragmentation Test
- c Heavy Metal Test
- d Hydrolytic Resistance Test

15 R &D, technology transfer, production, engineering, quality control and quality assurance departments of pharmaceutical industry are collectively involved in ------.
- a Technology transfer
- b Quality control
- c Pilot clinical study
- d Drug discovery

16 _____ is made up of 80% Silica, 10% Boric Oxide and small quantities of both Sodium Oxide and Aluminium Oxide
- a Type I Glass
- b Type II Glass
- c Type III Glass
- d Type IV Glass

17 Para III certification indicates that
- a No relevant patent is listed in the Orange Book.
- b The listed patent has expired
- c The listed patent, plus any other exclusivity, will expire before the requested approval
- d The listed patent is invalid or will not be infringed by the commercialization of the generic drug

18 Following document provides guidance on conducting stability study
- a ICH Q3A(R2)
- b ICH Q1B
- c ICH Q2B
- d ICH Q1A(R2)

19 Leakage test, Collapsibility test, Clarity of aqueous extract and Water vapor permeability test are carried out for
- a Plastic Container
- b Glass Container
- c Strip Packs
- d Aluminium Container

20 Which of the following documents are prepared as part of transfer of developed and validated analytical methods to the Quality control department?

a Method transfer protocol and method validation report

b Method transfer protocol and Instrument SOP

c Validation guidelines Method transfer and Validation protocol

d Instrument SOP, calibration and validation report

Q. II Attempt any two questions out of three **(20)**

I.	A.	Discuss the methodology of filing and approval process of NDA	5
	B.	Describe different approaches for solubility enhancement of poorly soluble drugs.	5
II.	A	Give an overview of preformulation studies conducted for the drug to be formulated as tablet.	5
	B	Discuss the significance of BACPAC	5
III	A	Discuss techniques for study of crystal properties and polymorphism.	5
	B	Write a note of significance of clinical trials in drug discovery	5

Q. III Attempt any seven questions out of nine **(35)**

I.	Discuss the objectives and functioning of CDSCO	5
II.	What is the significance of particle size, shape and surface area in preformulation study?	5
III	Write the activities involved in pilot plant scale up of tablet manufacturing by direct compression.	5
IV	Discuss typical layout followed in pharmaceutical manufacturing set-up and give advantages of any one of them.	5
V	Give an overview of documentation involved in technology transfer activity	5
VI	Elaborate on the role of SU and RU in technology transfer activity	5
VII	Discuss stability studies during product development.	5
VIII	Write a note on Scale up and Post Approval changes	5
IX	Write a note on medical devices packaging.	5

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