Sem-I. M. Pharm 2023 Quality Assurance

Paper / Subject Code: 90727 / Product Development and Technology Transfer (R-2019)

MQA104T

Time : 3 hours **Total Marks: 75 Marks**

N. B. : All questions are compulsory
Figures to the right indicate marks
Please check whether you have got the right question paper.

Q I Multiple Choice Questions (20)

1 In clinical studies for new chemical entity, safety assessment is done in
- a Phase II
- b Phase I
- c Phase III
- d Phase IV

2 Under following section of Federal Food Drug and Cosmetic Act, abbreviated new drug application is filed
- a 505 b1
- b 505 b2
- c 505 j
- d 505 a

3 Following techniques are used in characterisation of polymorphism except
- a HPLC
- b XRD
- c TGA
- d DSC

4 All the following studies are applicable for generic product development except
- a Bioequivalence study
- b Stability study
- c Dissolution study
- d Efficacy study

5 Change in source of diluent of similar specifications of an immediate release dosage form is referred to as SUPAC Level
- a 1
- b 2
- c 3
- d 4

6 Micronization of active pharmaceutical ingredient increases
- a density
- b bioavailability
- c porosity
- d amorphism

7 Which one of the following test is performed for evaluation of plastic containers
- a Fragmentation test
- b Collapsibility Test
- c Heavy metal test
- d Hydrolytic resistance test

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8 A deliquescent active pharmaceutical ingredient has tendency to
- a Liquefy at high temperature conditions
- b Liquefy at high humidity conditions
- c Liquefy when exposed to light
- d Liquefy when exposed to oxygen

9 In the GMP approved pharmaceutical company manufacturing operational area with number of particles of size 0.5 µm per cubic foot of air is 100 or less is called as
- a Grade C area
- b Grade D area
- c Grade A area
- d Grade B area

10 Following are the technology transfer documents except
- a Batch manufacturing record
- b Master formula card
- c Batch packaging Record
- d Bioequivalence study protocol

11 Following are the studies performed as part of Preformulation activity except
- a Bulk characterization study
- b Compatibility study
- c Drug Solution State study
- d Efficacy study

12 Brunauer Emmet Teller theory is used to estimate
- a Partition coefficient of active pharmaceutical ingredient
- b Dissociation constant of active pharmaceutical ingredient
- c Surface area of active pharmaceutical ingredient
- d Enthalpy of active pharmaceutical ingredient

13 Following are the important process parameters for validation of blending except
- a Mixing time
- b Mixing rpm
- c Blender load
- d Atomization Air

14 Elastomeric closures are evaluated for -
- a Water resistance test
- b Collapsibility test
- c Compressibility test
- d Fragmentation test

15 ICH Q3 A R2 provide guidelines for
- a Stability study
- b Analytical method development
- c Qualification of Impurities
- d Bioequivalence study

16 Hydrolytic resistance test is performed on
- a Plastic containers
- b Steel containers
- c Glass Containers
- d Aluminium Containers

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17 Full form of SUPAC is
- a Scale up pre agreement charges
- b Scale up pre approval changes
- c Scale up post approval charges
- d Scale up post approval changes

18 Post marketing surveillance is referred to as
- a Phase I trial
- b Phase II trial
- c Phase III trial
- d Phase IV trial

19 Which one of the following is most preferred method for terminal sterilization of a thermostable aqueous injectable solution ?
- a Dry heat sterilization
- b Membrane filtration
- c Radiation sterilization
- d Moist heat sterilization

20 IND is referred to as
- a Investigational New Drug
- b Investigational Novel Drug
- c Investigational Novel Dosage
- d Investigational New Dosage

(20)

Q. II Attempt any two questions out of three

1 A. Discuss under what circumstances SUPAC is applicable with respect to immediate release dosage forms. 5

B. Write a note on Preformulation studies conducted for the drug to be formulated as oral solid dosage form. 5

2. A Discuss various approaches for improvement of bioavailability of poorly soluble drug. 5

B Give an overview of NDA for drug development. 5

3 A Write a note on bulk characterization study and its importance 5

B Highlight the significance of Bulk Active Post approval changes 5

(35)

Q. II Attempt any seven questions out of nine

1. What is the objective of IND submission? What are its contents? 5
2. Give significance of particle size, shape and surface area in preformulation study. 5
3. Summarize the pilot plant scale-up considerations for an film coated tablet prepared by wet granulation 5
4. Discuss typical layouts followed in pharmaceutical manufacturing set-up and give advantages of any one of them. 5
5. Describe the pilot plant scale up activities of liquid oral Draw a pilot plant layout of liquid oral manufacturing unit 5
6. Enlist the issues facing in modern drug packaging and give approaches to control counterfeiting of drug 5
7. Summarize stability testing of capsules to be performed as per ICH guidelines. 5
8. Explain the different phases of a clinical study. 5
9. Write a note on elastomeric closures and its evaluation tests 5

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