MQA104T

Time: 3 Hrs **Marks: 75**

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 case of clinical study for new drug discovery efficacy study is conducted all these phases except
- a Phase II
- b Phase I
- c Phase III
- d Phase IV

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

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

4 Following studies are conducted as part of generic product development except
- a Bioavailability study
- b Stability study
- c Dissolution study
- d Preclinical study

5 SUPAC guidelines are applicable for following types of dosage forms except
- a Immediate release dosage forms
- b Modified release dosage forms
- c Non sterile semisolid dosage forms
- d Sterile dosage forms

6 Drug excipient compatibility study can be evaluated by following tests except
- a FTIR
- b HPLC
- c Zeta potential
- d XRD

7 Which one of the following test is performed for evaluation of glass containers-
- a Crushing strength
- b Fragmentation test
- c Heavy metal test
- d Hydrolytic resistance test

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8 ---------- drug must be stored in dry place because it readily absorbs water from its surroundings.
a Hydrated
b Crystalline
c Water insoluble
d Deliquescent

9 In case of Fluidized Bed Dryer following is an important process parameter.
a Hot air volume
b Nozzle position
c Humidity of the incoming air
d Filter Porosity

10 The objective of pilot plant and scale up study is to
a To identify critical process parameters of manufacturing
b To identify preformulation parameters
c To conduct stability study
d To test finished pharmaceutical product

11 Following study is performed as part of preformulation study
a Process analytical technology
b Drug excipient compatibility study
c Analytical method validation
d Batch manufacturing

12 Following document is transferred from analytical development lab to quality control lab of plant:
a Quality manual
b Instrument calibration report
c Master validation plan
d Method transfer protocol

13 Particle size reduction results in increase in
a Dissolution rate
b Porosity
c Density
d Crystallinity

14 Following test is performed on plastic containers
a water resistance
b collapsibility test
c compressibility
d folding endurance

15 Process performance qualification batches are part of ---------- activity.
a Optimisation
b Preformulation
c Pre technology transfer
d Process analytical technology

16 Borosilicate class is called as
a Type I glass
b Type II glass
c Type III glass
d Type IV glass

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17 The change in site of manufacturing from one building to adjacent building in same premises is considered as

a 1
b 2
c 3
d 4

18 On successful completion of preclinical study following application is filed

a IND
b NDA
c ANDA
d PAT

19 Which one of the following is most preferred method for sterilization of non-aqueous oily injectable solution?

a Dry heat sterilization
b Membrane filtration
c Radiation sterilization
d Moist heat sterilization

20 Following activity involves transferring knowledge, skill and method of manufacturing from formulation development lab to the production scale.

a Pilot plant scale up
b SUPAC
c Technology transfer
d QbD

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

I. A. Discuss in brief SUPAC with respect to different types of changes. 5
B. Write a note of evaluation techniques used to assess crystal behaviour of drug during preformulation study 5

II. A Write a note on various approaches to enhance solubility of BCS Class II drug 5
B Give an overview of generic drug development. 5

III A Discuss the role of stability testing during product development 5
B Mention in brief about BACPAC 5

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

I. Discuss the objective and contents of NDA 5
II. Write a note on importance of particle size, shape and surface area in preformulation study 5
III Discuss the pilot plant study of capsule dosage form 5
IV Discuss typical layout and equipments used in manufacturing of parenteral dosage form 5
V Write a note on documentation involved in technology transfer in pharmaceuticals. 5
VI Write a note on container closure systems used for liquid oral dosage forms 5
VII Discuss stability testing protocol of tablets as per ICH guidelines 5
VIII Discuss different phases of clinical trials 5
IX Write a note on quality control of primary packaging material 5

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