Duration: 3 Hours **Total marks: 75**

N.B.: 1. All questions are compulsory
2. Figures to right indicate full marks.

Q.I Multiple Choice Questions (Answer all) 20

1 The art of designing prototype using data obtained from pilot plant model is

a) Scaling

b) Act work

c) Scale up

d) Model design

2 Over lubrication of granules may result in

a) Faster dissolution

b) Faster Disintegration

c) Delay in disintegration

d) No effect on disintegration

3 According to SUPAC guidelines, Level 2 changes are those

a) Which have significant impact on formulation quality and performance

b) Which have no significant impact on formulation quality and performance

c) Which are unlikely to have any detectable impact on formulation

d) Which are unlikely to have any detectable impact on performance

4 Bloom strength determines the strength of

a) Tablet

b) Capsule

c) Pellets

d) Granules

5 Out of following functions of compression process, which one is optional

a) Filling of empty die cavity

b) Pre compression

c) Compression

d) Ejection of tablet

6 Technology transfer is brought about by

a) Quality Assurance department to manufacturing unit

b) Quality control department to manufacturing unit

c) Research and development department to manufacturing unit

d) Quality Assurance department to research and development department

7 BCIL facilitates

a) Batch technology transfer

b) Biological technology transfer

c) Biotechnology transfer

d) Bioenzyme technology transfer

8 ICH Q9 guidelines describe about

a) Technology transfer

b) Risk management

c) Stability study

d) Analytical method validation

9 Following is the regulatory agency of UK

a) CDSCO

b) FDA

c) MHRA

d) MHLW

10 Module 4 of NDA dossier as per CTD format includes

a) Clinical study reports

b) Quality overall summary

c) Preclinical study reports

d) Administrative information

11 The objective of Phase II clinical trial study is

a) To assess safety of drug

b) To assess efficacy of drug

c) To assess bioavailability of drug

d) To assess safety and efficacy of drug

12 In Clinical Research CRF implies

a) Compliance report form

b) Case report form

c) Constitution report form

d) Casualty report form

13 Following is the major part of toxicology study

a) Determination of bioavailability of drug

b) Determination of bioequivalence of drug

c) Determination of therapeutic index of drug

d) Determination of metabolism of drug

14 Following test is performed to indicate genotoxicity

a) Draize test

b) Ames test

c) LAL test

d) Endotoxin test

15 Variation within a batch belongs to which source of Quality variation

a) Methods

b) Machines

c) Materials

d) Personnel

16 ISO stands for

a) International Organization for Standardization

b) International Society Organization

c) International Organization Schedules

d) International Organization of Standards

17 The benefit of GLP is

a) More time spent on re-work

b) Reduces overall productivity

c) Decreases reliability

d) Increases right first time results

18 DTAB stands for

a) Department of Technology Advisory Body

b) Drug Technology Analysis Board

c) Drug Technical Advisory Board

d) Department of Technical Analysis Board

19 Which of the following is a function of CDSCO

a) Reduce waste

b) Import registration and licensing

c) Control process

d) Review of improvement

20 Which of the following provides guidelines and requirements for Clinical trials

a) Schedule X

b) Schedule M

c) Schedule H

d) Schedule Y

QII Answer the following (any Two) **20**

1 Discuss Pilot plant scaleup consideration for Liquid oral dosage form**.** **10**

2 Describe the various specifications of starting input materials in technology transfer. **10**

3 Differentiate between IND and NDA. Describe in details contents and stages involved in NDA application **10**

QIII Answer the following (any Seven) **35**

1 Discuss briefly SUPAC guidelines for IR formulation with respect to change of components & composition. **5**

2 Mention in brief the role and responsibilities of Receiving unit in technology transfer **5**

3 Write a note on technology transfer plan and report **5**

4 Write a note on bioequivalence studies **5**

5 What is QbD and discuss the key elements of QbD **5**

6 Explain the significance of Quality Management systems and write a note on TQM **5**

7 What is Six Sigma, give its key features and discuss any one methodology of six sigma **5**

8 Elaborate on the Indian approval procedure for New Drugs **5**

9 Discuss in detail the Common Technical Document **5**
