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

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

Question No.	Question	Max. Marks
Q.I	Multiple Choice Questions (Answer all)	**20**
1	Pilot plant model is used for	**1**
a)	Scaling	
b)	Act work	
c)	Scale up	
d)	Model design	
2	Parameter to be used in scale up of fluid bed processor is	**1**
a)	Mixing speed	
b)	Mixing time	
c)	Air flow rate	
d)	Speed of turrets	
3	Level 2 changes for change of site as per SUPAC guidelines is	**1**
a)	changes consist of site changes within a single facility	
b)	changes consist of site changes within a contiguous campus, or between facilities	
c)	changes consist of a change in manufacturing site to a different campu	
d)	changes consist of a change in manufacturing site to a different country	

4	An example of Process Scale up is	**1**
a)	Identification of critical component and excipient	
b)	Selection of equipment	
c)	Collection of product	
d)	Mixing Speed	
5	Sequence of steps during tablet compression is	**1**
a)	Filling, Pre compression, compression, Ejection	
b)	Pre compression, Filling, compression	
c)	Filling, Pre compression, Ejection	
d)	Pre compression, Filling, compression, Ejection	
6	Horizontal technology transfer takes place between	**1**
a)	Quality Assurance department to manufacturing unit	
b)	One Manufacturing unit to another manufacturing unit	
c)	Research and development department to manufacturing unit	
d)	Quality Assurance department to research and development department	
7	Full form of BCIL	**1**
a)	Batch Consortium India Limited	
b)	Biotech Consortium India Limited	
c)	Biologic Consortium India Limited	
d)	Bioenzyme Consortium India Limited	

8	ICH Q 10 guidelines describe about	**1**
a)	Technology transfer	
b)	Risk management	
c)	Stability study	
d)	Pharmaceutical Quality system	
9	Following is the regulatory agency of Japan	**1**
a)	CDSCO	
b)	FDA	
c)	MHRA	
d)	MHLW	
10	Module 5 of NDA dossier as per CTD format includes	**1**
a)	Clinical study reports	
b)	Quality overall summary	
c)	Preclinical study reports	
d)	Administrative information	
11	The objective of Bioequivalence study is	**1**
a)	To assess safety of drug	
b)	To assess efficacy of drug	
c)	To compare bioavailability of generic product with innovator product	
d)	To assess safety and efficacy of drug	

12	In Clinical Research ICF implies	**1**
a)	Informed Compliance form	
b)	Informed Consent form	
c)	Institute Compliance form	
d)	Institute Consent form	
13	Toxicology study is performed to determine	**1**
a)	bioavailability of drug	
b)	bioequivalence of drug	
c)	lethal dose of drug	
d)	metabolism of drug	
14	Genotoxicity is evaluated by following test	**1**
a)	Draize test	
b)	Ames test	
c)	LAL test	
d)	Endotoxin test	
15	Change control is affected by all the following reasons EXCEPT	**1**
a)	Management	
b)	Quality assurance	
c)	GMP requirement	
d)	Regulatory requirement	

16	_____ is defined as the systematic approach to development that begins with predetermined objectives and is based on quality risk management	**1**
a)	ISO Certification	
b)	Total Quality Management	
c)	Quality by Design	
d)	Six Sigma approach	
17	Which of the following is a Category of Change	**1**
a)	Temporary	
b)	Critical	
c)	Permanent	
d)	Neutral	
18	CDSCO stands for	**1**
a)	Central Data Standardization Control Organization	
b)	Central Drugs Standard Control Organization	
c)	Central Department Standards Control Organization	
d)	Central Drugs Standardization Check Organization	
19	Which of the following has prepared the COPP format	**1**
a)	CDSCO	
b)	ICH	
c)	US FDA	
d)	WHO	

20	Who is the head of CDSCO	**1**
a)	Health Minister	
b)	DCGI	
c)	Secretary of Health Ministry	
d)	Drug Inspector	
QII	Answer the following (any two)	**20**
1	Define pilot plant scale up. What are the objectives of pilot plant scale up? Explain the scale up of semisolid formulation.	
2	Describe the granularity of technology transfer with respect to active pharmaceutical ingredient, excipients and packaging materials.	
3	Differentiate between IND and NDA. Describe in details contents and approval process of IND	
QIII	Answer the following (any seven)	**35**
1	What is Platform Technology? Explain different Platform technologies.	**5**
2	Define Receiving unit and activities conducted by receiving unit in technology transfer	**5**
3	Describe the contents technology transfer plan and report	**5**
4	Write a note on clinical research protocol	**5**
5	Discuss the "Six Sigma Approach" as a QMS tool	**5**
6	Enlist the various Quality Management Systems and explain TQM in detail	**5**
7	Write a note on benefits, scope and procedure of NABL accreditation	**5**
8	Discuss the Indian regulatory requirements for New Drug Approval	**5**
9	Elaborate in brief on the various modules of the Common Technical Document	**5**

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