Duration: 3 Hours

Total marks: 75

N.B.: 1. All questions are compulsory

2. Figures to right indicate full marks.

Questi on No.	Question Max. Marks Multiple Choice Questions (Answer all) Pilot plant model is used for Scaling Act work Scale up Model design
Q.I	Multiple Choice Questions (Answer all)
1	Multiple Choice Questions (Answer all) Pilot plant model is used for
a)	Scaling Act work Scale up Charles And Act
b)	Act work
c)	Multiple Choice Questions (Answer all) Pilot plant model is used for Scaling Act work Scale up Model design Parameter to be used in scale up of fluid bed processor is 1
d)	Model design
2	Parameter to be used in scale up of fluid bed processor is
a) (Mixing speed
b)	Mixing time
c)	Mixing speed Mixing time Air flow rate Speed of turrets
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) $\sqrt{5}$	changes consist of a change in manufacturing site to a different country

36939

4	An example of Process Scale up is
a)	Identification of critical component and excipient Selection of equipment Collection of product
b)	Selection of equipment
c)	Collection of product
d)	Mixing Speed 4
5	Sequence of steps during tablet compression is
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
	Research and development department to manufacturing unit
(b) d)	Quality Assurance department to research and development department
AT O	
7,5	Full form of BCII
7 (a)	Full form of BCIL Batch Consortium India Limited
7 (a) b)	Biotech Consortium India Limited Biotech Consortium India Limited
(a) b)	Biologic Consortium India Limited Biologic Consortium India Limited
(a) (b) (c) (d)	Biologic Consortium India Limited Bioenzyme Consortium India Limited Bioenzyme Consortium India Limited
b) c) d)	Biotech Consortium India Limited Biologic Consortium India Limited Bioenzyme Consortium India Limited
7 (a) b) c) d) 36939	Quality Assurance department to research and development department Full form of BCIL Batch Consortium India Limited Biotech Consortium India Limited Bioenzyme Consortium India Limited Bioenzyme Consortium India Limited Page 2 of 6 X1132Y5AA7F4X1132Y5AA7F4X1132Y5AA7F4X1132Y5AA7F4

8	ICH Q 10 guidelines describe about
a)	Technology transfer Risk management Stability study Pharmaceutical Quality system Following is the regulatory agency of Japan CDSCO FDA MHRA MHLW Module 5 of NDA dossier as per CTD format includes 1
b)	Risk management
c)	Stability study
d)	Pharmaceutical Quality system
9	Following is the regulatory agency of Japan CDSCO FDA MHRA MHLW Module 5 of NDA dossier as per CTD format includes Clinical study reports Quality overall summary Preclinical study reports Administrative information The objective of Bioequivalence study is To assess safety of drug To assess efficacy of drug To compare bioavailability of generic product with innovator product To assess safety and efficacy of drug
a)	CDSCO
b)	FDA
c)	MHRA 4 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
d) 45	MHLW THAT A STATE THAT A STATE OF THE STATE
d), 4	Total Total Total Total Total Total
10 a) b)	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
a) b) c) d)	The objective of Bioequivalence study is
a)	To assess safety of drug
b)	To assess efficacy of drug
(c)	To compare bioavailability of generic product with innovator product
d) 0	To assess safety and efficacy of drug
137 SANTER TERM	15
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	X1132Y5AA7F4X1132Y5AA7F4X1132Y5AA7F4

		Paper / Subject Code: 69322 / Industrial Pharmacy II In Clinical Research ICF implies Informed Compliance form Institute Compliance form Institute Consent form Toxicology study is performed to determine bioavailability of drug bioequivalence of drug lethal dose of drug Genotoxicity is evaluated by following test I
		In Clinical Research ICF implies Informed Compliance form Institute Compliance form Institute Consent form Institute Consent form Toxicology study is performed to determine bioavailability of drug bioequivalence of drug lethal dose of drug metabolism of drug Genotoxicity is evaluated by following test Draize test Ames test LAL test Endotoxin test Change control is affected by all the following reasons EXCEPT 1
		Star Alice Alice
		And State And State Alice
	12	In Clinical Research ICF implies
	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
1132 SARIES	d)	metabolism of drug
15 P.P.	14	Genotoxicity is evaluated by following test Draize test Ames test LAL test Endotoxin test Change control is affected by all the following reasons EXCEPT 1 Management Quality assurance
132	a)	Draize test Ames test LAL test Endotoxin test
A ST	b)	Ames test
A STATE OF THE STA	c)	LAL test
15 AT	d)	Endotoxin test
	15	Change control is affected by all the following reasons EXCEPT 1
25	a)	Management
EAT C	b)	Quality assurance
TEAT LEATING	c) §	GMP requirement
	d)	Regulatory requirement
ST.		CATT STATE CATT
727		Cathy Str. And Cathy
	3777	Quality assurance GMP requirement Regulatory requirement Page 4 of 6
ATENTIAL STEELS	86939	Change control is affected by all the following reasons EXCEPT Management Quality assurance GMP requirement Regulatory requirement Page 4 of 6 X1132Y5AA7F4X1132Y5AA7F4X1132Y5AA7F4X1132Y5AA7F4
477	M.	X1132Y5AA7F4X1132Y5AA7F4X1132Y5AA7F4

16	is defined as the systematic approach to development that leading with productorminal objectives and is based on availty risk
	begins with predetermined objectives and is based on quality risk
	management
a)	ISO Certification
b)	Total Quality Management
c)	Total Quality Management Quality by Design Six Sigma approach
d)	Six Sigma approach
17	Which of the following is a Category of Change
a)	Temporary
b)	Critical 4
c)	Permanent
d)	Neutral A A A A A A A A A A A A A A A A A A A
18	CDSCO stands for
a) (**)	Central Data Standardization Control Organization
b)	Central Drugs Standard Control Organization
c)	Central Department Standards Control Organization
d)	Central Drugs Standardization Check Organization
×L	The State of the S
19	Which of the following has prepared the COPP format 1
a) >	CDSCO
b)	ICH A THE STATE OF
c)	Central Drugs Standardization Check Organization Which of the following has prepared the COPP format CDSCO ICH US FDA WHO
d)	WHO

86939 Page 5 of 6

20	Who is the head of CDSCO	1
a)	Health Minister	
b)	Health Minister DCGI	
c)	Secretary of Health Ministry	XX)
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.	15
2	Describe the granularity of technology transfer with respect to active pharmaceutical ingredient, excipients and packaging materials.	4
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
3,5	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

6939 Page 6 of 6