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	**Which of the following is not scale up process**	**1**
a)	Laboratory to pilot scale	
b)	Pilot to industrial scale	
c)	Industry to pilot scale	
d)	Laboratory to industrial scale	
2	**Rapid mixer granulators are used in**	**1**
a)	Wet granulation	
b)	Dry granulation	
c)	Compression granulation	
d)	Direct compression	
3	**Changes in the technical grade of excipients, comes under _____as per SUPAC guidelines**	**1**
a)	Level 1	
b)	Level 2	
c)	Level 3	
d)	Level 4	

4	**A group of Technologies that are used as base upon which other technologies or processes are developed is**	**1**
a)	PAT Technology	
b)	QBD Technology	
c)	Platform Technology	
d)	Platinum Technology	
5	**Slugging is used for**	**1**
a)	Ingredients which can be directly compresses	
b)	Ingredients which cannot be directly compressed	
c)	Ingredients which are stable to heat and moisture	
d)	Ingredients with excellent flow property	
6	**Technology transfer guidelines issued by**	**1**
a)	MHRA	
b)	WHO	
c)	FDA	
d)	CSCO	
7	**BMR stands for**	**1**
a)	Batch Manufacturing Record	
b)	Batch Marketing Record	
c)	Batch Marketing Report	
d)	Batch Manufacturing Report	
8	**Following ICH guideline mentions about product development**	**1**
a)	Q4	
b)	Q8	
c)	Q9	
d)	Q10	

9	**NRDC implies**	**1**
a)	National Revenue Development Council	
b)	National Research Development Council	
c)	National Research Design Council	
d)	National Revenue Design Council	
10	**Module 3 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 Phase III clinical trial study is**	**1**
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	**Safety Pharmacology studies are part of**	**1**
a)	Clinical study	
b)	Preclinical study	
c)	Bioequivalence study	
d)	Bioavailability study	
13	**In Clinical Research CRF implies**	**1**
a)	Clinical Report Form	
b)	Case Report form	
c)	Compliance report form	
d)	Candidate report form	
14	**Institutional Ethics Committee approves**	**1**
a)	Protocol involving study on animals	
b)	Protocol involving study on cell lines	
c)	Protocol involving study on humans	
d)	Protocol involving study on pathogens	
15	**In QbD the term CQA stands for**	**1**
a)	Critical Quantitative Attainment	
b)	Cumulative Quality Attributes	
c)	Critical Quality Attributes	
d)	Cumulative Quantitative Attributes	

16 **Which of the following parameters relates to the "Six sigma approach"** **1**

a) Errors

b) Cost

c) Safety

d) Defects

17 **_____ is a series of certification for international environmental management standards** **1**

a) ISO 9000

b) ISO 14000

c) ISO 27000

d) ISO 13000

18 **In CTD which of the following Modules is region specific** **1**

a) Module 1

b) Module 2

c) Module 3

d) Module 4

19 **DCGI stands for** **1**

a) Deputy Commissioner General of India

b) Drug Controller General of India

c) Drug Commissioner General of India

d) Deputy Controller General of India

20	**Which one of the following is the first document of submissions made in approval of a new drug**	**1**
a)	Post marketing surveillance data	
b)	Bioequivalence studies	
c)	Chemistry, manufacturing and controls	
d)	Onsite visit of facility	
QII	**Answer the following (any two)**	**20**
1	Give the detailed account of Pilot plant scale up of Tablet.	10
2	Describe in details the goals and phases of technology transfer	10
3	Differentiate between NDA and ANDA. Describe in details contents of ANDA	10
QIII	**Answer the following (any seven)**	**35**
1	Explain the SUPAC guidelines for the change of manufacture site for immediate release products.	5
2	Mention in brief the role and responsibilities of Sending unit in technology transfer	5
3	Enlist different technology transfer agencies in India and describe objectives and functions of any one agency	5
4	Describe in brief the scope and contents of Investigator's brochure	5
5	Elaborate on the elements of QbD as a part of QMS	5
6	Explain the objective and principles of GLP	5
7	Define OOS and explain methods to handle or investigate an OOS	5
8	What is CDSCO and explain in brief its organization and responsibilities.	5
9	Discuss the importance of Certificate of Pharmaceutical Product	5

X----------X----------X