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 20

1. Scale up consideration for dry blending process include- 1
a) Compression speed
b) Drying time
c) Drying temperature
d) Mixing time

2.. Platform Technology refers to 1
a) Scale up processes
b) Quality management tool
c) Base technology for advanced research
d) Validation techniques

3. Changes in batch size beyond a factor of ten times the size are considered as _____ change 1
a) Level I
b) Level II
c) Level III
d) Level IV

4. Following functions are carried out by pilot plant team- 1
a) Master formula, validation, vendor selection
b) Master formula, staff recruitment, validation
c) Staff recruitment, market survey, validation
d) Validation, vendor selection, market survey

5. SUPAC guidelines are applicable for- 1
a) Post marketing changes
b) Pilot plant scale up
c) Batch validation
d) Stability studies

6. VMP is _____ 1
a) Validation Mixing Plan
b) Validation Master Plan
c) Valuation Mixing Plan
d) Validation Measure Procedure

7. Example of vertical Tech Transfer is- 1
a) One Manufacturing unit to other unit in same country
b) R & D to Manufacturing
c) One Manufacturing unit to other in another country
d) Public sector to Private sector

8. Preparation of Master Formula Card is done in — phase of Tech Transfer 1
a) Planning phase
b) Research Phase
c) Development phase
d) Production phase

9. **Acceptance criteria for process validation are given by-** 1
a) Master Formula Card
b) Batch Manufacturing Record
c) Validation Master Plan
d) Receiving Unit

10. **CFR stands for** 1
a) Code of Federal Regulations
b) Center of Federal Regulations
c) Code of Federal Register
d) Center of Federal Regulator

11. **Investigational New drug application form is to provide data showing results of** 1
a) Clinical studies
b) Preclinical studies
c) Post clinical studies
d) None

12. **How many types of IND application form are available** 1
a) 5
b) 4
c) 3
d) 2

13. **Animal Drug metabolism studies are part of** 1
a) Preclinical study
b) Clinical study
c) Bioavailability study
d) Bioequivalence study

14. **21CFR part 312 used for** 1
a) Investigational New Drug Application
b) Orphan drug
c) Institutional Review Board
d) Drug Labelling

15. **'Drying temperature' can be considered as _____ while applying QbD** 1
a) Critical Quality Attribute
b) Critical Material Attribute
c) Critical Process Parameter
d) Critical Reference Attribute

16. **Identify the body responsible for accreditation of testing laboratories** 1
a) WHO
b) CDSCO
c) COPP
d) NABL

17. **_____ is used in the pharmaceutical industry to modify any process.** 1
a) Change Control
b) Six Sigma
c) Total Quality management
d) NABL accreditation

18.	**Under Drug and Cosmetic Act CDSCO is responsible for all EXCEPT,**	1
a)	Approval of drug	
b)	Conduct of Clinical Trial	
c)	Laying down the standards for drug	
d)	Content and reliability of linked website	
19.	**According to ICH M4 which format is used to assemble all the Quality, safety, efficacy information**	1
a)	Common Technical document	
b)	Drug Master File	
c)	Validation master Plan	
d)	Batch Manufacturing Record	
20.	**Full form of MAA**	1
a)	Marketing Authority Appliance	
b)	Marketing Authorization Application	
c)	Marketing Autonomous Application	
d)	Marketing Autonomous Authorization	

QII	**Answer the following (any two)**	20
1.	Enlist the areas covered by SUPAC guidelines. What are the different levels defined by them? Explain the levels with respect to any one change.	10
2.	What are the objectives of Technology Transfer? Explain the three phases of Tech Transfer in detail.	10
3.	Classify IND and Elaborate on general information regarding Investigational New Drug Application	10

QIII	**Answer the following (any seven)**	35
1.	Write in brief the objective & personnel requirement of the Pilot Plant.	5
2.	Elaborate on the information related to Process and Finished Product to be transferred by Sending Unit during Tech Transfer.	5
3.	State the role of TOT agencies in commercialization of products. State functions of any one agency.	5
4.	Write the role and responsibility of the Regulatory affairs department.	5
5.	State the objectives and key elements of Total Quality management	5
6.	Define OOS with a suitable example and discuss how to handle an OOS .	5
7.	Explain the term Quality and Discuss the key elements of ISO 9000 series.	5
8.	Define the role and responsibilities of CDSCO.	5
9.	Draw and discuss in brief the CTD Triangle	5