Semester Exam 7/12/2024
Final year B. Pharm Sem - VII

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**