

PHARMACEUTICS 11/04/25
Sem - I

Duration: 3 Hours

Total marks: 75

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

Question No.	Question	Max. Marks
Q.I	Multiple Choice Questions (Answer all)	20
1.	Lipophilicity of an organic compound is expressed in terms of _____.	1
a)	partition coefficient	
b)	pKa	
c)	solubility	
d)	crystallinity	
2.	Hixon and Crowell modified the Noyes-Whitney equation to take into account the changing _____.	1
a)	surface area	
b)	density	
c)	dissolution	
d)	porosity	
3.	ICH guideline for photostability testing of new drug substances and product is _____.	1
a)	Q1A	
b)	Q1B	
c)	Q1C	
d)	Q1D	
4.	Which one of the following strategies would not normally be expected to reduce the rate of oxidation of an API?	1
a)	Replacing air in package with nitrogen	
b)	Addition of heavy metal to the formulation	
c)	Protecting formulation from light	
d)	Reducing the temperature of the formulation	
5.	During experimental design, _____ variable is defined as _____.	1
a)	Treatment	
b)	Factor	
c)	Variance	
d)	Level	
6.	The following parameter is referred to as dependent variable in an optimization technique _____.	1
a)	type of polymer	
b)	content uniformity	
c)	rpm of blender	
d)	binder concentration	

7. Response Surface model includes following, except: **1**
- Models are Polynomial
 - Includes Term for Interaction & Curvature
 - Insignificant Terms are not discarded
 - Coefficient are established by regression analysis
8. Design qualification gives functional and _____ specifications of the **1**
instrument or equipment.
- operational
 - approximate
 - essential
 - trial
9. Checking any damage to the equipment is _____ qualification. **1**
- design
 - operational
 - installation
 - performance
10. To carry out operations for different samples and to check performance of **1**
the equipment is _____
- Performance qualification
 - Design qualification
 - Operational qualification
 - Installation qualification
11. The ABC concept of inventory control was outlined by _____ **1**
- V Pareto
 - Dr. Orlicky
 - Ford W.Harris
 - Herman Hollerith
12. Perpetual inventory system includes **1**
- Bin cards
 - Group essential items
 - Forecast sales
 - EOQ
13. The EOQ formula assumes gradual inventory depletion hence the lot size **1**
inventory is equal to:
- double the order quantity
 - quarter of the order quantity
 - half the order quantity
 - thrice the order quantity
14. Porosity is also known as _____ **1**
- Bulk volume
 - True volume
 - Filled volume
 - Void volume

15. Radial die -wall forces arise as a result of tablet mass attempting to expand in _____ **1**
- horizontal plane due to vertical compression force
 - vertical plane due to vertical compression force
 - horizontal plane due to horizontal compression force
 - vertical plane due to horizontal compression force
16. Lactose is an example of Type _____ material based on Heckel equation **1**
- A
 - B
 - C
 - First Order
17. According to Higuchi model, drug release from porous matrix is directly related to _____ **1**
- time
 - square root of time
 - cube root of time
 - log time
18. For f2 analysis the number of units each of test and reference products required are _____ **1**
- Twelve
 - Six
 - ten
 - Eight
19. Distance between inside bottom of the vessel and basket in case of USP type I (Basket apparatus) **1**
- is maintained at 25 mm ± 2mm during the test
 - is maintained at 15 mm ± 2mm during the test
 - is maintained at 25 mm ± 5mm during the test
 - is maintained at 15 mm ± 5mm during the test
20. The drug is considered highly permeable when the extent of drug absorption in humans is _____ or more of an administered dose based on a mass balance determination or in comparison to an intravenous reference dose. **1**
- 65%
 - 75%
 - 90%
 - 70%

QII Answer any Two **20**

- 1a. Discuss study of crystallinity and polymorphism as a part of preformulation study. **5**
- 1b. Explain the Following Terms: Factors, Levels & Interaction. **5**

- 2a. Explain the concept of Economic Order Quantity (EOQ). 5
 - 2b. Elaborate on cGMP requirements for services, equipment and maintenance. 5
 - 3a. Explain the correlation between compression force & properties of the tablet influenced due to compression. 5
 - 3b. Explain the bonding mechanism during compression of the tablet. 5
- QIII Answer any Seven 35**
- 1. Discuss the ICH guidelines for stability testing of a finished pharmaceutical product. 5
 - 2. Explain with suitable example 3² factorial design. 5
 - 3. Explain the validation protocol for performance qualification for Small Volume Parenteral 5
 - 4. Write a short note on the concept of Total Quality Management. 5
 - 5. Give salient features of the ABC method of inventory control. 5
 - 6. Write the difference between the following during compression: Fragmentation & Deformation 5
 - 7. Give the graphical description of the compression process. 5
 - 8. Comment on selection of dissolution media based on physicochemical properties of drug and dosage form. 5
 - 9. What is IVIVC? Describe the four levels of IVIVC. 5
