F.Y. M.Pharm
Sem - II
23/08/2025

TIME: 3HRS **MAX MARKS: 75**

Q. 1 Attempt all multiple-choice questions (MCQ) **20M**

Sr. No	Questions		Options
1	Which of these is a key element in streamlining qualification and validation processes?	a	Avoiding documentation to save time
		b	Integrating qualification phases and harmonizing protocols and templates
		c	Using separate teams for each validation phase without coordination
		d	Repeating all tests for every batch indiscriminately
2	Which type of water is required for parenteral drug manufacturing?	a	Water for Injection (WFI)
		b	Highly Purified Water
		c	Purified Water
		d	Drinking Water
3	During Performance Qualification (PQ), which of the following is assessed?	a	Equipment functioning under actual operating conditions
		b	Correct installation of equipment components
		c	Verification of design parameters before purchase
		d	Documentation of user requirements
4	Which type of validation involves testing during the actual routine production of saleable product?	a	Prospective validation
		b	Concurrent validation
		c	Retrospective validation
		d	Analytical validation
5	In dry heat sterilization tunnel qualification, which of the following is a critical parameter?	a	Temperature and duration of exposure
		b	pH measurement
		c	Photometric accuracy
		d	Detector sensitivity
6	In India, the time limit to file a complete specification after a provisional patent application is:	a	6 months
		b	12 months
		c	18 months
		d	36 months
7	Following are typically verified during the Operational Qualification (OQ) of an LC-MS system except_____.	a	Mass accuracy, , and
		b	resolution
		c	detection sensitivity
		d	Instrument dimensions

8	The primary purpose of the HVAC system in pharmaceutical manufacturing is to	a	Increase humidity
		b	Provide lighting
		c	Control contamination and environmental conditions
		d	Reduce costs
9	Which section would describe the timeline of validation activities in the VMP?	a	Validation strategy
		b	Validation scope
		c	Validation schedule
		d	Change control procedure
10	Which of these is an objective of the SAT?	a	Confirm that the equipment is installed properly and operates as intended in the actual site environment
		b	Adjust the instrument calibration standards at the vendor site
		c	Estimate the production batch siz
		d	Verify supplier's manufacturing process
11	Tablet compression machine qualification includes all of the following parameters except:	a	Tablet weight uniformity
		b	Compression force and hardness
		c	Drying efficiency
		d	Tablet thickness
12	Which of the following cities hosts the head office of the Indian Patent Office?	a	Delhi
		b	Chennai
		c	Bengaluru
		d	Kolkata
13	Following activities are typically part of preventive maintenance except	a	Cleaning and lubrication of mechanical parts
		b	Calibration of instruments
		c	Conducting factory acceptance (FAT)
		d	Replacement of worn compone before failure
14	Which of the following is typically checked during FAT?	a	Equipment installation and calibration at the production si
		b	Functional tests, and complian against user specifications at t supplier's site
		c	Batch release testing
		d	Finished product quality cont

5	Following cell lines are used to determine the permeability of drugs	1
	SiHa	
b)	Hela	
c)	Caco2	
d)	HaSi	
16	For statistical significance in bioequivalence studies, probability must be	1
a)	more than 0.05	
b)	more than 0.1	
c)	more than 0.01 and less than 0.05	
d)	more than 0.05 and less than 0.1	
17	Monoclonal antibodies used in targeted drug delivery are an example of:	1
a)	active targeting	
b)	passive targeting	
c)	non-specific targeting	
d)	physical targeting	
18	Which of the following statement is true for a controlled release dosage form?	1
a)	Rate limiting step in the absorption is rate of drug release from the controlled release formulation (i.e. Kr < Ka)	
b)	Drug disposition does not follow first order kinetics	
c)	Released drug is slowly absorbed	
d)	Released drug is incompletely absorbed	
19	Carbon tetrachloride and ethanol (ethyl alcohol) are individually toxic to the liver, but together they produce much more liver injury than the sum of their individual effects on the liver. This is commonly referred to as	1
a)	antagonism	
b)	addition	
c)	synergism	
d)	summation	
20	An ideal controlled release formulation should show a pharmacokinetic profile mimicking which of the following?	1
a)	Constant rate IV infusion	
b)	One compartment IV bolus	
c)	Two compartment IV bolus	
d)	Two compartment EV administration	
Q II	**Answer any TWO of the following:**	
1a)	Explain the process of passive absorption of drugs in terms of Ficks' Laws.	5
b)	Explain how a drug's ionization state affects its ability to cross the biological membranes and be absorbed.	5
2	Define IVIVC? Discuss the various levels of IVIVC. Enlist its applications.	10

3a A new antibiotic drug was given in a single intravenous bolus of 4 mg/kg to five healthy male adults ranging in age from 23 to 38 years (average weight 75 kg). The pharmacokinetics of the plasma drug concentration–time curve for this drug fits a one-compartment model.
The equation of the curve that best fits the data is $C = 0.78e^{-0.46t}$
Determine the following (assume units of g/mL for C_p and hr for t):

a. $t_{½}$ **1**

b. AUC and V_D **2**

c. What is the plasma level of the drug after 4 hours? **2**

d. How much drug is left in the body after 6 hours **2**

3b Describe in brief Wagner Nelson method and highlight its merits and demerits **3**

OR

3b A single oral dose (200 mg) of an antibiotic was given to an adult male patient (43 years, 72 kg). The pharmacokinetics of this drug fits a one-compartment open model. The equation that best fits the pharmacokinetics of the drug is
$Cp = 45 (e^{-0.17t} - e^{-1.5t})$
Assume C p is in g/mL and the first-order rate constants are in hours.
From the above equation calculate
(a)t max, **1**
(b)C max **2**

QIII Answer any SEVEN of the following: **35**

1 Explain how dissolution rate of a drug influences its oral bioavailability.

2 Explain the effects of binders, diluents, disintegrants, and lubricants on drug absorption from tablets with adequate examples.

3 Discuss the conditions that affect dissolution testing with respect to the apparatus.

4 How is the similarity between two formulations compared by means of their dissolution profiles?

5 Differentiate between linear and nonlinear kinetics.

6 Discuss the trial designs of bioequivalence studies.

7 Give an account of drug products for which bioavailability studies may be waived.

8 Discuss the development and approval of biosimilar drugs.

9 Explain the pharmacokinetics of biopharmaceuticals.