Duration: 3 Hours **Total marks: 75**

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

Q. No.	Question	Marks
Q.I	**Multiple Choice Questions (Answer all):**	**20**
1	A transport mechanism where the drug does not have to be in aqueous solution to be absorbed is	**1**
a)	ion-pair transport	
b)	passive diffusion	
c)	endocytosis	
d)	pore transport	
2	Percutaneous absorption of ionic drugs can be improved using ultrasound technique called	**1**
a)	iontophoresis	
b)	electrophoresis	
c)	phonophoresis	
d)	plasmaphoresis	
3	Metoclopramide improves absorption of levodopa due to	**1**
a)	increased gastric emptying	
b)	complex formation	
c)	favourable pH microclimate	
d)	decreased GI transit	
4	A highly permeable drug with a dose of 1mg/kg must have solubility	**1**
a)	100 mg/kg	
b)	10 mg/kg	
c)	1 mg/kg	
d)	0.1 mg/kg	
5	If f2 value is 100, the test and reference mean profiles are	**1**
a)	identical	
b)	different	
c)	half identical half different	
d)	multiple	

6 Which dissolution apparatus is used for dissolution testing of poorly soluble drugs? **1**

a) Paddle apparatus

b) Paddle over disc

c) Reciprocating cylinder

d) Flow through cell

7 Level A, IVIVC co-relationship is based on **1**

a) Comparison of any one dissolution parameters with any Pharmacokinetic parameter

b) Comparison of one or more dissolution parameters with any Pharmacokinetic parameter

c) Point to point correlation between in vitro dissolution and in vivo rate of absorption

d) Correlation based on statistical moment theory

8 Flow through cell type of dissolution Apparatus is **1**

a) USP Dissolution Test Apparatus II

b) USP Dissolution Test Apparatus III

c) USP Dissolution Test Apparatus IV

d) USP Dissolution Test Apparatus V

9 The first-order constant for the distribution phase in a multi compartment model is denoted by **1**

a) α

b) β

c) μ

d) γ

10 Volume of distribution is defined as correlation between **1**

a) rate of elimination and plasma concentration

b) rate of absorption and plasma concentration

c) rate of elimination and rate of absorption

d) amount of drug administered and plasma concentration

11 Mixed-order pharmacokinetics is also called **1**

a) Zero order pharmacokinetics

b) Dose independent pharmacokinetics

c) First order pharmacokinetics

d) Dose dependent pharmacokinetics

12 Absorption rate constant can be determined using **1**

a) Sigma Minus method

b) Wagner Nelson Method

c) Urinary Excretion Method

d) Sigma Plus method

13 What is the primary objective of conducting bioequivalence studies? **1**

a) To assess the safety profile of a drug candidate.

b) To determine the maximum tolerated dose of a drug.

c) To compare the pharmacokinetic parameters of two formulations of the same drug.

d) To evaluate the long-term efficacy of a drug in clinical trials.

14 Which study design is commonly employed in bioequivalence studies to minimize inter-subject variability? **1**

a) Parallel-group design

b) Crossover design

c) Retrospective cohort design

d) Case-control design

15 Which method is commonly used for in vitro assessment of drug permeability? **1**

a) Dissolution test

b) Caco-2 cell monolayer assay

c) Intradermal injection

d) PET imaging

16 What term is used to describe generic versions of biologic drugs that are highly similar but not identical to the reference product? **1**

a) Biocompatible biologics

b) Biosimilar drug products

c) Bioequivalent biologics

d) Biogenetic generic drugs

17 Following is the major mode of elimination for monoclonal antibodies **1**

a) renal clearance

b) hepatic clearance

c) binding to antigens

d) first pass metabolism

18 Following protein drug has been approved for delivery by pulmonary route **1**

a) Calcitonin

b) Insulin

c) Erythropoietin

d) Lactoferrin

19 The drug release profile of a controlled release formulation comprising of both the loading and maintenance dose will be **1**

a) Zero order release

b) First order release

c) Initial rapid release followed by first order release

d) Initial rapid release followed by zero order release

20 Following are the mechanisms of enzyme induction, except **1**

a) Increase in liver size

b) Increased stability of Cytochrome P 450

c) Increased microsomal protein content

d) Increased perfusion rate

QII Answer any Two questions: **20**

1 Elaborate on any five physico-chemical characteristics of drugs that affect its absorption, with suitable examples. **10**

2 Write the objectives and study design for conduct of bioequivalence study. Explain the methods to assess bioequivalence. **10**

3a A 75 kg patient was given a single IV dose of a drug at a dose level of 4 mg/kg. The pharmacokinetics of the plasma concentration -time curve for this drug fits a one compartment model and the instantaneous plasma concentration was found to be 46mg/L and half life was 7.5 hrs. Calculate following parameters assuming drug follows first order kinetics **7**

a) Volume of distribution and total systemic clearance **2**

b) What is the plasma concentration of drug after 8 hours? **2**

c) How much drug is left in the body after 8 hours? **1**

d) Time required to eliminate 70% of the dose of drug? **2**

3b A single oral dose of 2.8g of a drug (F=0.8) was given to a 60 kg patient. The plasma concentration time profile can be described by **3**

$C_p = 173 (e^{-0.421t} - e^{-2.4t})$

where Cp = mg/L, t = hours

Calculate:

a) tmax

b) Cmax

OR **1**

		2
3b	Explain the concept of one compartment open model along with key assumptions.	**3**
QIII	Answer any Seven questions:	**35**
1	Discuss the limitations of the pH partition hypothesis.	**5**
2	Elaborate on the characteristics of Facilitated diffusion and Ion-pair as mechanisms of drug absorption.	**5**
3	Outline various factors affecting dissolution rate and explain any two of them in detail.	**5**
4	Explain any one IP Dissolution Test apparatus.	**5**
5	Explain the concept of loading dose and maintenance dose of iv infusion and derive them.	**5**
6	Explain any two in vitro methods used for determination of drug permeability.	**5**
7	Write a note on generic biologics.	**5**
8	Write a brief note on distribution interactions of drugs.	**5**
9	Write a note on pharmacokinetics of protein and peptide drugs.	**5**