

Duration: 3 Hours

Total marks: 75

- N.B.:** 1. All questions are compulsory  
 2. Figures to the right indicate full marks.  
 3. Use of Scientific Calculator is permitted.

Question No.	Question	Max. Marks
<b>Q.I</b>	<b>Multiple Choice Questions (Answer all)</b>	<b>20</b>
<b>1</b>	Ion-pair transport is for absorption of	<b>1</b>
	a) highly lipophilic drugs	
	b) drugs forming positively charged complexes	
	c) drugs forming negatively charged complexes	
	d) drugs which ionize at all pH	
<b>2</b>	An excipient forming an unabsorbable complex with Amphetamine is	<b>1</b>
	a) dicalcium phosphate	
	b) EDTA	
	c) Sodium CMC	
	d) sodium lauryl sulphate	
<b>3</b>	The maximum amount of solute dissolved in a given solvent under standard conditions of temperature, pressure and pH is called	<b>1</b>
	a) absolute solubility	
	b) dissolution rate	
	c) saturated solution	
	d) limited solubility	
<b>4</b>	The absorption of phenytoin ( $pK_a > 8$ )	<b>1</b>
	a) takes place in the stomach	
	b) is independent of pH	
	c) is poor	
	d) takes place in the small intestine	
<b>5</b>	Which of the following is non-official dissolution apparatus	<b>1</b>
	a) Rotating basket	
	b) Paddle over disc	
	c) Reciprocating holder	
	d) Bottle method	
<b>6</b>	What is meant by IVIVC?	<b>1</b>
	a) Invitro-invivo correlation	
	b) Invivo-invivo correlation	
	c) Invivo-invivo correlation	
	d) Invitro-invivo correlation	

- 7 Low solubility and low permeability is BCS class **1**
- a) Class I
  - b) Class II
  - c) Class III
  - d) Class IV
- 8 When solvent molecule entrapped in the crystalline structure of polymorph it is called as **1**
- a) Pseudo-polymorphism
  - b) Amorphous
  - c) Crystallinity
  - d) Metastable
- 9 In Michaelis- Menten equation, When value of  $K_m=C$  **1**
- a) Rate of Process is half the maximum rate
  - b) Rat of Process is equal to maximum rate
  - c) Rate of process is double the maximum rate
  - d) Rate of process is triple the maximum rate
- 10 Drugs which selectively bound to Extravascular tissues have apparent volume of distribution **1**
- a) Smaller than their real volume of distribution
  - b) Larger than their real volume of distribution
  - c) Equal to their real volume of distribution
  - d) Not predictable
- 11 The steady state concentration following IV infusion administration determined by **1**
- a)  $C_{ss} = \text{Infusion Rate} - \text{Clearance}$
  - b)  $C_{ss} = \text{Clearance} / \text{Infusion Rate}$
  - c)  $C_{ss} = \text{Infusion Rate} \times \text{Clearance}$
  - d)  $C_{ss} = \text{Infusion Rate} / \text{Clearance}$
- 12 Approximately total volume of body water is **1**
- a) 22 Lit
  - b) 42 Lit
  - c) 62 Lit
  - d) 82 lit
- 13 The study design suitable for bioequivalence of a depot injection is **1**
- a) parallel design
  - b) replicated crossover
  - c) Latin cross-over
  - d) steady state design

- 14 Which of the following will be a parameter that should be examined for urinary excretion data? **1**
- C<sub>max</sub>
  - (dX<sub>u</sub>/dt)<sub>max</sub>
  - AUC
  - T<sub>max</sub>
- 15 What is pharmaceutical equivalence? **1**
- Two or more drug products contain the same labeled chemical substance in the same amount
  - Two or more drug products are identical in quality, purity, uniformity, disintegration, dissolution
  - Two or more drug products contain different labeled chemical substance giving the same therapeutic effect
  - Two or more drug products contain the same labeled chemical substance giving a different therapeutic effect
- 16 Which of the following is measured in acute pharmacological response study? **1**
- Plasma drug concentration
  - Urinary drug concentration
  - EEG
  - Serum drug level
- 17 Ideally drug should have half life to be formulated in controlled release dosage form **1**
- 3-4 hr
  - 1-2 hr
  - 6-7 hrs
  - 9-10 hrs
- 18 Pharmacodynamic interaction affect **1**
- Activity of drug not plasma concentration
  - Metabolism of drug and its distribution
  - Plasma concentration and activity of drug
  - Protein binding of drug
- 19 Delivery of drug to tumor cell is **1**
- Second order targeting
  - First order targeting
  - Zero order targeting
  - Third order targeting
- 20 Following are the major mechanism of excretion interaction, except **1**
- alteration in renal pH
  - alteration in urine pH
  - enzyme inhibition
  - forced diuresis

- QII Answer any Two questions: 20**
- 1 Explain any five formulation related factors affecting drug absorption. 10
  - 2 What is Bioequivalence? Write the objectives for conductance of Bioequivalence study. Explain crossover design. 10
  - 3 A volunteer is given an intravenous dose of 400mg of antibiotics and plasma drug concentrations at the 2 and 6 hours were found to be 4.5 mg/Lit and 3.7 mg/lit respectively. Calculate the following Pharmacokinetic parameters assuming one compartment kinetics.
    - a. Elimination rate constant and half life 1
    - b. Initial Plasma drug concentration 1
    - c. Volume of distribution and total systemic clearance 2
    - d. Time required to eliminate 60% dose of drug 2
    - e. Plasma drug concentration at the end of 8 hours. 2
    - f. Amount of drug remaining in the body after 11 hrs 2
- QIII Answer any Seven questions: 35**
- 1 Explain the Film theory of dissolution. 5
  - 2 Discuss the mechanism of active transport of drugs. 5
  - 3 Elaborate on dissolution test parameters affecting in vitro drug dissolution. 5
  - 4 Write a note on statistical methods for comparison of dissolution profiles. 5
  - 5 What is non-linear pharmacokinetics? Write the causes of non linearity in drug metabolism and excretion with one example of each. 5
  - 6 Explain any two in vitro methods for determining drug permeability. 5
  - 7 Write a note on Biopharmaceutic Classification System of drugs. 5
  - 8 Discuss Pharmacodynamic drug interactions with suitable examples. 5
  - 9 Write the applications of Pharmacokinetic in Targeted drug delivery systems with examples. 5

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