**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 |
|---|---|---|
| **Q.I** | **Multiple Choice Questions (Answer all)** | **20** |
| **1** | Ion-pair transport is for absorption of | **1** |
| a) | highly lipophilic drugs | |
| b) | drugs forming positively charged complexes | |
| c) | drugs forming negatively charged complexes | |
| d) | drugs which ionize at all pH | |
| **2** | An excipient forming an unabsorbable complex with Amphetamine is | **1** |
| a) | dicalcium phosphate | |
| b) | EDTA | |
| c) | Sodium CMC | |
| d) | sodium lauryl sulphate | |
| **3** | The maximum amount of solute dissolved in a given solvent under standard conditions of temperature, pressure and pH is called | **1** |
| a) | absolute solubility | |
| b) | dissolution rate | |
| c) | saturated solution | |
| d) | limited solubility | |
| **4** | The absorption of phenytoin (pKa > 8) | **1** |
| a) | takes place in the stomach | |
| b) | is independent of pH | |
| c) | is poor | |
| d) | takes place in the small intestine | |
| **5** | Which of the following is non-official dissolution apparatus | **1** |
| a) | Rotating basket | |
| b) | Paddle over disc | |
| c) | Reciprocating holder | |
| d) | Bottle method | |
| **6** | What is meant by IVIVC? | **1** |
| a) | Invitro-invivo correlation | |
| b) | Invivo-invitro correlation | |
| c) | Invivo-invivo correlation | |
| d) | Invitro-invitro 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 Km=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) | Css = Infusion Rate - Clearance | |
| b) | Css= Clearance / Infusion Rate | |
| c) | Css= Infusion Rate X Clearance | |
| d) | Css= Infusion Rate/ 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**

a) Cmax

b) (dXu/dt)max

c) AUC

d) Tmax

**15** What is pharmaceutic equivalence? **1**

a) Two or more drug products contain the same labeled chemical substance in the same amount

b) Two or more drug products are identical in quality, purity, uniformity, disintegration, dissolution

c) Two or more drug products contain different labeled chemical substance giving the same therapeutic effect

d) 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**

a) Plasma drug concentration

b) Urinary drug concentration

c) EEG

d) Serum drug level

**17** Ideally drug should have half life to be formulated in controlled release dosage form **1**

a) 3-4 hr

b) 1-2 hr

c) 6-7 hrs

d) 9-10 hrs

**18** Pharmacodynamic interaction affect **1**

a) Activity of drug not plasma concentration

b) Metabolism of drug and its distribution

c) Plasma concentration and activity of drug

d) Protein binding of drug

**19** Delivery of drug to tumor cell is **1**

a) Second order targeting

b) First order targeting

c) Zero order targeting

d) Third order targeting

**20** Following are the major mechanism of excretion interaction, except **1**

a) alteration in renal pH

b) alteration in urine pH

c) enzyme inhibition

d) 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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