BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: B.PHARM **SEMESTER : VII**
BRANCH: PHARMACY **SESSION : MO/19**

SUBJECT: PS7403 BIOPHARMACEUTICS & PHARMACOKINETICS

TIME: 3:00 HOURS **FULL MARKS: 60**

INSTRUCTIONS:
1. The question paper contains 7 questions each of 12 marks and total 84 marks.
2. Candidates may attempt any 5 questions maximum of 60 marks.
3. The missing data, if any, may be assumed suitably.
***4*. Before attempting the question paper, be sure that you have got the correct question paper.**
5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

Q.1(a) Define following terms (a) Bioavailability and (b) Pharmaceutical alternatives. [2]

Q.1(b) Differentiate between (a) Absolute Bioavailability and (b) Relative Bioavailability. [4]

Q.1(c) The bioavailability of a new investigational drug was studied in 12 volunteers. Each volunteer received either a single oral tablet/solution containing 200 mg of the drug, or single IV bolus injection containing 50 mg of the drug. The average AUC values is given in the table below. [6]

Drug Product	Dose (mg)	AUC (mcg.hr/mL)
Oral Tablet	200 mg	89.5
Oral Solution	200 mg	86.1
IV Bolus Injection	50 mg	37.8

Calculate Relative Bioavailability and Absolute Bioavailability and discuss the findings

Q.2(a) Differentiate between Passive diffusion and Carrier mediated diffusion. [2]

Q.2(b) Discuss Fick's law of diffusion. [4]

Q.2(c) Explain pH partition hypothesis to understand the extent of ionization (and unionization) of weakly acidic and basic drugs. [6]

Q.3(a) Illustrate different stages of drug dissolution from tablets. [2]

Q.3(b) How sink condition is ensured during dissolution studies. [4]

Q.3(c) Illustrate and discuss Film theory and Danckwert's theory of drug dissolution. [6]

Q.4(a) Draw plasma level time curve for an orally administered drug. [2]

Q.4(b) Consider a drug that has been administered orally. Explain various steps to elucidate absorption rate constant using method of residuals. [4]

Q.4(c) If the plasma concentration of Viomycin after IV bolus administration was found to be 12.0 and 6.0 mcg/mL at 2 and 8 hrs respectively, assuming one compartment kinetics calculate: (a) half-life of drug, (b) Concentration of drug in plasma at time zero and (c) Volume of distribution if dose administered is 500 mg [6]

Q.5(a) Consider KE>Ka for a drug administered orally. Explain the phenomena associated with it. [2]

Q.5(b) Prove that when rate constants for absorption and elimination are equal, the maximum plasma concentration is independent of these constants and time at which Cmax occurs is the reciprocal of either Ka or KE. [4]

Q.5(c) Derive and discuss two methods to estimate urinary excretion rate constant. [6]

Q.6(a) Draw plasma concentration time curve when the drug is administered orally when administered *repetitively* conferring one compartment model. [2]

Q.6(b) Consider a drug that is administered repetitively at constant intervals. How accumulation factor is determined in this case. [4]

Q.6(c) Derive an equation when the drug administered intravenously at repeated constant intervals that confers the characteristics to one compartment model. [6]

Q.7(a) Enumerate important characteristics observed by drug that follows capacity limited pharmacokinetics. [2]

Q.7(b) A drug is metabolized by capacity limited pharmacokinetics. Assume that Km is 50 mcg/mL and Vmax of 20 mcg/mL.h. The initial plasma drug concentration is 0.5 mcg/mL. How much time is necessary for the drug to get 50% metabolized. [4]

Q.7(c) Phenytoin was administered to a patient at dosing rates of 150 and 300 mg/day, respectively. The steady state plasma concentration was 8.6 mg/L and 25.1 mg/L, respectively. Find Km and Vmax of this patient using *graphical method*. What dose is needed to achieve a steady state concentration of 11.3 mg/L? [6]