

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

CLASS: M. Pharm.  
BRANCH: PHARMACEUTICS

SEMESTER: II  
SESSION: SP2022

SUBJECT: Advanced Biopharmaceutics and Pharmacokinetics (MPH202T)

TIME: 3.00 Hours

FULL MARK: 75

INSTRUCTIONS:

1. The missing data, if any, may be assumed suitably.
  2. Before attempting the question paper, be sure that you have got the correct question paper.
  3. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.
  4. Attempt any Five out of Seven
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- 1a. Differentiate between passive and active diffusion of drug from gastro-intestinal tract. [7]  
1b. Develop 'level A' *in vitro* and *in vivo* correlation (IVIVC) for BCS class I drug [8]
- 2a. Design a parallel and crossover bioequivalence study for test drug 'A' and reference drug 'B' [7]  
2b. Examine Fick's law of diffusion and discuss various parameters associated to improve dissolution of drug. [8]
- 3a. Investigate the influence drug's pKa and Gastrointestinal pH in drug absorption from GI tract. [7]  
3b. Explain pharmacokinetic method to assess bioequivalence study. [8]
- 4a. Derive double reciprocal equation to estimate association constant and number of binding sites on protein molecule. [7]  
4b. Using suitable example defend the statement "Apparent volume of distribution has no true anatomical or physical volume relation". [8]
- 5a. Discuss challenges in executing pharmacokinetics study of biopharmaceutical products. [7]  
5b. Develop a method with illustration to prepare monoclonal antibodies. [8]
- 6a. Derive an equation to estimate area under the curve of plasma concentration time plot for a drug given orally. [7]  
6b. A 70-kg volunteer is given an intravenous dose of an antibiotic, and serum drug concentrations were determined at 4 hours and 8 hours after administration. The drug concentrations were 2.5 and 1.25 mcg/mL, respectively. Calculate Elimination rate constant (KE) and biologic half-life for this drug, assuming first order elimination kinetics? [8]
- 7a. Derive a method to estimate absorption rate constant and elimination rate constant using method of residuals when the drug is given orally that confers one compartment model (Assume  $K_a \gg K_E$ ) [7]  
7b. Investigate various cases in Nonlinear Pharmacokinetics that result in different order of kinetics in Michaelis-Menten curve. [8]

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