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

**CLASS: MPHARM / Pre-PhD** **SEMESTER : II/NA**
**BRANCH: PHARMACY** **SESSION : SP/19**

**SUBJECT: MPH202T ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**
**TIME: 3:00 Hr** **FULL MARKS: 75**

**INSTRUCTIONS:**
**1. The question paper contains 7 questions each of 15 marks and total 105 marks.**
**2. Candidates may attempt any 5 questions maximum of 75 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.**

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Q.1(a) Pointing out the limitations and significance of dissolution studies, explain theories of drug dissolution. [7]
Q.1(b) Describe the various mechanisms of drug absorption. [8]

Q.2(a) Describe the formulation factors affecting absorption of drug from gastrointestinal tract. [7]
Q.2(b) Stating the objectives, write a detailed note on *in vitro- in vivo* correlation. [8]

Q.3(a) Describe various methods for measurement of bioavailability. [7]
Q.3(b) Discuss the term bioequivalence and its significance. Explain different study design used in BA/BE studies. [8]

Q.4(a) Define following terms: (i) Pharmaceutical equivalence, (ii) Therapeutic equivalence, (iii) Pharmaceutical alternatives, (iv) Chemical equivalence, and (v) Relative bioavailability. [5]
Q.4(b) Define bioavailability. Write in detail, the factors enhancing bioavailability. [10]

Q.5(a) Derive and discuss two methods to estimate average plasma concentration when the drug is administered intravenously at constant dosing intervals with fixed dosage size. [7]
Q.5(b) Derive equations for $C_{max}$ and $T_{max}$. [8]

Q.6(a) What is Flip Flop Phenomena? Explain Wagner-Nelson method. [7]
Q.6(b) Discuss of method residuals to estimate various rate constants, when the drug is given orally conferring *two* compartment model. [8]

Q.7(a) The elimination half-life of an antibiotic is 3.5 hours and the apparent volume of distribution is 40 % of body weight. The therapeutic window for this drug is from 2 to 10 microgram/mL. Adverse toxicity is often observed at drug concentration above 15 microgram/mL. The drug is given by multiple IV bolus injections. [7]
(a) Calculate the dose for an adult male patient (52 yrs, 75 kg) to be given every 8 hours.
(b) Calculate the expected $C_{min}$ and $C_{avg}$.
(c) Comment on the adequacy of the dosage regimen.

Q.7(b) The drug phenytoin is administered to a patient at dosing rates of 200 and 400 mg/day on different occasions and the steady rate serum concentration are 3.77 and 18.2 mg/L, respectively. Find the $K_m$ and $D_{max}$ for this patient using (i) Graphical method and (ii) Direct method. What would be the dose needed to achieve a steady sate of 11.5 mg/L? [8]

**:::::22/04/2019 M:::::**