

PARUL UNIVERSITY
FACULTY OF PHARMACY
M.Pharm. Examination, Summer 2017-18

Semester: 2**Subject Code: MPH202T****Subject Name: Advanced Biopharmaceutics & Pharmacokinetics****Date: 16/05/2018****Time: 10:00 am to 1:00 pm****Total Marks: 75****Instructions:**

1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

Q.1 Essay Type Questions. (any 2 out of 3) (15 Marks Each) (30)

1. What is suprabioavailability? Enlist methods for bioavailability measurement and describe method based on plasma drug data.
2. Why IVIVC is an important stage in formulation development? Explain any two methods for correlation studies.
3. What is bioequivalency? Explain latin-square cross-over design with layout.

Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) (25)

1. How transport across biomembrane of a drug is evaluated? What is its significance in formulation development?
2. Write a short note on Waiver of Bioavailability/Bioequivalence Studies.
3. What is biological classification system? How it helps in finalizing formulation type and dissolution in-vivo drug profiles?
4. Differentiate Absolute and Relative Bioavailability. Calculate these values for tablet based on given data. Tablet (Dose-100 mg Oral, AUC -20); Solution (Dose-100 mg Oral, AUC- 30) and Injection (Dose-50 mg IV bolus, AUC- 50).
5. Enlist various approaches for pharmacokinetic analysis of experimental data and explain compartmental models in detail.
6. What process of drug ADME are known to show non linearity. Explain giving suitable examples.

Q.3 Short Answers. (2 Marks Each) (20)

1. Explain pharmacokinetic drug interactions giving suitable examples.
2. What do you mean by dissolution mimicking?
3. Enlist various factors to be considered in dissolution media and conditions determination.
4. Define clearance, total body clearance and organ clearance.
5. Explain schematic diagram of sequential absorption of oral solids.
6. Mention the different routes of clearance.
7. Give compositions for Biorelevant dissolution media.
8. Define biological half-life and volume of distribution. How are they related?
9. How dissolution medium is selected for new API?
10. What is multi-compartment model? Enlist such models.