

Jadavpur University
Department of Pharmaceutical Technology
Kolkata-700032.

M.Pharm (IP)/ 1st year/2nd Sem/Time 3 hrs/ FM 75/ 2025

Course: Advanced Biopharmaceutics & Pharmacokinetics

Code: MIP 201T

Note: 1. Answer ALL the questions.

2. Question 1 is Compulsory.

1. Answer the following questions. 10x2M=20 Marks

- i. Give the composition of cell membrane.
- ii. Acidic drugs are best absorbed from which part of the GIT?
- iii. Which form of Chloramphenicol is more water soluble & why?
- iv. State the rate determining step for absorption of hydrophilic and lipophilic drug with example.
- v. Give the name of different approaches for pharmacokinetic analysis of experimental data.
- vi. Name the different methods available for bio-availability and bio-equivalence study.
- vii. How absolute bioavailability can be defined?
- viii. Define reference listed drug.
- ix. Who proposed BCS classification system and define high solubility according to BCS classification?
- x. Give one examples of in vitro binding study as suggested by FDA.

Short Answer Question

7 x 5Marks = 35Marks

(Answer 7 out of 9)

2. Write a note on Thalidomide disaster.
3. Major site for drug absorption is Small intestine-----explain.
4. Enlist the dissolution test apparatus as per IP & USP with their applications.
5. Describe the various pharmacokinetic & pharmacodynamic parameters from plasma level-time curve.
6. Define dosage regimen, therapeutic window, MRT, V_d & clearance.

[Turn over

7. Prove mathematically that when an i.v loading dose followed immediately by a constant rate infusion, the plasma concentration remains steady as long as the infusion is continued.
8. A drug is given by i.v infusion. The $t_{1/2}$ is 22 h and V_d is 15.7 Ltr and the desired steady-state plasma conc. is 0.0002 mcg/ml. Assuming one compartment kinetics, calculate –
 - a). The infusion rate to achieve desired C_{ss} .
 - b). The loading dose to attain C_{ss} rapidly.
9. The plasma conc. of a drug after i.v bolus administration was 10 and 5.5 mcg/ml at 2 h and 4 h. Assuming one compartment kinetics calculate –
 - a) Half-life of the drug.
 - b) Drug conc. in plasma at time zero.
10. Write short note on sink condition.

Long Answer Questions. 2 x 10M = 20 Marks

(Answer 2 out of 3)

11. Discuss in vivo measurement of active moiety or moieties in biological fluid through pharmacokinetic study.
12. How Bio-equivalence Studies can be done for new drug development.
13. Discuss on cross over study design, replicate cross over study design and parallel study design employed for bioequivalence study. 4.5+2.5+3