Jadavpur University

Department of Pharmaceutical Technology

Kolkata-700032.

M.Pharm (IP)/ 1st year/2nd Sem/Time 3 hrs/ FM 75/ 2024

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 formula for similarity factor and difference factor for dissolution profile comparison of drugs.
ii. ER of a drug is 0.75.....explain it.
iii. Give the formula for Half-life of zero-order & first-order kinetics.
iv. Vit-B12, water soluble small molecules and Polio vaccine are absorbed by which mechanism?
v. To be bioabailable what should be the minimum aqueous solubility of a drug?
vi. Which parameters should be considered for bioequivalent basic study design?.
vii. Write some disadvantages of parallel study design?
viii. What some advantages of coss over study design.
ix. What is the full form RLD? Define RLD.?
x. Name the approaches which are guided by FDA for Bioequivalence study .

Short Answer Question **7 x 5Marks = 35Marks**

(Answer 7 out of 9)

2. Define polymorphism. How it affects drug absorption. Explain with example.
3. Give the importance of biopharmaceutic considerations in drug product design.
4. Write a short note on simulated gastric & intestinal fluid and *in-vitro* drug dissolution.
5. 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.
6. 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 steadt-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.

7. Describe bioequivalence study based on clinical end points.
8. What is Bioavailability and bioequivalence? Describe in details the terms Relative bioavailability and absolute bioavailability.
9. How bioequivalence studies are done for New Drug Development.
10. How PKPD relationship can be presented graphically.

Long Answer Questions. **2 x 10M = 20 Marks**

(Answer 2 out of 3)

11. 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.
    c) Vd if dose administered was 300 mg.
    d) Total systemic clearance.
    e) Renal clearance if fraction excreted unchanged in urine is 0.8.
12. Write about the *In Vitro–In Vivo* Correlation of drug dissolution and dissolution profile comparison.
13. Describe the term and define modified release.What is the difference between extended release,delayed release, sustained release, and controlled release?.Write advantages and disadvantages of extended release drug product. [2+4+4]