INDIRA UNIVERSITY, PUNE

SCHOOL OF PHARMACY- MPHARM (Pharmaceutics)

Term End Examination (2025 Pattern) April- May – 2026- Semester – II

Course Name: Advanced Biopharmaceutics & Pharmacokinetics **Max. Marks: 75**
Course Code: MPH202T **Time: 3:00 Hrs.**

Instructions

- All Questions are Compulsory. Write two sections on separate answersheets.
- Neat diagram must be drawn wherever necessary.
- Figures to the right indicate full marks.

Section : I

Q.1 Solve any ONE from the following **15 Marks**

a. Illustrate various official apparatuses used for performing dissolution studies with their applications

b. Discuss physico-chemical properties of a drug considered in drug product design

Q.2 Solve any FOUR from the following **20 Marks**

a. Discuss passive transport of drugs

b. Explain the criteria for meeting the dissolution requirements of immediate release tablets.

c. Discuss various theories of drug dissolution process.

d. Elaborate on Level A in vitro- in vivo correlation

e. Discuss the role of microenvironmental pH on drug absorption and bioavailability

f. Discuss the formulation factors that would affect the bioavailability of immediate release tablets

Section : II

Q.3 Solve any ONE from the following **15 Marks**

a. Illustrate the one compartment model to determine the pharmacokinetic parameters of the drug administered by I.V. bolus dose followed by I.V. infusion.

b. Define absolute and relative bioavailability. Discuss in detail the plasma concentration time method to compute the bioavailability of a drug.

Q.4 Solve any TWO from the following **15 Marks**

a. Explain the Michaelis Menten equation and causes of non-linearity related to the metabolism and excretion

b. Describe the in vitro and in-situ methods to determine the oral permeability of the drugs

c. Differentiate between compartment modelling and physiologic modelling

d. Discuss the viral and non-viral vector based gene delivery along with its pharmacokinetics with suitable examples

Q.5 Solve any TWO from the following **10 Marks**

a. Define pharmaceutical equivalence, bioequivalence and therapeutic equivalence. Explain the statistical considerations for establishing the bioequivalence

b. Discuss the selection of healthy subjects Vs patients and single dose Vs multiple dose in BE studies

c. Elaborate on the causes of nonlinearity in pharmacokinetics due to absorption and distribution.

d. Discuss the Cytochrome P 450 enzymes related interactions with suitable examples

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