Question Paper

Exam Date & Time: 15-May-2024 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS [PCE-MPH202T-S1]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1)	Using suitable diagrams, explain the construction, working and applications of basket and paddle apparatus for dissolution testing of drug products.	(10)
2)	Discuss the effects of polymorphism and dissociation constant on the absorption of drugs.	(10)
3)	What do you mean by pharmacokinetic models? How they are helpful? Classify and briefly explain the pharmacokinetic models [7 marks]. A drug has to be administered as a continuous IV infusion to reach a steady state concentration of 0.3 mcg/ml. What should be the infusion rate ($\mathbf{K_0}$) if it follows the one-compartment model? Given: $\mathbf{t_{1/2}}$ = 7 h and $\mathbf{V_d}$ = 12 L [3 marks].	(10)
4)	What should be the duration of the washout period between any two bioavailability studies in the same subjects? Why? [5 marks]. Explain the significance of the parameters used in bioavailability determination by plasma-level studies [5 marks].	(10)
5)	Write a short note on therapeutic, pharmacodynamic and pharmacokinetic drug monitoring [6 marks]. Drug A when administered at a dose of 50 mg showed an initial concentration of 0.5 mcg/ml. Given the half-life of the drug to be 1.5 h, what is the total clearance of the drug in **L**/**h**? [4 marks]	(10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6)	Write about the levels A and C of IVIVC.	(5)
7)	Explain the effects of emulsion and suspension dosage forms on the absorption of drugs.	(5)
8)	Discuss the application of pharmacokinetics in the formulation development of controlled-release drug products.	(5)
9)	Define and explain the extraction ratio. How is it related to the oral bioavailability of a drug? What is the influence of blood flow rate and protein binding on the total clearance of drugs with high and low ER values?	(5)
10)	Define dose-dependent kinetics. Mention and briefly explain the important sources that result in nonlinearity in drug absorption [2 + 3 marks].	(5)

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