## BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI (END SEMESTER EXAMINATION)

CLASS: B. PHARM. SEMESTER: VI BRANCH: PHARMACY SESSION: SP2024

SUBJECT: BP604T BIOPHARMACEUTICS & PHARMACOKINETICS

TIME: 3.00 Hours FULL MARK: 75 INSTRUCTIONS:

- 1. The missing data, if any, may be assumed suitably.
- 2. Before attempting the question paper, be sure that you have got the correct question paper.
- 3. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.
- 4. This question paper consists of (03) three parts. Read the part wise instructions before attempting the questions.

**PART-I** Objective types questions (Instruction: Answer all questions) Q1.  $(10 \times 2 = 20 \text{ Marks})$ A. Excessive tissue binding of drug ....... Volume of distribution CO1 BL<sub>1</sub> B. Justify the term "apparent volume of distribution" CO2 BL4 C. In fasted condition the phase II in GI tract last for ...... min CO3 BL2 D. In the following figure which curve corresponds to non-linear pharmacokinetics C04 BL5 100 Plasma level 10 E. Small polar molecules follow passive diffusion through pores. True/False. Justify CO5 BL2

F.	Define relative and absolute bioavailability.	CO1	BL1
G.	Write down the criterion for establishing bioequivalence.	CO2	BL2
Н.	Write down the important assumptions for applying method of residuals to determine the absorption rate constant.	CO3	BL1
I.	Write the relation between the amount of drug with plasma concentration.	CO4	BL4
J.	Define pharmaceutical equivalent.	CO5	BL1

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## PART-II Short Answers

## (Instruction: Answer seven out of nine questions)

Q2. Differentiate between active and passive diffusion CO1 BL<sub>2</sub> Analyse vesicular transport and ion pair transport system in GIT with suitable CO2 Q3. BL4 Q4. Discuss and comment on various phases of GI motility under fasted condition CO3 BL3 Q5. Using suitable example, comment on various in vitro cases to justify the term CO4 BL4 "apparent Vd" Q6. Derive and discuss kinetics of plasma protein binding of drug CO5 BL1 Q7. Describe the method of residuals to determine the absorption rate constant CO1 BL3 with citing proper assumptions. Q8. Determine the overall elimination rate constant from urinary excretion data CO2 BL4 obtained after IV infusion administration. 09. Derive the equation to determine apparent volume of distribution and systemic CO3 BL4 clearance from plasma concentration vs. time data after an IV infusion administration following one compartmental pharmacokinetic model. Determine Cmax and Tmax from the plasma concentration vs. time data after CO4 Q10. BL4 an extravascular administration following one compartmental pharmacokinetic model.

## PART-III Long Answers (Instruction: Answer two out of three questions)

 $(2 \times 10 = 20 \text{ marks})$ 

 $(7 \times 5 = 35 \text{ Marks})$ 

- Q11. A drug eliminated from the body by capacity-limited pharmacokinetics has a KM of 100 mg/L and a Vmax of 50 mg/h. If 400 mg of the drug is given to a patient by IV bolus injection, calculate the time for the drug to be 50% eliminated. If 320 mg of the drug is to be given by IV bolus injection, calculate the time for 50% of the dose to be eliminated. Explain why there is a difference in the time for 50% elimination of a 400-mg dose compared to a 320-mg dose. Also calculate the time for 50% elimination of the dose when the doses are 10 and 5 mg. Explain why the times for 50% drug elimination are similar even though the dose is reduced by one-half.

  Q12. Determine the elimination rate constant using the declining drug concentration in CO2 BL5
- Q12. Determine the elimination rate constant using the declining drug concentration in CO2 plasma versus time data collected after stopping the infusion after an IV infusion administration following one compartmental pharmacokinetic model.
- Q13. 100 mg of a drug was administered by rapid IV injection to a 70-kg, healthy adult CO3 BL5 male. Blood samples were taken periodically after the administration of drug, and the plasma fraction of each sample was assayed for drug. Formulate the equation which demonstrate the two-compartment pharmacokinetic model. The following data were obtained:

Time (hr)	Plasma Concentration (µg/mL)	
0.25	43.00	
0.5	32.00	
1.0	20.00	
1.5	14.00	
2.0	11.00	
4.0	6.50	
8.0	2.80	
12.0	1.20	
16.0	0.52	

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