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

CLASS: B. Pharm. **SEMESTER: VI**
BRANCH: PHARMACY **SESSION: SP2022**

SUBJECT: BP604T- BIOPHARMACEUTICS AND 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 x 2 = 20 Marks)

A. At Cmax, which of the following option is correct?
i. dXa/dt > dXe/dt
ii. dXa/dt < dXe/dt
iii. dXa/dt = dXe/dt
iv All above options are correct

B. In zero order half-life is
i. independent on concentration
ii. directly dependent on concentration
iii. Inversely dependent on concentration
iv. All of the above

C. Half-life of a drug that follows first order kinetics is
i. dependent on Initial Plasma Concentration
ii. independent on initial Plasma concentration

D. Total amount of drug in the body is equal to dose given plus amount of drug already in the body (T/F)
i. True
ii. False

E. The equation to estimate $(Xn)_{max}$ when the drug is given intravenously at 'tau' time unit is…….

F. Write the final equation to calculate "average plasma drug concentration at steady state" when the drug is given intravenously at regular time intervals

G. If the elimination process is saturated, amongst following which option is correct
i. Drug concentrations in the blood can increase rapidly
ii. Drug concentrations in the blood will decline rapidly

H. When KE>Ka, the residual line slope is ……

I. If there is no tissue-drug interaction, volume of distribution is likely to be ……

J. When concentration of drug in plasma is relatively very less than drug concentration at GI tract, Fick's law of diffusion reduces to ……..

PART-II
Short Answers
(Instruction: Answer seven out of nine questions)

(7 x 5 = 35 Marks)

<table>
<tr><td>Q2.</td><td>Discuss kinetics of protein binding in brief.</td></tr>
<tr><td>Q3.</td><td>The bioavailability of a new investigational drug was studied in 12 volunteers. Each volunteer received either a single oral tablet containing 400 mg of the drug, 5 mL of a pure aqueous solution containing 400 mg of the drug, or a single IV bolus injection containing 100 mg of the drug. The average AUC values (0-48 hours) are given in the table below. From these data, calculate (a) the relative bioavailability of the drug from the tablet compared to the oral solution and (b) the absolute bioavailability of the drug from the tablet.
<table>
<tr><th>Drug product</th><th>Dose (mg)</th><th>AUC (mcg.h/mL)</th></tr>
<tr><td>Oral Tablet</td><td>400</td><td>120.45</td></tr>
<tr><td>Oral Solution</td><td>400</td><td>126.54</td></tr>
<tr><td>IV Bolus Injection</td><td>100</td><td>62.14</td></tr>
</table></td></tr>
<tr><td>Q4.</td><td>Compare and discuss parallel and crossover design in Bioequivalence study.</td></tr>
<tr><td>Q5.</td><td>Prove that amount of drug in the body remains constant throughout the time course of drug administration with simultaneous IV bolus and IV infusion.</td></tr>
<tr><td>Q6.</td><td>Derive a method to estimate Absorption rate constant using method of residuals.</td></tr>
<tr><td>Q7.</td><td>Derive and discuss a method to determine accumulation of drug in the body (accumulation factor) when a drug given intravenously at regular intervals.</td></tr>
<tr><td>Q8.</td><td>Why IV loading dose is given in intravenous therapy. Derive an equation to calculate Loading dose.</td></tr>
<tr><td>Q9.</td><td>Discuss non-linear pharmacokinetics in brief.</td></tr>
<tr><td>Q10.</td><td>Develop a method to estimate Vmax and Km in Non-linear pharmacokinetics.</td></tr>
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PART-III
Long Answers
(Instruction: Answer two out of three questions)

(2 x 10 = 20 marks)

<table>
<tr><td>Q11.</td><td>Derive a method to estimate area under the curve for a drug given orally.</td></tr>
<tr><td>Q12.</td><td>Derive an equation to estimate $(Xn)_{max}$ when the drug is given multiple times intravenously at regular time intervals.</td></tr>
<tr><td>Q13.</td><td>A drug eliminated from the body by capacity-limited pharmacokinetics has a KM of 100 mg/L and a Vmax of 50 mg/h. Calculate and discuss the time for drug to be 50% eliminated in following four cases:
Dose 1: 600 mg
Dose 2: 300 mg
Dose 3: 5 mg
Dose 4: 2.5 mg</td></tr>
</table>

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