0073

THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF PHARMACY
ACADEMIC YEAR 2019/2020 – SEMSETER I

BACHELOR OF PHARMACY HONOURS
FMU6301- BIOPHARMACEUTICS
FINAL EXAMINATION
DURATION: THREE HOURS

DATE: 16th SEPTEMBER 2020 TIME: 01.30 P.M. – 04.30 P.M.

Index No .....

Part B (20 Marks)

01.

1.1 A patient was given an IV infusion of drug X. The infusion pump was removed after 30 minutes. It achieves its steady state concentration (10 mg/mL) 10 min after initiating the infusion. Within 20 min, the drug was completely eliminated from the body. Draw the graph which represent these data. (07 marks)

1.2 What are plasma level time curves? (03 marks)

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Index No .....

02.

2.1 What is meant by 'clinical pharmacokinetics'? (04 marks)

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2.2 Define 'drug bioavailability'. (03 marks)

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2.3 State three (03) commonly used pharmacokinetic models. (03 marks)

I).....

II).....

III).....

Part C

01.

1.1 Drug X is administered orally as its HCL salt (S=0.95). It undergoes degradation through stomach pH and liver enzymes. Therefore 75% is unable to reach the systemic circulation. What will be the effective dose for a 5 mg tablet of drug X? (03 marks)

1.2 Write the equation for renal clearance and define its terms. (03 marks)

1.3 The fictitious drug disolvprazole is almost completely eliminated by renal excretion. A 10mg dose was administered IV to a healthy subject. Urine samples were collected over various periods and the plasma concentration was measured at the midpoint of each collection period. The data are given in following table.

Urine data			Plasma data	
Collection Period (h)	Volume of urine (mL)	Urine drug concentration (mcg/mL)	Time (h) (Midpoint of urine collection Period)	Cp (mcg/mL)
0-1	200	15	0.5	240
1-3	180	19.4	2	142
3-5	140	12.8	4	71
5-10	400	3.5	7.5	21

a. Draw the graph using suitable graph paper. (06 marks)

b. Determine the renal clearance of the drug. (03 marks)

02.

2.1 What is meant by the half-life ($t_{1/2}$) of a drug? (01 mark)

2.2 $A \longrightarrow$ Metabolites

This is the chemically balanced equation for the degradation of drug A. Rate of the reaction (R) is depend on the concentration of drug A. What is the order of the above reaction?

(02 marks)

2.3 Write the half-life ($t_{1/2}$) equation for the above order reaction in 2.2. Define the terms.

(02 marks)

2.3 How many $t_{1/2}$ s would it take to decompose 99.9% of any initial concentration of a drug ? Assume it follows first order kinetics. (10 marks)

03.

500 mg of a drug was administered by rapid IV injection to a 70kg healthy adult male. Blood samples were taken periodically after the administration of the drug and the plasma fraction of each sample was assayed for the drug. Following data were obtained.

Time (hours)	Drug concentration (mg/ L)
0.5	20.6
1	13.4
2	7.3
3	5.0
4	3.7
6	2.2
8	1.4
10	0.82
12	0.50

3.1 Plot the graph in a provided graph paper. (04 marks)

Following are useful equations and their terms have usual meanings.

$$D_p = D^0_p \left(\frac{k_{21} - a}{b-a} e^{-at} + \frac{k_{21} - b}{a-b} e^{-bt} \right)$$

$$D_t = D^0_p \left(\frac{k_{12}}{b-a} e^{-at} + \frac{k_{12}}{a-b} e^{-bt} \right)$$

$a+b = k_{12}+k_{21}+k$

$ab = k_{21} * k$

$C_p = A e^{-at} + B e^{-bt}$

$A = Do (a-k_{21}) / \{V_p(a-b)\}$

$B = Do (k_{21}-b) / \{V_p(a-b)\}$

$k = ab(A+B) / \{Ab+Ba\}$

$k_{12} = AB(b-a)^2 / \{(A+B)(Ab+Ba)\}$

$k_{21} = (Ab+Ba)/(A+B)$

3.2 Calculate the elimination rate constant of elimination phase of the drug. (03 marks)

3.3 Plot the linear graph for the distribution phase of the drug. (05 marks)

3.4 State the equation for the whole graph by using calculated data and show its validity at t=4 hour. (03 marks)

04.

"An approval for a new drug is requested through a new drug application"

4.1 What is meant by 'bioequivalence studies'. (03 marks)

4.2 State three (03) main areas where bioequivalence studies asses. (03 marks)

4.3 Briefly explain the use of bioequivalence studies in generic drug development. (08 marks)

4.4 Explain 'relative bioavailability'. (01 mark)