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

BACHELOR OF PHARMACY HONOURS
BPU4140- BIOPHARMACEUTICS AND PHARMACOKINETICS
FINAL EXAMINATION
DURATION: TWO HOURS

DATE: 16th SEPTEMBER 2020   TIME: 01.30 P.M. – 03.30 P.M.

INDEX NO: ………………………………..

IMPORTANT INSTRUCTIONS

- Write your Index Number in the space provided.

- Answer **All** questions.

- Do **NOT** remove any page/part of this question paper from the examination hall.

- Do **NOT** keep unauthorized material, including mobile phones and other electronic equipment, with you during the examination.

- Use non-programmable calculators.

INFORMATION TO CANDIDATES

- This question paper consists of **04 pages** with **04 Structured Essay Questions.**

- **Structured Essay Questions:** Write answers in the provided booklet/ sheets.

Structured Essay Questions (100 marks)

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 the drug X?   (04 marks)

1.2 Write the equation for renal clearance and define its terms.   (04 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.   (10 marks)

b. Determine the renal clearance of the drug.   (07 marks)

02.

2.1 What is meant by the half-life ($t_{1/2}$) of a drug? (04 marks)

2.2 $$A \longrightarrow \text{Metabolites}$$
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?

(03 marks)

2.3 Write the half-life ($t_{1/2}$) equation for the above order reaction in 2.2. Define the terms. (04 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. (14 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. (05 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.   (05 marks)

3.3 Plot the linear graph for the distribution phase of the drug.   (08 marks)

3.4 State the equation for the whole graph by using calculated data and show its validity at t=4 hour.   (07 marks)

04.

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

4.1 What is meant by "bioequivalence studies".   (04 marks)

4.2 State three (03) main areas where bioequivalence studies asses.   (06 marks)

4.3 Briefly explain the uses of bioequivalence studies in generic drug development.   (12 marks)

4.4 Explain 'relative bioavailability'   (03 marks)