THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF PHARMACY
THE ACADEMIC YEAR 2022/ 2023 – SEMESTER I

BACHELOR OF PHARMACY HONOURS
FMU6301 – BIOPHARMACEUTICS – LEVEL 6
FINAL EXAMINATION
DURATION: THREE (03) HOURS

DATE: 30TH MARCH 2023 TIME: 1.30 P.M. – 4.30 P.M.

Part B – 02 Short Answer Questions (20 Marks)

1.

1.1 Define the term "order of a reaction". (01 mark)

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1.2 State the typical equation which represents the plasma drug concentration of a drug following a two-compartment open model. Define its terms. (04 marks)

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1.3 List three (03) biopharmaceutical factors affecting oral drug absorption. (03 marks)

I. .....

II. .....

III. .....

1.4 State two (02) causes for exhibiting non-linear pharmacokinetics after the drug administration. (02 marks)

I. .....

II. .....

Index No.....

2.

2.1 Define the term bioavailability. (02 marks)

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2.2 State four (04) advantages of IV infusions. (04 marks)

I. .....

II. .....

III. .....

IV. .....

2.3 A drug is given as a constant IV infusion to a patient. The desired steady-state drug concentration (10 µg/ mL) is reached after 1 hour of drug initiation. 3 hours after that, the infusion pump was removed. Within the next 2 hours, the drug was completely eliminated from the body. Draw a graph to represent the above data. (04 marks)

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Part C – 04 Structured Essay Questions (60 Marks)

1.

1.1 Describe the one-compartment open model for IV bolus drug administration. (04 marks)

1.2 A single IV bolus dose of an antibiotic was given to a 55 kg woman at a dose level of 20 mg/ kg. Blood samples were collected periodically and assayed for the parent drug. The following data were obtained.

Time (hours)	Cp (µg/ mL)
0.25	4.2
0.5	3.5
1	2.5
2	1.25
4	0.31
6	0.08

1.2.a Draw the plasma drug concentration vs time graph using suitable graph paper. (05 marks)

1.2.b Calculate the values for k, $t_{1/2}$, and V_d for this drug. (03 marks)

1.2.c This antibiotic is not effective at a plasma concentration of less than 2 µg/ mL. What is the duration of action of the drug? (03 marks)

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2. An antibiotic is given as a constant IV infusion to a patient. Assume the drug kinetics follow one compartment open model.

2.1 Write the typical equation which can be used to calculate plasma drug concentration before it reaches the steady state drug concentration (Cp_{ss}). Define its terms. (03 marks)

2.2 How many half-lives ($t_{1/2}$) does it take to reach 95% of steady-state plasma drug concentration (Cp_{ss})? (05 marks)

2.3 The desired steady-state concentration, volume of distribution, elimination rate constant, and salt factor of the drug are as follows.
$Cp_{ss} = 10\ \mu g / mL$, $S = 1$, $V_d = 10\ L$ and $k = 0.2\ h^{-1}$
Calculate the infusion rate constant (R) needed to maintain this concentration? (04 marks)

2.4 Assume the patient has a uremic condition and the elimination rate constant decreased to $0.1\ h^{-1}$. Determine the new R to maintain the same steady-state concentration? (03 marks)

3.

3.1 Define drug product performance (DPP). (02 marks)

3.2 List three (03) types of biopharmaceutical considerations in the design of a drug product. (03 marks)

3.3 10 g of a drug was dissolved in 100 mL of water. The solution was stored at room temperature. Samples from the solution were removed periodically and assayed for the drug. The data are given in the following table.

Time (min)	Concentration (mg/ mL)
4	70
10	58
20	42
30	31
60	12
90	4.5
120	1.7

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3.3.a Draw the graph on suitable graph paper. (05 marks)

3.3.b What is the order of the rate of decomposition of the drug? (01 mark)

3.3.c What is the rate of decomposition of the drug? (02 marks)

3.3.d Give the equation for the line that best fits the experimental data. (02 marks)

4.

4.1 What is drug clearance? (02 marks)

4.2 Rate method and sigma minus method are used to study the excretion of a drug/ its metabolites in urine after drug administration. Compare these two methods. (04 marks)

4.3 10 mg IV dose of a drug was administered to a 70 kg male patient. Urine was collected at various times over 12 hours. Plasma drug concentrations were measured at the midpoint of each collection period. The data is given in the following table.

Urine data			Plasma data	
Collection period (hours)	Volume of urine (mL)	Urinary concentration ($\mu g\ mL^{-1}$)	Time (h) (midpoint of urine collection period)	Plasa drug con./Cp ($\mu g\ L^{-1}$)
0-1	250	20	0.5	200
1-3	150	25	2	150
3-5	50	50	4	100
5-10	250	05	7.5	50

4.3.a Calculate the rate of drug excretion for each urine collection period. (02 marks)

4.3.b Plot the graph, rate of drug excretion vs Cp. (05 marks)

4.3.c Calculate the renal clearance. (02 marks)