

THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF PHARMACY
ACADEMIC YEAR 2020/2021 – SEMESTER I



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

DATE: 08TH MARCH 2022

TIME: 9.30 A.M. – 12.30 P.M.

Part B – Short Answer Questions (20 marks)

I.

1.1 What is the meaning of drug clearance?

(02 marks)

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1.2 Write the typical equation which can be used to calculate plasma drug concentration at any time point in two compartment model. Define its terms.

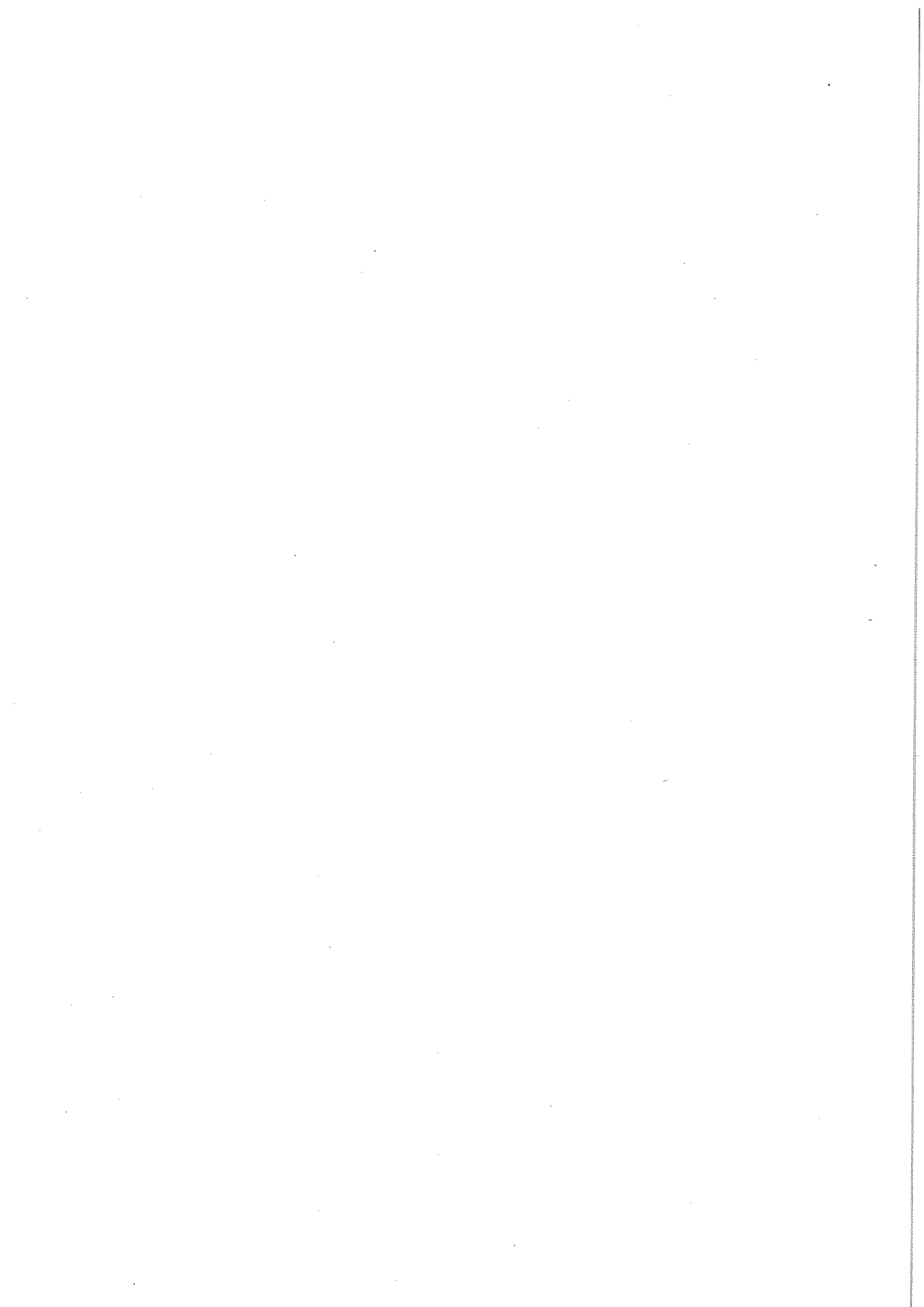
(04 marks)

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1.3 State four (04) advantages of IV infusions.

(04 marks)

I.
II.
III.
IV.



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2.

2.1. Six IV multiple doses of drug "X" were given to a patient eight hourly. One dose was 10 mg/L. Sixth dose was the $C_{pmax,ss}$ and it was between 20 mg/L and 25 mg/L. Draw a graph to show the above data. (08 marks)

2.2. Briefly describe how you would obtain plasma level time curves of a drug? (02 marks)

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Part C – 04 Structured Essay Questions (60 marks)

1.

1.1 State the meaning of rate of a reaction? (01 mark)

1.2 State four (04) assumptions that need to be considered when one compartment open model is applied. (02 marks)

1.3 Write four (04) significance of volume of distribution of a drug. (02 marks)

1.4 A 50 kg woman was given a single IV dose of an antibiotic at a dose of 6 mg/kg. Blood samples were collected at various time intervals and the plasma drug concentration was determined as given below.

Time (hours)	C_p (mcg/mL)
0.25	8.21
0.5	7.87
1	7.23
3	5.15
6	3.09
12	1.11
18	0.40

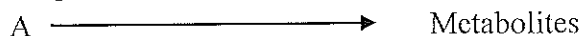
- a. Draw the plasma drug concentration vs time graph using a suitable graph paper. (05 marks)
- b. Calculate the values for V_d , k and $t_{1/2}$? (03 marks)
- c. This antibiotic is not effective if the C_p is less than 2 mcg/mL. Determine the duration of action of the drug? (02 marks)

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2.

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

2.2 The chemically balanced equation for the degradation of drug "A" is given below.



The rate of the reaction (R) of drug "A" depends on its concentration. State the order of the above reaction (02 marks)

2.3 Write the half-life ($t_{1/2}$) equation for the above reaction given in 2.2. Define the terms. (02 marks)

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

3.

3.1 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. Determine the effective dose for a 5 mg tablet of drug X? (03 marks)

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

3.3 Drug "A" is completely eliminated by renal excretion. 10 mg dose of it was administered intravenously 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 the 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)	C _p (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 suitable graph using a graph paper. (06 marks)

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

4.

A 10 g of a new antibiotic drug was dissolved in 100 mL of distilled water and placed the solution at room temperature. At various time intervals, samples were removed from the solution and the drug concentrations were determined. Following table represent the data.

Antibiotic concentration (mg/mL)	Time (hr)
100.00	0
50.00	4
25.00	8
12.50	12
6.25	16
3.13	20
1.56	24

- 4.1 Draw the graph in a suitable graph paper. (06 marks)
- 4.2 What is the order of rate of decomposition of the drug? (02 marks)
- 4.3 What is the rate of decomposition of this antibiotic? (03 marks)
- 4.4 Give the equation for the line that best fits the experimental data. (02 marks)
- 4.5 Calculate the drug concentration when $t=36$ hr. (02 marks)