THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF PHARMACY
THE ACADEMIC YEAR 2023/2024 – SEMESTER II

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

DATE: 22ND OCTOBER 2024 TIME: 9.30 A.M. – 12.30 P.M.

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Part B- Short Answer Questions (20 marks)

1.

1.1 List two (02) examples of plasma proteins that can bind drugs. (02 marks)

I.....

II.....

1.2 List two (02) factors influencing drug-protein binding. (02 marks)

I.....

II.....

1.3 State the effect of drug-plasma protein binding on the apparent volume of distribution. (03 marks)

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1.4 State how drug-protein binding affects the elimination of drugs. (03 marks)

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2.

2.1 Define the term drug clearance. (02 marks)

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2.2 List two (02) ways by which drugs can be accumulated in the body. (02 marks)

I.....

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II.....

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III.....

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2.3 List two (02) factors affecting drug distribution. (02 marks)

I.....

II.....

2.4 State the two (02) phases of biotransformation reactions. (04 marks)

I.....

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II.....

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Part C – Structured Essay Questions (60 marks)

1.

1.1 List two (02) body fluids that can be used to measure free drug concentration. (02 marks)

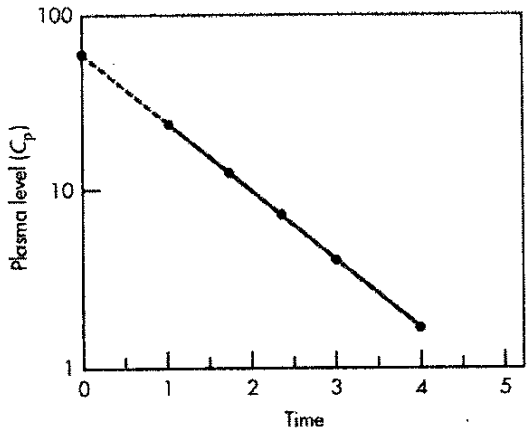
1.2 State the four (04) pharmacokinetic processes. (04 marks)

1.3 Briefly explain the following terms using plasma drug concentration versus time curve for orally administered drugs.

1.3.1. Minimum effective concentration of a drug
1.3.2. Minimum toxic concentration of a drug
1.3.3. Therapeutic window (09 marks)

2.

2.1 In an experiment, drug B was given as an intravenous bolus to a healthy male of 60 kg body weight at a dose of 5 mg/kg, and the plasma drug concentration (mg/L) versus time (hrs) curve was plotted. The data were plotted in a semi-logarithmic graph as follows.



The equation for the graph is, y= -0.125x + 80. (Note: the slope was calculated $\log_{10}$ based on values of the y-axis). Assuming, the drug follows a compartment open model and the elimination process follows first-order kinetics, calculate the following pharmacokinetic parameters of the drug B.

2.1.1 Elimination half-life ($t_{1/2}$) (02 marks)
2.1.2 Apparent volume of distribution (V_d) (02 marks)
2.1.3 Clearance (02 marks)

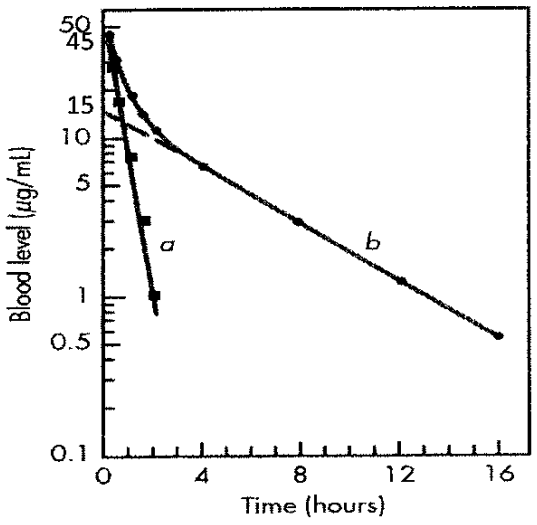
2.2 Drug B mentioned above in 2.1 was experimented with as a multiple dosage regime where repetitive injections of drug B were given 3 hourly. Calculate the following at the steady state.

2.2.1 The fraction of drug remaining in the body	(02 marks)
2.2.2 Maximum plasma drug concentration	(02 marks)
2.2.3 Minimum plasma drug concentration	(02 marks)
2.2.4 Average plasma drug concentration	(03 marks)

3. Drug C was administered to a healthy male of 60 kg body weight at a dose of 10 mg/kg and plasma drug concentration (Cp) was measured. Data were plotted in a semi-logarithmic graph as follows. The curve resulted can be represented by following the biexponential equation;

$$Cp = Ae^{-\alpha t} + Be^{-\beta t}$$

Drug C was shown to follow a two-compartment open model and its pharmacokinetic processes follow first-order kinetics.



The intercept of the elimination curve (curve b) is 15 and the slope is 0.09
The intercept of the residual concentration curve (curve a) is 45 and the slope is 0.78.
(Note: The values from the y-axis were considered as $\log_{10}$ based on the calculation of slopes)

3.1 Write the biexponential equation for the above plot using appropriate values.	(06 marks)
3.2 Calculate the elimination half-life of Drug C	(02 marks)
3.3 Calculate the distribution half-life of Drug C	(02 marks)
3.4 Calculate the apparent volume of distribution at the central compartment.	(05 marks)

4.

4.1 Define the following terms.

4.1.1. Bioavailability

4.1.2. Bioequivalence (04 marks)

4.2 What is meant by the term biowaiver? (04 marks)

4.3 Drug A is formulated in three different dosage forms an oral tablet, oral solution, and IV injection. In an *in vivo* experiment, the oral tablet, oral solution, and IV injection at doses of 100 mg, 100 mg, and 25 mg, respectively were administered separately for health subjects, and plasma drug concentration versus time curve was plotted.

The area under the curve (AUC) values of plasma drug concentration versus time curves resulted for oral tablet, oral solution, and IV injection were 45 µg.h/L, 40 µg.h/L, and 15 µg.h/L respectively.

4.3.1 Calculate the absolute bioavailability of oral tablets. (03 marks)

4.3.2 Calculate the relative bioavailability of oral tablet compared to oral solution. (04 marks)