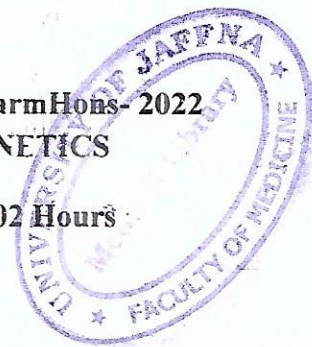


**UNIVERSITY OF JAFFNA, SRI LANKA**  
**FACULTY OF ALLIED HEALTH SCIENCES**  
**FOURTH YEAR SECOND SEMESTER EXAMINATION IN BPharmHons- 2022**  
**PHABP 4212 BIOPHARMACEUTICS AND PHARMCOKINETICS**

**Date: 13/08/2024**

**Time: 02 Hours**



**Answer All Six (06) Questions**

1.

- 1.1 Write the definition of "critical-dose drugs". (20 Marks)
- 1.2 List three (03) objectives of medication therapy management. (20 Marks)
- 1.3 Briefly explain four (04) age related changes that influence the pharmacokinetics in older adults. (60 Marks)

2.

A patient weighing 80 kg was given an antibacterial drug of a single intravenous bolus dose of 8 mg/kg. Blood samples were collected at various time intervals from this patient after dosing. The concentration of the drug ( $C_p$ ) was determined in the plasma fraction of each blood sample. Answer the following questions based on the data provided in the following table.

Time	Plasma concentration of the drug ( $C_p$ )
0.25 hours	12.00 $\mu\text{g/mL}$
0.50 hours	7.00 $\mu\text{g/mL}$
1.00 hours	4.00 $\mu\text{g/mL}$
3.00 hours	2.00 $\mu\text{g/mL}$
6.00 hours	1.00 $\mu\text{g/mL}$
12.0 hours	0.50 $\mu\text{g/mL}$

- 2.1 Plot the data on the standard semi-log graph. (40 Marks)
- 2.2 Calculate following pharmacokinetic parameters of this patient.
- 2.2.1 Apparent volume of distribution ( $V_D$ ) (20 Marks)
- 2.2.2 Elimination constant ( $k$ ) (10 Marks)
- 2.2.3 Half-life ( $t_{1/2}$ ) (10 Marks)
- 2.3 Calculate the duration of action of this antibacterial following a single intravenous bolus dose considering that this antibacterial agent is not effective at a plasma concentration less than 3 mg/mL. (10 Marks)
- 2.4 How long would it take for 99.9% of this drug to be eliminated from this patient's body after administration of the drug as an intravenous bolus in the dose mentioned? (10 Marks)

3. A 40-year-old, patient with normal renal function and weighing 70 kg is to be given a drug by intravenous infusion. The elimination half-life of this drug is 7 hours and the apparent volume of distribution ( $V_D$ ) is 23.1% of body weight. The desired steady-state plasma concentration for this antibiotic is 10  $\mu\text{g/mL}$ . Answer the following questions assuming first-order pharmacokinetic process.
- 3.1 Assuming no loading dose, how long would it take to reach 99% of the steady-state concentration, after the start of the intravenous infusion? (10 Marks)
- 3.2 Calculate the loading dose for this patient. (15 Marks)
- 3.3 Calculate the proper infusion rate for this patient. (25 Marks)
- 3.4 Calculate the total body clearance of this drug (20 Marks)
- 3.5 If the patient suddenly develops partial renal failure, comment on the time it takes for a new steady-state plasma concentration to be established? (10 Marks)
- (Assume that 99% of the steady-state plasma concentration is a reasonable approximation)
- 3.6 If the total body clearance of this patient declined 50% due to partial renal failure, calculate the new infusion rate would you recommend to maintain the desired steady-state plasma concentration of 10  $\text{mg/mL}$ . (20 Marks)
4. Write a short explanatory note on the following:
- 4.1 Non-compartmental model (40 Marks)
- 4.2 Apparent volume of distribution (30 Marks)
- 4.3 Drug elimination half-life (30 Marks)

5. The manufacturer of an immediate release tablet of medicine X. The tablets are produced in two strengths of 100 mg and 50 mg.
- 5.1 Briefly justify conducting a bioequivalence study for the 100 mg tablet product. (30 Marks)
- 5.2 Briefly explain two (02) factors that **disqualify** conducting a biowaiver study for the lower strength 50 mg tablet product. (30 Marks)
- 5.3 Write four (04) reasons to restrict participants taking medicines other than the study medicines during a bioequivalence study. (40 Marks)
6. Briefly explain possible reasons for the following,
- 6.1 The drug dissolution rate of a tablet is increased when the granules used for tableting were milled. (40 Marks)
- 6.2 The absorption of a drug is increased when it was taken orally with food. (30 Marks)
- 6.3 Patients are likely to experience drug induced toxic side-effects during liver failure. (30 Marks)

