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 µg/mL
0.50 hours	7.00 µg/mL
1.00 hours	4.00 µg/mL
3.00 hours	2.00 µg/mL
6.00 hours	1.00 µg/mL
12.0 hours	0.50 µg/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 µg/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 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)**