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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES

DEPARTMENT OF PHARMACY

FOURTH BPHARM PART II EXAMINATION - SEPTEMBER 2023

PH 4242 BIOPHARMACEUTICS – SEQ PAPER

TIME: TWO HOURS

INSTRUCTIONS

- There are **four** questions in part **A** and **B** in this SEQ paper.
- Answer all questions.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

PART A

1.

1.1. Write three factors that affect the diffusion of a medicine across a capillary membrane. (***15 marks***)

1.2. List five factors affecting the accumulation of a medicine in body tissues. (***20 marks***)

1.3. Medications given in multiple dosage regimen could cause accumulation followed toxicity in patients with renal impairment. Explain the statement. (***25 marks***)

1.4. Mr. KG (50-year-old, 70 Kg body weight) was prescribed 800mg of medicine P. The plasma protein binding of the medicine P is 20%, and tissue binding is 40%.

1.4.1. If the plasma volume is 18 L and tissue volume is 12 L calculate V_{app} of P. (***20 marks***)

1.4.2. Considering 90% absorption, calculate the plasma concentration of P at the steady state. (***20 marks***)

2.

2.1. Draw the time vs plasma concentration graph to show the elimination characteristics of a typical medicine that follows zero order kinetics. Briefly describe important characteristics of zero order kinetics elimination process. (***30 marks***)

2.2. Pharmacokinetic studies conducted on a newly developed anticancer medicine (A) revealed that the drug follows first order elimination kinetics.

Volume of distribution	250 mL/kg
Elimination rate constant	0.24 h^{-1}

2.2.1. Determine the elimination half-life of A. (***10 marks***)

2.2.2. Calculate the total body clearance of this medicine in a 65 kg weight male patient. (***10 marks***)

2.2.3. The medicine A eliminates via renal and hepatic excretion. If the renal excretion rate constant is 0.11 h^{-1} calculate the renal clearance of A. (***15 marks***)

2.2.4. What is the fraction of the medicine metabolized by hepatic enzymes? (***15 marks***)

2.2.5. Calculate the hepatic extraction ratio of the medicine A in a patient whose effective hepatic blood flow is 3 Lh^{-1}. (***20 marks***)

PART B

3. 200 mg of drug D was administered by rapid IV injection to an adult male (80 kg body weight). After the injection, blood samples were frequently withdrawn, and the plasma dug concentration was measured. The results obtained from this analysis is given in below table. Plot the graph and write the equation which best describes it. (***100 marks***)

Time (hrs)	Plasma concentration (µg/ml)
0.25	43
0.5	32
1	20
2	11
4	6.5
8	2.8
12	1.2
16	0.52

4. A new antibiotic drug was given in a single intravenous bolus of 4 mg/kg to five healthy male adults ranging in age from 23 to 38 years (average weight 75 kg). The pharmacokinetics of the plasma drug concentration–time curve for this drug fits a one-compartment model. The equation of the curve that best fits the data is $Cp = 78e^{-0.46t}$. Calculate the following (assume units of µg/mL for C_p and hour for t):

4.1. Calculate the $t_{1/2}$. (***20 marks***)

4.2. Calculate the V_D. (***20 marks***)

4.3. What is the plasma level of the drug after 4 hours? (***20 marks***)

4.4. How much drug is left in the body after 4 hours? (***20 marks***)

4.5. Assuming the drug is no longer effective when levels decline to less than 2 µg/mL, determine when should you administer the next dose? (***20 marks***)

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