

※ 考生請注意：本試題不可使用計算機。請於答案卷(卡)作答，於本試題紙上作答者，不予計分。

1. What is the expected initial plasma concentration after an intravenously bolus dose of 20 mg/kg of a drug to a 40-kg patient? The apparent volume of distribution (V) of the drug is 0.5 L/kg. (6%)
(a) 4 mg/L (b) 40 mg/L (c) 400 mg/L (d) 800 mg/L
2. Following oral administration of a drug, only 60% of the dose is released from the dosage form and absorbed through the GI tract. Half of the drug absorbed through the GI tract is metabolized by enzymes in the enterocytes before entering the portal vein. After entering the liver, the drug is highly metabolized with only 20% escaped from extraction and reaches the systemic blood circulation. What is the oral bioavailability of this drug? (6%)
(a) 0.06 (b) 0.12 (c) 0.2 (d) 0.8
3. A 60-kg, 50-year-old man was treated with theophylline. The desired steady-state concentration is 10 mg/L. The volume of distribution is 0.5 L/kg and the oral bioavailability is 60% ($F=0.6$). What would be the most appropriate oral loading dose? (6%)
(a) 180 mg (b) 250 mg (c) 300 mg (d) 500 mg
4. A 50 kg patient was receiving intravenously 8 mg/kg *Drug X* every eight hours (q8h). His mean steady-state plasma concentration was 5 mg/L. What was the clearance of *Drug X* in this patient? (6%)
(a) 10 kg/L (b) 10 L/hr (c) 50 mg/hr (d) 80 L
5. The maintenance dose of a drug is determined by its (6%)
(a) elimination half-life. (b) clearance. (c) molecular weight. (d) volume of distribution.
6. A basic *Drug B* is used as an antifungal in the treatment of vaginal infections. Its conjugate acid (HB^+) has a pK_a of 6.4. In pre-menopause female the vaginal secretions have a pH of 4.5. In post menopause females, however, the pH of vaginal secretions is 7.0. It is advantageous in the treatment of vaginal infections if the drug is concentrated in the secretions rather than absorbed into vaginal wall. (6%)
The drug will probably be less effective
(a) in pre-menopause females as it will stay neutral in the vaginal secretions.
(b) in pre-menopause females as it will stay protonated in the vaginal secretions.
(c) in post-menopause females as it will stay neutral in the vaginal secretions.
(d) in post-menopause females as it will stay protonated in the vaginal secretions.

7. Describe the pharmacokinetics parameters that are commonly used to assess the bioequivalence of two drug products. Discuss the principles behind bioequivalence testing. (14%)
8. Describe the dosage form of emulsion. Discuss the major factors affecting the formulation of emulsion and its stability. (10%)
9. What penetration pathways may a drug molecule take during its percutaneous absorption processes? Discuss how the physicochemical properties of a drug influence its penetration through different pathways. (10%)
10. Describe two controlled-release mechanisms for the design of solid dosage forms. One of them can be divided or triturated for clinical use, but the other is not recommended to do so. (10%)
11. Describe pharmacopeia sterilization methods and pyrogen test for injectables. (10%)
12. A new chemical entity of MW 350 was selected as a lead for pharmaceutical development. It is practically insoluble in water and light-sensitive. Discuss possible strategies for oral delivery of the new drug. (10%)