

※ 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。

- Describe four possible chemical reactions for drug degradation. For each mechanism, give one drug example and explain the approaches to improve its stability. (12%)
- Describe five sterilization methods for sterile preparations and compare their advantages and disadvantages. (15%)
- Pharmacokinetics of a drug follows one compartment model in the body with elimination half-life of 2 hour, volume of distribution of 10 L/60 kg, and therapeutic window of 0.4-0.6 $\mu\text{g/mL}$. A pharmaceutical company intended to develop the drug's transdermal patch system. Three formulations were designed with *in vitro* characteristics as follows:

Formulation	A	B	C
Release rate ($\mu\text{g/h/cm}^2$)	120	80	160
Skin penetration rate ($\mu\text{g/h/cm}^2$)	40	60	80

If protein binding is not concerned,

- What would be the approximate target skin penetration rate of the transdermal patch? (4%)
 - Which formulation presents the best controlled-release effect, and why? (4%)
 - Which would be the optimal formulation if a patch size within $5 \times 5 \text{ cm}^2$ is desired? (4%)
- Explain the formulation strategies that may be employed for oral delivery of BCS class II drugs. (11%)
 - Describe the mechanism of competitive, noncompetitive and uncompetitive enzyme inhibition. (12%)
 - Describe the effects of drug metabolic enzymes and transporters on the four classes of BDDCS (Biopharmaceutics Drug Disposition Classification System) drugs. (16%)
 - What are the main pharmacokinetic parameters that influence (1) time for peak drug concentration and (2) peak drug concentration? (10%)
 - The plasma concentration (C_p , mg/L)-time (t , hr) profile of a drug following a single intravenous bolus of 600 mg is best described by the equation $C_p = 75e^{-0.231t}$. Estimate (1) the elimination half-life, (2) the volume of distribution and (3) the plasma drug concentration after 6 hr. (12%)