

1. Choose the best answer for each question (3% each)

(1). The content uniformity test for tablets is used to ensure which of the following qualities? (A)Bioavailability (B)Dissolution (C)Disintegration (D)Potency (E)Purity

(2). The Shells of soft gelatin capsules may be made elastic or plastic-like by the addition of (A)hydroxypropyl methylcellulose (B)lactose (C)polyethylene glycol (D)povidone (E)sorbitol

(3) The pH of a buffer system can be calculated by using the (A)Arrhenius equation (B)Fick's law (C)Henderson-Hasselbach equation (D)Michaelis-Menten equation (E)Noyes Whitney equation

(4) The equation that describes the rate of drug dissolution from a tablet is known as (A)Arrhenius equation (B)Fick's law (C)Henderson-Hasselbach equation (D)Michaelis-Menten equation (E)Noyes Whitney equation

(5). Which of the following equation is used to predict the stability of a drug product at room temperature from experiments at accelerated temperatures? (A)Arrhenius equation (B)Fick's law (C)Henderson-Hasselbach equation (D)Michaelis-Menten equation (E)Noyes Whitney equation

(6) The rate of drug absorption is most rapid when the drug is formulated as a (A)compressed tablet (B)hard gelatin capsule (C)soft gelatin capsule (D)solution (E)suspension

2. Drug X has a molecular weight of 300 g/mole, an apparent volume of distribution of 2 L/kg, and an elimination half-life of 6 hours. Drug X is normally given at 15 mg four times a day. Suggest an approach for designing a 12-hour zero-order release product. (12%)

(1). Calculate the desired zero-order release rate.

(2). Calculate the concentration of the drug in an osmotic pump type of oral dosage form that delivers 0.5 mL/hr of fluid.

(背面仍有題目,請繼續作答)

3. If *in vitro* drug dissolution and/or release studies for an oral solid dosage form does not correlate with the bioavailability of the drug *in vivo*, why should the pharmaceutical manufacturer continue to perform *in vitro* release studies for each production batch of the solid dosage form? (10%)

4. Describe the methods for assessing bioavailability and bioequivalence. (10%)

5. Explain the role of aqueous solubility in the design of drug dosage forms. Discuss the approaches to improve it. (10%)

6. Describe and discuss with examples the pharmaceutical applications of polymers. (10%)

7. Ointment is one of the major topical formulations to be applied onto the skin to directly treat cutaneous disorders, or the cutaneous manifestations of general diseases.
 - (1) Write down the equation which governs the release of the active ingredient from the ointment base. Explain the meanings of each denotation. (10%)
 - (2) Write down the equation which governs the skin penetration rate of the active ingredient from the ointment base. Explain the meanings of each denotation. (10%)
 - (3) Describe general classification of ointment bases. How to choose appropriate bases for a specific drug? (10%)