系所組別： 臨床藥學與藥物科技研究所乙組

考試科目： 藥劑學

考試日期：0220，節次：1

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1. Describe and explain the following terms (16%):

(1) Generic Biologics (4%)

(2) Genetic Polymorphism (4%)

(3) Noyes-Whitney Equation (4%)

(4) Similarity Factor (4%)

2. Write down the equation which governs the drug permeability through skin. Explain the role of molecular size and lipophilicity of a drug on its skin permeability. (10%)

3. More and more new drugs discovered belong to the poorly soluble compounds. What are the pharmacopeial classifications of solubility? Describe the strategies to improve the aqueous solubility of those drugs. Explain the role of aqueous solubility in the design of drug dosage forms. (20%)

4. What are the pharmacopeial requirements for content uniformity test of tablets? Describe the detailed procedures to perform the test. (10%)

5. A study was conducted in rat to obtain the pharmacokinetic profile of a weak acidic drug (pKa = 4.5). Blood samples were withdrawn from the animal at different time points. Describe the general extraction procedures to purify the blood samples in order to analyze their plasma concentrations using high performance liquid chromatography. (10%)

(背面仍有題目,請繼續作答)

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6. A mobile phase consists of organic solvents and acetate buffer is used in a high performance liquid chromatographic method to quantify the plasma concentrations of an investigational new drug. Calculate the amount of sodium acetate to be added to 100 cm^3 of a 0.1 mol/L acetic acid solution to prepare a buffer of pH 5.26. The pKa of acetic acid is 4.76, and the molecular weight of sodium acetate is 82.03 g/mol. Note that $\sqrt{2}$ =1.414, $\sqrt{3}$ =1.732, $\sqrt{5}$ =2.236. (10%)

7. A new drug was given in a single intravenous bolus of 10 mg/kg to a rat weighted 0.3 kg. The kinetics of the plasma-drug concentration (C, mg/L)-time (t, hr) curve for this drug fits a one-compartment model. The equation of the curve that best fits the data is (14%)

$$C = 10\ e^{-0.462t}$$

(1) Estimate the elimination half-life, volume of distribution and clearance of the drug. (9%)

(2) What is the plasma concentration of the drug after 6 hr? (5%)

8. Describe the factors that affect the elimination half-life of a drug. (10%)