編號： 463　系所：臨床藥學研究所乙組　　科目：藥劑學

本試題是否可以使用計算機：☑可使用 ，☐不可使用　（請命題老師勾選）

1. Describe and explain the current "Good Manufacturing Practice" standards for pharmaceutical industry in Taiwan. (10%)

2. Discuss the general considerations in the design of appropriate drug delivery systems. (10%)

3. Describe five pharmaceutical mechanisms employed to provide controlled release dosage forms. What are the advantages of those controlled-release forms? (10%)

4. Ten lorazepam tablets with labeled content of 1 mg/tab sampled from a batch were assayed for drug content and the following results obtained by HPLC analysis: 1.02, 0.90, 0.88, 1.10, 0.93, 0.81, 1.15, 1.04, 0.86, 0.91 mg.
   (1) What is the mean lorazepam content? (2%)
   (2) What is the standard deviation of lorazepam content in the analyzed tablets? (2%)
   (3) What is the percent relative standard deviation (%RSD) for this lorazepam tablet analysis? (2%)
   (4) What are the Ch.P 5th requirements for content uniformity of the tablets? (4%)
   (5) Does the batch of lorazepam tablets pass the content uniformity test? (2%)

5. Calculate and answer the following questions:
   (1) What is the pH of 0.1 M acetic acid solution, pKa = 4.76? (2%)
   (2) What is the molar ratio of [salt]/[acid], required to prepare an acetate buffer of pH 5.0? (2%)
   (3) To prepare 1 liter of 0.1 M acetate buffer of pH 5.0, how many moles of acetic acid and sodium acetate are required? (4%)

（背面仍有題目，請繼續作答）

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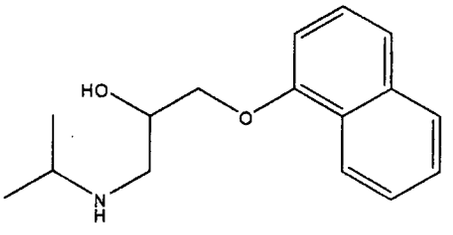
6. Draw a diagram describing a three-compartment model with zero-order absorption and first-order elimination from the central compartment. (10%)

7. Describe and explain the following terms (20%):
   (1) Arrhenius equation
   (2) Fick's law of diffusion
   (3) Henderson-Hasselbach equation
   (4) First -pass effect

8. Drug X has a pKa value of 9.4 and a Log P value of 2.65. The chemical structure of drug X and its pharmacokinetic parameters for an adult male subject (40 yr, 75 kg) are as follows:



Elimination half-life = 3 hr
Unbound fraction in plasma = 0.1
Bioavailability = 0.25
Volume of distribution = 4 L/kg
Fraction excreted unchanged in urine = 0.5%

   (1) Calculate the total body clearance for drug X in this subject.
   (2) Assuming that the subject was prescribed 120 mg drug X every 12 hours for 7 days, estimate the average steady-state concentration of drug X in plasma.
   (3) From the information above, estimate the ratio of ionized form to non-ionized form of drug X in a solution with physiological pH of 7.4.
   (4) Drug X is extracted from plasma by hexane for therapeutic drug monitoring. The pH of plasma samples need to be adjusted in order to maximize the extraction recovery. Which of the following pH would you use for the purpose: (a) pH 1.2, (b) pH 4.6 (c) pH 6.8 (d) pH 9.4 (e) pH 12.　(20%)