編號：E465　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. A technician is requested to construct a standard curve of a compound at concentrations of 0.2, 0.4, 0.6, 0.8 and 1 μg/ml. Describe the procedures to prepare those solutions. The compound is only slightly soluble in water and freely soluble in methanol. An analytical balance with a sensitivity of 1 mg, 50-ml volumetric flasks, and a 1-ml adjustable pipet are available in the laboratory for use. (10%)

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

3. Describe the characteristics of biotechnology-derived therapeutics that require special consideration in designing their delivery systems. What strategies can be used to deliver these drugs? (10%)

4. Describe the theory for skin permeability. From the theory, discuss the properties of a compound that influence its skin permeability. (10%)

5. Why is the knowledge of solubility important for the design of drug dosage forms? Discuss the approaches to improve it. (10%)

6. Describe the factors that affect hepatic clearance of a drug. (8%)

7. Describe and explain the level A, level B and level C *in vitro-in vivo* correlations for the evaluation of modified-release products. (10%)

8. Describe and explain the following terms:
   (a) Absorption window
   (b) Bioequivalence
   (c) Biopharmaceutics Classification System
   (d) Method of residuals
   (e) Physiologic pharmacokinetic model. (20%)

(背面仍有題目,請繼續作答)

9. The pharmacokinetic parameters of a drug X for an adult male subject (42 yr, 80 kg) are:

   Bioavailability = 0.60
   Elimination half-life = 2.31 hr
   Unbound fraction in plasma = 0.16
   Volume of distribution = 1.0 L/kg
   Fraction excreted unchanged in urine = 0.20.

   This subject was prescribed 480 mg drug X every 6 hours for 7 days. From the above data, estimate the following:

   (a) Total body clearance
   (b) Renal clearance
   (c) Average steady-state concentration
   (d) Time to steady state (12%)