1. Explain the role of molecular size and lipophilicity of a drug on its skin permeability. (10%)

2. Design a bioequivalence study of a generic 3-day transdermal fentanyl patch using Duragesic 50 μg/h as the reference. (10%) What parameters and information will be obtained and compared in this bioequivalence study? (10%)

3. Due to the lack of commercially available oral liquid dosage forms for pediatric patients, pharmacists are often requested to prepare extemporaneous compounded powder packets for small children. Describe the procedures to prepare 42 packets of propranolol 2 mg/packet from propranolol 10-mg tablets. (5%) What need to be considered in preparation of such formulations ? (5%)

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

5. Describe the applications of the following excipients in drug formulations. (10%)
(1). Ascorbic acid
(2). Carboxymethylcellulose sodium
(3). Cyclodextrins, their derivatives
(4). Microcrystalline cellulose
(5). Sodium lauryl sulfate

6. Describe the compendial methods of dissolution, according to the current edition of USP. (10%)

7. Explain the Biopharmaceutics Classification System and comment on the correlation of in vitro drug dissolution of immediate release solid oral drug products with in vivo bioavailability for each class. (15%)

8. The pharmacokinetic parameters of a drug X (Molecular weight: 34,000 g/mole) in patients with end-stage renal disease after single intravenous (i.v.) and subcutaneous (s.c.) administrations of 40 units/kg on separate occasions are listed in following Table. The mean weight of the patients was 60 kg. (15%)

(背面仍有題目,請繼續作答)

Route	Maximum concentration (units/L)	Time of Maximum concentration	AUC (units*hr /L)	Terminal Half-Life (hr)
i.v.	420	5 min*	3030	7
s.c.	41	12 hr	1300	16

* time when first blood was taken

(1). Estimate the clearance and volume of distribution of this drug.

(2).Calculate the bioavailability of drug X after s.c. administration in these patients. How might you explain your answer?

(3). The maximum concentration observed was much lower after the s.c. dose. How do you explain this observation?