

※ 考生請注意：本試題不可使用計算機。請於答案卷(卡)作答，於本試題紙上作答者，不予計分。

1. Describe the types, quality and usage of water for pharmaceutical purposes. (10%)
2. Describe the classification, components and methods of preparation for emulsion. (10%)
3. Describe and explain the current "Good Manufacturing Practices" standards for the pharmaceutical industry in Taiwan. (10%)
4. What are pyrogens and endotoxins? Describe pyrogen test and bacterial endotoxin test in the pharmacopoeia. (10%)
5. Describe two modified release mechanisms for the design of oral solid dosage forms. One of them can be divided or triturated for clinical use, but the other is not recommended to do so. (10%)
6. How do efflux transporters in the gastro-intestinal tract affect the rate and extent of absorption of a drug? (10%)
7. Describe the important issues need to be considered when switching a drug from intravenous to oral dosing. (8%)
8. Describe how protein binding affects the volume of distribution, clearance, and half-life of a drug in the body. (12%)
9. From 0 to 4 hr after a 100-mg i.v. bolus dose of drug to a 70-kg, 22-year-old subject, the area under plasma-concentration time curve (AUC) is 5 mg*hr/L. The total AUC is 25 mg*hr/L and the cumulative amount excreted unchanged in urine is 21 mg. The drug has negligible binding to plasma proteins. (20%)
 - (1). What percentage of the administered dose remains in the body as drug at 4 hr? (4%)
 - (2). Calculate the total body clearance. (4%)
 - (3). What is the fraction of the dose that is eliminated by renal excretion? (4%)
 - (4). Calculate the renal clearance of the drug. (4%)
 - (5). State the likely involvement of filtration, secretion, and tubular reabsorption in the renal handling of this drug, given the glomerular filtration rate (GFR) of this subject is 120 mL/min. (4%)