1. Pharmacists are requested by physician's prescription to prepare fortified antibiotics containing 2% amikacin for ophthalmic use, which is not commercially available. Amikacin is available as 500 mg/2 ml vial sterile injection in the hospital. Describe the procedures, considerations and storage in preparation of such formulations. (10%)

2. Ten rosuvastatin tablets with labeled content of 5 mg/tab sampled from a batch were assayed for drug content and the following results were obtained by HPLC analysis: 4.55, 4.30, 5.20, 5.75, 4.05, 4.65, 5.50, 4.40, 4.50, 5.10 mg.

   (1) What is the mean rosuvastatin content? (2%)

   (2) What is the standard deviation of rosuvastatin content in the analyzed tablets? (2%)

   (3) What is the percent relative standard deviation (%RSD)? (2%)

   (4) What is the Ch.P. 6^{th} requirements for content uniformity of tablets? (2%)

   (5) Does the batch of rosuvastatin tablets pass the content uniformity test? (2%)

3. Ointment is one of the major topical formulations to be applied onto the skin to directly treat cutaneous disorders, or the cutaneous manifestations of general diseases.

   (1) What parameters may influence the release of the active ingredient from the ointment? Write down the governing equation and explain the meanings of each denotation. (10%)

   (2) What parameters may influence the skin penetration rate of the active ingredient from the ointment? Write down the governing equation and explain the meanings of each denotation. (10%)

4. Describe two controlled-release mechanisms for the design of solid dosage forms. One of them can be divided or triturated for clinical use, but the other is not recommended to do so. (10%)

(背面仍有題目,請繼續作答)

5. How does drug protein binding affect drug distribution and elimination? (10%)
6. Describe and explain the Biopharmaceutics Classification System. Given example(s) of drugs in each Class. (10%)
7. Describe the methods (compendial and alternative) of dissolution. (15%)
8. The desired plasma level for Drug X is 10 mg/L. The drug has an apparent volume of distribution of 173 mL/kg and an elimination half-life of 2 hr. the kinetics of the drug follow the kinetics of a one-compartment open model. (15%)
   (1) What loading dose and infusion rate would you suggested for a patient with a body weight of 75 kg?
   (2) The patient did not respond very well to drug therapy. Plasma concentration was monitored and found to be 4 mg/L. How would you readjust the infusion rate to increase the plasma drug level to the desired 10 mg/L?
   (3) How long would it take to achieve 90% of steady-state plasma drug levels in this patient assuming no loading dose was given and the apparent volume of distribution was unaltered?