國立成功大學

113學年度碩士班招生考試試題

編　號：266

系　所：臨床藥學與藥物科技研究所

科　目：藥劑學

日　期：0202

節　次：第 1 節

備　註：不可使用計算機

※ 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. Explain the following equation/terminology and their applications in pharmaceutics. (15%)

   (1) Arrhenius equation (5%)

   (2) Colligative properties (5%)

   (3) Zeta potential (5%)

2. Define emulsion and microemulsion. What are the differences between their characteristics and preparation? (10%)

3. What are the three types of non-Newtonian materials? Plot their rheograms (shear rate vs. shear stress) and explain their characteristics. (10%)
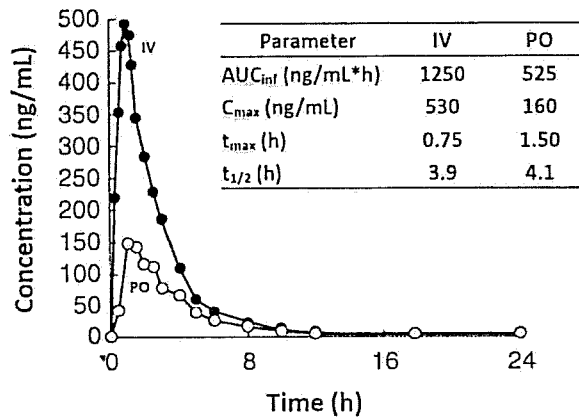
4. A pharmaceutical company designed two megestrol acetate oral suspension formulations. MA-ES is a nanosized formulation, while MAOS is a micronized formulation. The plasma concentrations of megestrol acetate following administration of 625 mg MA-ES or 800 mg MAOS under fed and fasting conditions are compared in the following figures. (15%)
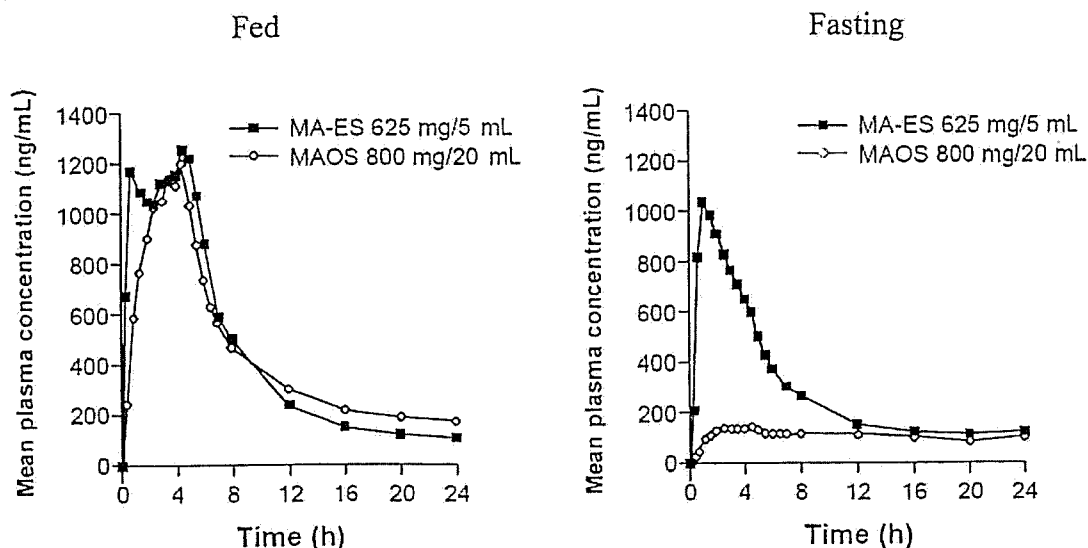
   (1) From the figures, compare the effect of particle size on the plasma concentration-time curve. (7%)

   (2) Using theoretical equations to explain the possible mechanism of particle size influences on plasma concentration-time curve. (5%)

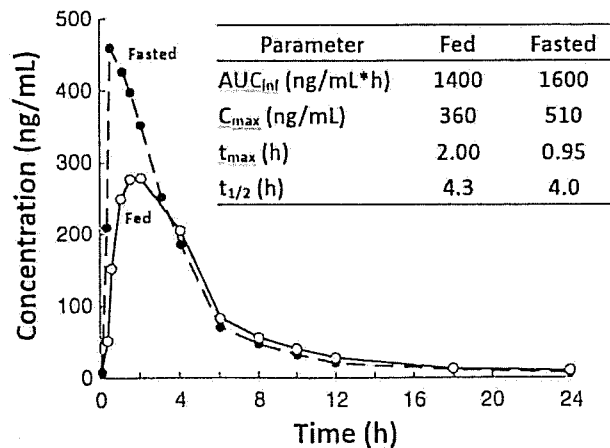   (3) Which BCS class may the drug belong to? (3%)

5. The figure below shows the mean plasma concentration-time profiles of a drug X following oral administration (PO) and a 50-min intravenous infusion (IV) of 50 mg of the drug to healthy subjects. The mean values of kinetic parameters shown in the table are the area under the plasma concentration-time curve extrapolated to infinity (AUC_{inf}), maximal plasma concentration (C_{max}), time to reach maximal plasma concentration (t_{max}), and the terminal half-life ($t_{1/2}$). (20%)

   (1) Determine the absolute bioavailability of the tablets. (5%)

   (2) Determine the clearance (CL) of the drug. (5%)

   (3) Determine the volume of distribution (V) of the drug. (5%)

   (4) Studies with radiolabeled X have shown that 92% of the drug is absorbed, although much less intact drug is detected in plasma. Can you explain this difference? (5%)

Parameter	IV	PO
AUC_{inf} (ng/mL*h)	1250	525
C_{max} (ng/mL)	530	160
t_{max} (h)	0.75	1.50
$t_{1/2}$ (h)	3.9	4.1

6. The figure below shows the mean plasma concentration-time profiles of the drug X after oral administration of 100 mg of the drug to fasted and fed volunteers. (10%)

   (1) Describe the food effect on the oral absorption of drug X. (5%)

   (2) Would you recommend to take drug X with food? Why? (5%)

| Parameter	Fed	Fasted
AUC_{inf} (ng/mL*h)	1400	1600
C_{max} (ng/mL)	360	510
t_{max} (h)	2.00	0.95
$t_{1/2}$ (h)	4.3	4.0

7. The in vitro enzyme kinetics are depicted in the figure below, where V is the rate of drug metabolism and S is the concentration of drug. The enzym kinetics is described by the following equation: (10%)

$$V = \frac{V_{max} \cdot S}{K_M + S}$$

V_{max}: the maximum metabolic rate
K_M : the Michaelis constant

(1) Determin the V_{max} and K_M of the system. (5%)

(2) What is the rate of drug metabolism when the concentarion of drug in the system is 12 mg/L? (5%)
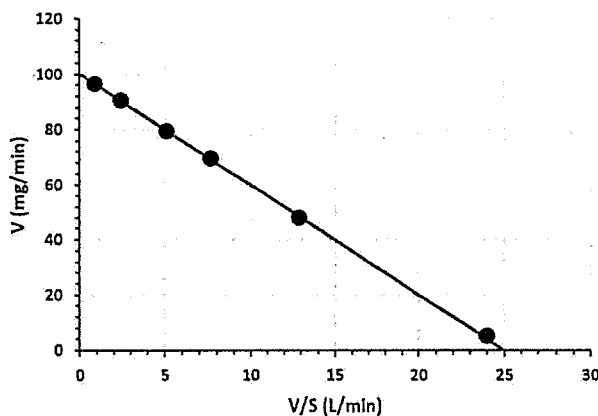
8. Describe the categories of in vitro-in vivo correlation (IVIVC) of drug product performance. (10%)