

I. Choose one of the best answer. (5% each)

1. The difference between peak and trough concentrations is greatest when a drug is given at dosing intervals

- A. about equal to half-life
- B. much longer than half-life
- C. much shorter than half-life
- D. equal to the time it takes to reach peak concentration following a single oral dose
- E. equal to half-life times serum creatinine

2. If an oral capsule formulation of drug A produces a serum concentration time-curve having the same area under the curve as that produced by an equivalent dose of drug A given IV, it can generally be concluded that

- A. the IV route is preferred to the oral route
- B. the capsule formulation is essentially completely absorbed
- C. the drug is very rapidly absorbed
- D. all oral dosage forms of drug A will be bioequivalent
- E. there is no advantage to the IV route

II. Describe the factors that affect oral drug bioavailability. (10%)

III. Based on the pH partition theory, estimate the degree of ionization of a weak acid drug ($pK_a = 3$) in the stomach in the fasted state. (10%)

IV. Describe the important issues/points that should be considered in the evaluation of modified-release products. (10%).

V. In bioequivalence studies, what parameters are generally used to demonstrate the bioequivalence of two drug products? And why? (10%)

VI. Define and describe the two primary pharmacokinetic parameters. (10%)

- (1) Clearance
- (2) Volume of distribution

VII. Explain the differences between transdermal and topical drug delivery. (10%)

VIII. What are the approaches available to evaluate the bioavailability/bioequivalence of topical dermatologic products? (15%)

IX. Describe the characteristics of protein/peptide drugs that require special consideration in designing their drug delivery systems. What strategies can be used to deliver protein/peptide drugs? (15%)