1.請回答下列問題：

(1)列出會影響學名藥和原廠藥生體相等性(bioequivalence)之製劑中所含療效主成分(active pharmaceutical ingredient, API)的 3 項物化性質。(9 分)

(2)製劑中相同療效主成分的不同鹽類(例如：鹽酸鹽、磷酸鹽)或其前驅物(prodrug)不視為 pharmaceutical equivalents 之合理原因。(8 分)

2.根據 Biopharmaceutics Classification System (BCS)，請回答下列問題：

(1)寫出 BCS 分類所依據的 2 個參考指標。(12 分)

(2)寫出 BCS 分類藥品中哪 2 類藥品，其口服給予的速放劑型學名藥在符合一些特定條件下(例如：體外溶離)，是可以免除執行生體相等性試驗 (Biowaiver)。(8 分)

(3)延續(2)，寫出須符合的體外溶離試驗之 pH 值以及溶離%。(8 分)

3. An adult female patient (42 years old, 60 kg) was given 200 mg of a single oral dose. From the literature this drug is about 80% bioavailable and has an apparent volume of distribution of 2.0 L/kg. The elimination half-life is about 6 hours. The absorption rate constant is 0.92 h^{-1}. From this information, calculate:

(1) the time at which maximum plasma drug concentration occurs, t_{max}. (8 分)

(2) the maximum plasma drug concentration, C_{max}. (6 分)

4.請回答下列有關藥品與蛋白或組織結合以及體內分佈之問題：

(1)寫出藥品與組織結合(tissue binding)影響擬似分佈體積(apparent volume of distribution)的相關公式，並說明之。 (10 分)

(2)有一高蛋白結合之藥品 A (> 90%)，與藥品 B 併用時，發現藥品 B 會競爭藥品 A 的蛋白結合位置，致使藥品 A 的蛋白結合率降低，請分析該狀況對藥品 A 在體內藥動藥效可能造成的影響。(10 分)

5. An adult male patient (46 years old, 81 kg) was given 250 mg of drug orally every 8 hours for 2 weeks. From the literature this drug is about 75% bioavailable and has an apparent volume of distribution of 1.5 L/kg. The elimination half-life is about 10 hours. The absorption rate constant is 0.9 h^{-1}. From this information, calculate:

(1) plasma drug concentration C_p at 4 hours after the seventh dose. (8 分)

(2) minimum plasma drug concentration at steady state, $C_{min,\infty}$. (7 分)

(3) average plasma drug concentration at steady state, $C_{av,\infty}$. (6 分)

試題隨卷繳回