1. Show the change of AUC of any drug given orally if the protein binding is increased. Assume that the drug undergoes hepatic first pass metabolism. Hint: F=1-E.

2. A patient (m, 35y, 74 kg) with a subtherapeutic theophylline (5 μg/mL) is admitted to the ICU. Based on average pharmacokinetics parameters (Vd = 0.5 L/kg, t1/2 = 8 h)), calculated an i.v. bolus loading dose and a maintenance dose (i.v. infusion) to increase the level to 15 μg/mL.

3. A drug has a total body clearance of 45 mL/min and a volume of distribution of 35 L. It is completely absorbed. The therapeutic range is 10-20 μg/ml. Make a dosing recommendation for chronic use.

4. A drug tablet [S=0.62, with bioavailability F = 0.7] follows one-compartmental pharmacokinetics and has a total body clearance of 2.5 L/hr and a volume of distribution of 50 L. The oral absorption rate constant ka is 0.4 /hr. Calculate the Tmax, Cmax, AUC if a 250 mg tablet is taken.

5. Please mark the following questions with TRUE (T) or FALSE (F):

a. For an oral drug, it is possible that the metabolite has a shorter terminal half-life than the parent drug.

b. In general, in bioequivalence studies blood is collected for 3 or more terminal half lives.

c. In general, a multiple dose BE study for modified release dosage forms is not recommended.

d. The AUC extrapolated to time infinity for the first dose is equal to steady-state AUC values over a single dosing day at steady state.

e. In general, bioequivalence study is required for all strengths if the strengths are proportionally similar and meet dissolution profile comparison criteria.