PHASE 5128
Homework #2

1. Estimate the half-life of gentamicin in two male patients with normal renal function (CL=0.12 L/min) if their weight is 63 kg and 88 kg, respectively. Assume a height of 6’ for both patients. (2 points)

2. Drug A has the following average pharmacokinetic parameters: CL 0.08 ml/min/kg, Vd 0.16 l/kg, fb 93%, Fren 49%. For a 70 kg, 50 year old male patient with a serum creatinine of 0.7 mg/dl, calculate the necessary intravenous daily dose to produce an average unbound serum concentration of 15 mg/l. How would you have to modify the dose, if the patient develops renal problems and his serum creatinine rises to 2.8 mg/dl? (2 points)

3. A drug has a total body clearance of 40 mL/min and a volume of distribution of 35 L. It is quickly and completely absorbed. The therapeutic range is 10-25 mg/ml. Make an oral dosing recommendation for chronic use. (2 points)

4. a) You are working as a pharmacokineticist in a pharmaceutical company, and have been assigned the task of assessing what kind of studies will have to be performed to approve a new syrup form of a drug that your company currently has on the market as an oral solution. Your team asks if it will be necessary to perform a clinical study. What is your answer? Please elaborate. (1 point)

b) Under what circumstances can product quality BA and BE can be documented using in vitro approaches? (1 point)

5. a) Your patient, a pharmacy student, is suffering from generalized anxiety disorder. He was prescribed Xanax 0.5 mg tablets t.i.d. by his doctor. Look up in the Orange Book how many AB-rated products are available right now, and what are the brand name and generic product prices. What would be the monthly savings for your patient if he were to take the generic product(s)? (1 point)

b) The same patient returns the following month complaining that he cannot remember to take his drug three times a day. He has seen very enticing commercials on TV for an extended release version of Xanax, which can be taken once daily. Is generic Xanax XR available? If not, when is the earliest that a Xanax XR AB-rated product could be available? (1 point)