PHA 5128
Homework #2,
2008

1. Please choose the correct answer (1 point):

a) Bioavailability is defined as the rate and extent to which the active ingredient is absorbed from a drug product
b) Bioequivalence is the presence of a significant difference in rate and extent to which the active ingredient from a pharmaceutical alternative becomes available
c) Bioequivalent products are therapeutically interchangeable
d) Bioequivalence studies are required for all strength of a pharmaceutical alternative

Answers:

1) a,b
2) b,c
3) b,c,d
4) a,c
5) all of the above

2. Please mark the following questions with TRUE (T) or FALSE (F) (0.5 point each):

(T) (F) Parameters that are determined in bioequivalence studies are C_{max} and AUC.
(T) (F) In Bioavailability studies, only highest strength is needed in vivo.
(T) (F) In general, only parent drugs need to be measured in bioequivalence studies..
(T) (F) A drug is considered bioequivalent if the difference in average AUC and Cmax between the two products is less than ±20%.
(T) (F) Cytochrom P450 3A4 is an important drug metabolizing enzyme that is also located in the intestine and might be inhibited by components of grapefruit juice.
(T) (F) Weakly or moderate lipophilic drugs are well distributed in obese patients.

3. Look up in the Orange Book, find the AB-rated products of fentanyl extended release transdermal film. List 5 manufacturers and the dose strengths that are available. Find the reference drug identified by FDA. List at least three other dosage forms that are available right now. (3 points)

4. A 45-year old female patient (65kg, Cp_{creat}=1mg/dL, 5'6") is treated with 100mg gentamicin i.v. short-term infusions (30min) TID. Assuming linear pharmacokinetics (V_d=0.25L/kg, $Cl=Cl_{creat}$), predict the measured peak concentration one hour after the infusion was started and the measured through concentration 30min before the next infusion at steady state. (3 points)