

Homework #2
PHA 5128

Question #1: (3 points)

A 45-year old female patient was (65kg, $C_{p_{creat}}=0.9\text{mg/dL}$, 5'6'') is treated with 100mg gentamicin i.v. short-term infusions (30min) TID. Assuming linear pharmacokinetics ($V_d=0.25\text{L/kg}$, $Cl=Cl_{creat}$), predict the measured peak concentration one hour after the infusion was started and the measured trough concentration 30min before the next infusion at steady state.

Question #2: (1 point)

Please choose the correct answer:

- 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

Question #3: (2 points)

H.T. is a 69 year old male who is being treated for a post surgical wound infection (gram negative) with gentamicin for a 21 day course of antibiotics. He is currently day seven of gentamicin. He is 6 feet tall and weighs 172 lbs and has been experiencing a decline in his urine output for the last 24 hours. His $C_{p_{creat}}$ prior to antibiotic therapy was 0.9 mg/dl. But currently, his $C_{p_{creat}}$ increased to 1.3 mg/dL. You suspect that his renal function may be declining due to this aminoglycoside. It is known that gentamicin is eliminated almost entirely by the renal route, so creatinine clearance can be used as an estimate for gentamicin clearance. Calculate the new creatinine clearance.

Question #4: (3 points)

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

- (T) (F) Parameters that are determined in bioequivalence studies are C_{\max} and AUC. (0.5 points)
- (T) (F) In general, in bioequivalence studies blood is collected for 3 or more terminal half lives. (0.5 points)
- (T) (F) A drug is considered bioequivalent if the difference in concentration between the two products is less than $\pm 20\%$ (0.5 points)
- (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 (0.5 points)
- (T) (F) Weakly or moderate lipophilic drugs are well distributed in obese patients (0.5 points)
- (T) (F) Effect of body weight on volume of distribution depends on the lipophilicity of the drug (0.5 points)