

**PHA 5128
Homework II
Spring 2005**

Question 1: (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 strengths of a pharmaceutical alternative

Answers:

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

Question 2: (3 points)

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

- (T)** (F) The parameters that are determined in bioequivalence studies are C_{max} and AUC.
- (T)** (F) In general, in bioequivalence studies blood is collected for 3 or more terminal half lives.
- (T)** **(F)** A drug is considered bioequivalent if the difference in concentration between the two products is less than $-20\%/+20\%$.
- (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
- (T)** (F) The effect of body weight on volume of distribution depends on the lipophilicity of the drug

Question 3: (2 points)

A.D. is a 75 years old male, living at a retired community in Florida. He is currently taking 500mg of a drug X that is 70% excreted into the urine. Suddenly his creatinine clearance drops from 90 ml/min to 30 ml/min.

Determine the new dose of his Drug X.

$$\begin{aligned} D_{pat} &= D_{norm} \cdot [1 - f_{ren} \cdot (1 - RF)] \\ &= 500 \text{ mg} \cdot [1 - 0.7 \cdot (1 - 0.33)] \\ &= \mathbf{265 \text{ mg}} \end{aligned}$$

Question 4: (2 points)

J.D. is a 25 years old male burger lover. He is 5'1" and weighs 80kg. His serum creatinine is normal with 1.0 mg/dl. Please calculate his creatinine clearance and his volume of distribution for gentamicin.

$$IBW = 50 + (2.3) * (\text{Height in inches} > 60) = 50 + 2.3 = 52.3$$

Clinically obese:

if $(TBW/IBW) * 100 > 120 \rightarrow 80/52.3 * 100 = 152.9 \rightarrow$ clinically obese \rightarrow use ABW

$$\begin{aligned} ABW &= IBW + 0.4(TBW-IBW) \\ &= 52.3 + 0.4(80-52.3) \\ &= 63.38 \end{aligned}$$

$$Cl_{Cr} = [(140 - \text{age}) * (\text{weight})] / (72 * SCr) = [(140 - 25) * 52.3] / (72 * 1) = 83.5 \text{ ml/min (use IBW)}$$

$$Vd = 0.25 * 63.4 = 15.9 \text{ L (use ABW)}$$

Question 5: (2 points)

I) Please choose the correct answer:

- (1) Obese patients may receive an overdose of a weakly or moderately lipophilic drug
- (2) because
- (3) obese patients have a higher percentage of body fat.

Answers:

- A) Only statement 1 is right
- B) Only statement 3 is right
- C) Statement 1 and 3 are right but the causality connection 2 is wrong
- D) Statement 1 and 3 are right and the causality connection 2 is right**

II) Please choose the correct answer:

- (1) The degree of renal function can be quantified by the creatinine clearance
- (2) because
- (3) all drugs are eliminated by the kidney

Answers:

- A) Only statement 1 is right**
- B) Only statement 3 is right
- C) Statement 1 and 3 are right but the causality connection 2 is wrong
- D) Statement 1 and 3 are right and the causality connection 2 is right

