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 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 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<sub>max</sub> 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) Cytochrome 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 lipophillic drugs are well distributed in obese patients.
(T) (F) The effect of body weight on volume of distribution depends on the lipophillicity 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 to 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.

\[
D_{pat} = D_{norm} \cdot [1 - f_{ren} \cdot (1 - RF)]
\]

\[
= 500 \text{ mg} \cdot [1 - 0.7 \cdot (1 - 0.33)]
\]

\[
= 265 \text{ mg}
\]
**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)*(Height in inches > 60) + = 50 + 2.3 = 52.3

Clinically obese:

\[ \frac{TBW}{IBW} \times 100 > 120 \Rightarrow \frac{80}{52.3} \times 100 = 152.9 \Rightarrow \text{clinically obese} \Rightarrow \text{use ABW} \]

\[ ABW = IBW + 0.4(TBW-IBW) \]
\[ = 52.3 + 0.4(80-52.3) \]
\[ = 63.38 \]

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

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

**Question 5: (2 points)**

I) Please choose the correct answer:

1) Obese patients may receive an overdose of a weakly or moderately lipophillic 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