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MPH 202 T

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Roll No. of candidate .

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2019

M.Pharm 2nd Semester End-Term Examination

**ADVANCED BIOPHARMACEUTICS AND
PHARMACOKINETICS**

(New Regulation)

(w.e.f 2017-2018)

Full Marks – 75

Time – Three hours

The figures in the margin indicate full marks
for the questions.

1. Choose the correct answer of the followings :
(10 × 1 = 10)
- (i) The major mechanism of drug transport involved in the transport of drug out of the blood into tissues is :
- (a) Aqueous diffusion
 - (b) Lipid diffusion
 - (c) Active transport
 - (d) Facilitated transport

[Turn over

- (ii) Noyes and Whitney equation is used to describe
- (a) Absorption
 - (b) Dissolution
 - (c) Distribution
 - (d) Disintegration
- (iii) The Volume of distribution of drug is _____
- (a) An expression of total body volume
 - (b) A measure of total fluid volume
 - (c) A relationship between the total amount of drug in the body and the concentration of the drug in the blood
 - (d) Proportional to bioavailability of the drug
- (iv) The rate of drug bioavailability is most rapid when the drug is formulated as a
- (a) Controlled release product
 - (b) Hard gelatin capsule
 - (c) Tablet
 - (d) Solution
- (v) Protein binding of drugs helps to maintain _____ for absorption of drugs.
- (a) Nonsink condition
 - (b) Sink condition
 - (c) Biological condition
 - (d) None of the above

(vi) According to pH partition theory, a weakly acidic drug will most likely be absorbed from the stomach because the drug which exist primarily in the

- (a) Un ionized, more lipid soluble form
- (b) Ionised, more water soluble form
- (c) Form of weak acid and more soluble in acid media
- (d) Ionic form of the drug, which facilitates diffusion

(vii) Which of the following is carrier mediated transport system?

- (a) Passive diffusion
- (b) Active transport
- (c) Pore transport
- (d) None of the above

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(viii) Absorption of poorly soluble drug is

- (a) Diffusion rate limited
- (b) Dissolution rate limited
- (c) Both (a) and (b)
- (d) None of the above

- (ix) Micronized form of drug absorbed fast because
- (a) Surface area increased
 - (b) Viscosity increased
 - (c) Angle of distribution increased
 - (d) None of the above
- (x) The rate of drug transport across a cell membrane by lipid diffusion depends on all of the following except
- (a) Surface area of absorption
 - (b) Lipid partition coefficient
 - (c) Density of transporters

2. Answer the following questions (any seven) :

(7 × 5 = 35)

- (a) State the pH-partition hypothesis briefly. On what assumptions this statement is based?
- (b) Discuss factors influencing GI absorption of drug.
- (c) Discuss in vitro methods for studying drug uptake.
- (d) Differentiate between compartment and physiological models.
- (e) What are the two major mechanisms by which drug-drug interactions can develop? Quote examples of beneficial drug interaction.

- (f) What are pharmacokinetic models? What is the importance and utility of developing such models? Discuss briefly the types of Pharmacokinetic models.
- (g) Define dose-dependent kinetics. Mention the tests used to detect nonlinearity in pharmacokinetics.
- (h) What are the applications and limitations of methods of residuals? What is the influence of K_a and K_E on C_{max} , t_{max} and AUC?
- (i) What is noncompartmental analysis of drug? Discuss the merits and demerits of such an approach.

3. Answer the following questions (any *three*) :
(3 × 10 = 30)

- (a) What are the objectives of dissolution profile comparison? Discuss the method for comparison of dissolution profile with proper statistical equations.
- (b) Discuss the objectives for conductance of bioequivalence studies. Enlist the elements of bioequivalence study protocol.
- (c) Derive K_a values by method of residuals and explain the flip-flop phenomenon with proper illustration.

(d) Write notes (any two) :

(i) In viro-in vivo correlation

(ii) Loo-Riegelman method for estimation of K_a .

(iii) Causes of nonlinearity in pharmacokinetics.

(e) A product is degraded according to first-order kinetics. When prepared, the concentration of active ingredient was $23 \mu\text{g/mL}$ and after 5 months, the concentration of active ingredient was $21 \mu\text{g/mL}$. Calculate time, when concentration of active ingredient in the product will be $17.5 \mu\text{g/mL}$.

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