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MPH 202 T ✓

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M.Pharm. 2nd Semester End-Term Examination

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS

(New Regulation)

Full Marks – 75

Time – Three hours

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

Answer question No. 1 and any six from the rest.

- I. Answer the following questions : (20 × 1 = 20)
- (i) BCS Class II drugs are classified as
- (a) High Permeability/High Solubility
 - (b) Low Solubility/Low Permeability
 - (c) Low Solubility/High Permeability
 - (d) High Solubility/Low Permeability
- (ii) The major mechanism of drug absorption is
- (a) Facilitated diffusion
 - (b) Passive diffusion
 - (c) Active Transport
 - (d) Pore Transport
- (iii) Controlled Release from a Osmotic Pump follows
- (a) Zero Order
 - (b) First Order
 - (c) Mixed Order
 - (d) Exponential Kinetics

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- (iv) The rate of absorption will be most rapid from
- (a) Solution
 - (b) Tablet
 - (c) Suspension
 - (d) Capsules
- (v) Which of the following is most suitable for dissolution study of Transdermal Formulations?
- (a) Type I
 - (b) Type II
 - (c) Type IV
 - (d) Type V
- (vi) Which among the following utilizes statistical moment theory?
- (a) Level A IVIVC
 - (b) Level B IVIVC
 - (c) Level C IVIVC
 - (d) Multiple Level C IVIVC
- (vii) Which of the following is a Carrier mediated Transport
- (a) Passive Diffusion
 - (b) Active Transport
 - (c) Pore Transport
 - (d) None of the above.
- (viii) Binding of drug with enzymes/proteins results in
- (a) Zero order kinetics
 - (b) First Order Kinetics
 - (c) Mixed order kinetics
 - (d) Linear Kinetics
- (ix) Passive diffusion of drug is expressed by
- (a) Fick's First Law
 - (b) Fick's second Law
 - (c) Zero Order
 - (d) First Order
- (x) Which of the following is an in silico model for determining drug absorption
- (a) CaCO₂ model
 - (b) Doluisio method
 - (c) Everted Sac Technique
 - (d) PAMPA model

- (xi) Very _____ (strong/weak) bases are ionized in entire pH range in GIT.
- (xii) Distribution of highly soluble drug is _____ (Dissolution/Permeation) limited.
- (xiii) _____ is defined as study of pharmacokinetic differences of drug in various populations.
- (xiv) As per IP _____ type apparatus are known as Dissolution Type I apparatus.
- (xv) Noyes Whitney equation is used to describe _____.
- (xvi) Maximum absorbable dose (MAD) is equal to _____.
- (xvii) Protein binding of drugs help to maintain _____ condition of drug.
- (xviii) Apparent Volume of distribution (V_d) = _____.
- (xix) Zero order process are _____ (dependent/independent) of concentration.
- (xx) Parallel designs are suitable for bioequivalence study of drugs with _____ (long/short) half life.

2. Answer any SEVEN from the following : (7 × 5 = 35)

- (a) Explain the Diffusion double layer model in drug absorption.
- (b) What do you mean by In-vitro-in-vivo correlations (IVIVC)? Explain in brief?
- (c) Explain the various pharmaceutical factors affecting drug absorption.
- (d) Write a brief note on pH-Partition hypothesis and its limitations.
- (e) Describe with suitable derivations 'One Compartment open model by IV Bolus dose'.
- (f) Explain the Biopharmaceutical Classification Systems (BCS) with suitable examples.
- (g) Write the application of pharmacokinetics in targeted drug delivery system.
- (h) Explain the various methods for determining absorption of drugs in-vitro.
- (i) Pharmacokinetics of 500 mg paracetamol after oral administration is best described by the equation $C = 1.18(e^{-0.24t} - e^{-1.6t})$. Calculate the C_{max} , t_{max} and $t_{1/2}$ of the drug.

3. Answer any two out of THREE : (2 × 10 = 20)

- (a) (i) Write in detail about mechanism of drug absorption with suitable diagrams. (6)
- (ii) Write in details about the Michaelis-Menten equation. (4)
- (b) Discuss the importance and objectives of Bioequivalence study. Enlist the elements of bioequivalence study protocol. (3 + 7)
- (c) (i) Explain the various biopharmaceutical Considerations in dosage form design. (6)
- (ii) Classify the various methods for assessment of bioavailability. (4)