Time: 3 Hours   Max. Marks: 70

Instructions:
1. Attempt all questions.
2. Write each section in a separate answer book.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks.
5. Draw diagrams/figures whenever necessary.

Section I

Q-1 (A) **Do as directed**   **[7]**
  I) Define bioavailability and bioequivalence.
  II) Define polymorphism and pseudopolymorphism.
  III) Define steady state concentration.
  IV) How does a size of a compound and polar functional group determine its solubility?
  V) How does common ion effect affect on drug absorption?
  VI) Define the term pharmaceutical alternatives.
  VII) Which are different cell lines used for absorption study?

Q-1 (B) **Answer the following in brief: (Any 4)**   **[8]**
  I) Explain a mathematical method to estimate solubility of an organic solute.
  II) Give the significance of fine particle characterization in preformulation phase.
  III) What do you mean by biowaiver? Explain.
  IV) The Vd and t_{50} of drug are 3000 ml and 4 hrs respectively. Calculate the elimination rate constant and amount of drug in the body when the plasma concentration is 1 mcg/ml.
  V) The AUC from a single 325 mg intravenous bolus dose of a drug administered was found to be 285 mcg.hr/ml and the AUC from a similar dose administered from a tablet was found to be 265 mcg.hr/ml. What is the extent of absorption from the tablet formulation?
  VI) Define the residual solvents and classify them.

Q-2 **Answer the following.**   **[10]**
  A) Enlist the various methods for solubilization. Explain the concept of cosolvency.
                                      OR
  A) Explain the mechanism of hydrotropic solubilization and cyclodextrin solubilization in solubility improvement of poorly soluble drug.
  B) Describe the applications of Caco-2 cell model to drug absorption and transport studies.
   **OR**
  B) Explain the physiological factor affecting on drug absorption.

Q-3 **Answer the following in detail. (Any 2)**   **[10]**
  A) Applications of thermal methods of analysis in preformulation study
  B) Wagner Nelson method for estimation of K_a
  C) Compartment models

Section II

Q-4 (A)   **Do as directed**   **[7]**
     I)   What is the difference between releasing media and discriminating media?
     II)   How to determine the solubility of a drug substance for the Biopharmaceutical Classification System (BCS)?
     III)   Define IVIVC and IVIVR.
     IV)   What is a "highly variable drug or drug product"?
     V)   What do you mean by significant change?
     VI)   What apparatus is used to evaluate drug release from semisolid dosage forms?
     VII)   Identify the degradation pathway of following reaction and comment on.
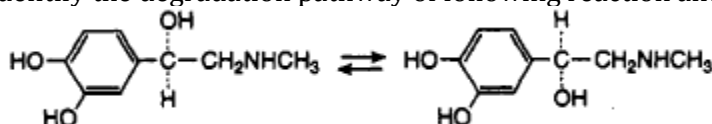
Q-4 (B)   **Answer the following in brief: (Any 4)**   **[8]**
     I)   What are the levels of IVIVC? Explain.
     II)   Explain the class boundaries in BCS.
     III)   What do you mean by shelf life and overages? Explain.
     IV)   Give a brief note on formulation of cold cream.
     V)   Accelerated stability studies are valid only the energy of activation is about 10 to 30 kcal/mole in a chemical reaction. Comment.
     VI)   Describe different climatic zones in stability testing.

Q-5   **Answer the following.**   **[10]**
     A)   How is accelerated stability study carried out? How the results of it can be correlated with real time study?

<div align="center">OR</div>

     A)   Discuss the bracketing design for stability testing.

     B)   Explain various factors to be considered in dissolution media and conditions selection.

<div align="center">OR</div>

     B)   Why IVIVC is an important stage in formulation development? Explain. Write any one method for correlation studies.

Q-6   **Answer the following in detail. (Any 2)**   **[10]**
     A)   Write a note on formulation and evaluation of shampoo.
     B)   Explain biorelevant dissolution testing.
     C)   Calculate similarity factor for the given data and state whether the products are similar or not?

Time (min)	5	10	15	20	25	30
CPR (Reference)	53.63	65.85	70.88	74.65	76.78	84.72
CPR(Test)	50.63	57.19	66.25	69.42	75.60	82.98

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