UKA TARSADIA UNIVERSITY

M.Pharm. (Pharmaceutics) (1st Semester)

Subject :040040102 - Pharmaceutical Formulation Development and Biophamaceutics

Duration: 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 allocated to that question.
5. Draw diagrams/figures whenever necessary.

Section-1

Q-1 (A) Do as directed.   [07]

I)   What are hydrates and solvates?
II)   What is Carr's index? Give its formula.
III)   Define particle size distribution.
IV)   What do you understand by metastable forms? Give an example.
V)   What is the difference between total body clearance and renal clearance?
VI)   Define re-distribution.
VII)   What do you understand by pharmaceutical alternatives? Give an example.

Q-1 (B) Answer the following in brief. (Any 4)   [08]

I)   Give the working principle of X-ray diffraction.
II)   Enlist the methods of particle size determination.
III)   What do you understand by physiological pharmacokinetic models?
IV)   Volume of distribution of two drugs, X and Y, are 7 and 250 Litres, respectively. What does it mean in pharmacokinetic terms?
V)   Enlist the methods used to perform pharmacokinetic analysis. Why has compartment modeling received more acceptability in comparison to the other methods? Draw the schematic diagram showing the rate transfer constants of one compartment open model (first order absorption) and two compartment open model (i.v. bolus).
VI)   Draw the plasma concentration time profile of: a) one compartment open model (i.v. bolus), b) one compartment open model (i.v. infusion), c) one compartment open model (e.v. administration) and d) two compartment open model (e.v. administration).

Q-2 Answer the following.   [10]

A) What do you understand by polymorphism? Write a note on the role and importance of polymorphism in pharmaceutical formulations.

OR

A) Write a note on 'residual solvents'.

B) Discuss the estimation of K_a and K_E by the method of residuals, as applied for a drug following one compartment open model characteristics (e.v. administration). Also, explain the occurrence of flip-flop phenomena.

OR

B) Enlist the methods to perform bioavailability studies. State the criteria and protocol to have a valid urinary excretion data. What are the pharmacokinetic parameters which can be estimated from such data?

Q-3 Answer the following in detail. (Any 2)   [10]

A) What do you understand by solubilized pharmaceutical systems? Write a note on the techniques to achieve drug solubilization.
B) Describe the important considerations in the design and conduct of bioavailability studies.
C) Define the term 'randomization'. Discuss the importance of cross-over designs over parallel design in context to the conduct of bioequivalence studies? State the criteria of bioequivalence between two drug products.

Section-2

Q-4 (A) Do as directed.   [07]

I)   Define shelf life of a pharmaceutical product.
II)   What do you understand by accelerated stability studies?
III)   Define and give an example of zero order reaction.
IV)   Define IVIVC.
V)   Enlist the methods for dissolution profile comparison.
VI)   What do you understand by BCS Class II drugs? Give example(s).
VII)   What do you understand by cosmoceuticals? Give example(s).

Q-4 (B) Answer the following in brief. (Any 4)   [08]

I)   Enumerate the objectives of performing in vitro dissolution studies.
II)   What are the factors which govern the selection of dissolution media?
III)   Write a short note on herbal shampoos.
IV)   How does light affect the stability of a formulation? Enlist the techniques for its stabilization against the effect of light.
V)   How would you compare the dissolution profiles of two products using model-independent methods? State their acceptance criteria.
VI)   State the constraints in achieving IVIVC for pharmaceutical products.

Q-5 Answer the following.   [10]

A) What are the official methods of in vitro dissolution testing as per I.P.? Discuss the importance of dissolution testing in pharmaceutical development.
                                              OR
A) Write a note on preparation and evaluation aspects of lipsticks.
B) Discuss the factors which govern the choice of in vitro dissolution method and conditions.
                                              OR
B) Write a note on matrixing techniques with reference to their applications in stability testing of pharmaceuticals.

Q-6 Answer the following in detail. (Any 2)   [10]

A) What are the methods for establishing an IVIVC? Explain level A correlation. Why is it termed as 'point-to-point' correlation?
B) Discuss the methods for predicting shelf life and half life of pharmaceutical products.
C) Discuss the challenges in the development and evaluation of herbal pharmaceutical products.