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) Define preformulation.
II) Define intrinsic dissolution rate.
III) Define particle size distribution.
IV) What do you understand by amorphous forms?
V) Define clearance.
VI) What do you understand by volume of distribution?
VII) What are pharmaceutical equivalents?

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

I) Give the principle of differential scanning calorimetry.
II) Enlist the physiological factors affecting drug absorption.
III) What do you understand by compartment models?
IV) Enlist the techniques of solubilization?
V) Give a brief note on the methods for the evaluation of polymorphic forms.
VI) Explain, in brief, the effects of plasma protein binding on distribution of a drug.

Q-2 Answer the following. **[10]**

A) Discuss the estimation of K_E and K_a by stripping method for a drug following one compartment open model characteristics (e.v. administration). Explain the occurrence of flip-flop phenomena.

OR

A) Discuss the pharmaceutical factors which affect the formulation of dosage form.
B) What are the objectives of carrying out drug-excipient compatibility studies? Describe the methods to perform drug-excipient compatibility studies

OR

B) 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) Discuss the guidelines which govern the preformulation of biotechnological products.
B) Discuss various pharmacokinetic models which have been proposed to describe the fate of drugs in a biological system. Highlight the merits and demerits of each model.
C) Enlist the characteristics studied during preformulation studies of a drug. Discuss the importance of studying the solubility of a drug. Describe the method for solubility determination of drugs.

Section-2

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

I) Define photosensitivity.
II) Define anti-oxidants. Give two examples of anti-oxidants used in pharmaceutical systems.
III) Define BCS Class IV drugs. Give an example.
IV) Define IVIVC.
V) What do you understand by first order reaction?
VI) Give the examples of Class I and Class III solvents as per ICH guideline Q3C.
VII) Define hygroscopicity. Give examples of hygroscopic substances.

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

I) Explain the importance of similarity and difference factors.
II) Differentiate between shelf life and half life of a drug.
III) Differentiate between absolute and relative bioavailability.
IV) Enlist the merits and demerits of estimating drug transport through cell line studies.
V) What do you understand by Level A correlation?
VI) What is the method of estimating the mean residence time of a drug?

Q-5 Answer the following. **[10]**

A) Enlist various cosmetics used for skin. Describe formulation and evaluation aspects of any two of them.

OR

A) Classify cosmetics. Describe the formulation and evaluation aspects of cosmetics used for hair.
B) Discuss the factors which govern the selection of *in vitro* dissolution method and conditions.

OR

B) Discuss the applications of matrixing techniques in the stability testing of pharmaceuticals.

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

A) Discuss the factors which affect the stability of pharmaceutical products.
B) Describe the methods for establishing IVIVC. Highlight their merits and demerits.
C) Discuss the challenges in the development and evaluation of herbal pharmaceutical products.