UKA TARSADIA UNIVERSITY

M. Pharm. (I Semester) (Pharmaceutics)

Subject: 040040102 Pharmaceutical Formulation Development & Bio-pharmaceutics

Time : 10:00 am to 1:00 pm Date : **23**/12/2013

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. Draw diagrams/figures wherever necessary.

SECTION 1

1	**a.**	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). Also draw the schematic diagram showing the rate transfer constants in the above-mentioned cases.	**4**
		OR	
		Define 'randomization'. Discuss the importance of cross-over designs over parallel design for conducting bioequivalence studies? State the statistical criteria of bioequivalence between two drug products.	
	b.	Explain extraction ratio. How is it related to oral bioavailability of a drug? What is the influence of blood flow rate and plasma protein binding on total clearance of drugs with high and low extraction ratios?	**4**
	c.	What is the difference between absolute and effective surface area? How does micronization of hydrophobic drugs result in reduction of their effective surface area?	**3**
2	**a.**	Discuss the anatomical and physiological reasons for differences in the rate and extent of drug absorption from various regions of GIT. Give appropriate example(s).	**6**
	b.	Explain Wagner-Nelson method of the estimation of absorption rate constant. How does it differ from the method of residuals? Highlight its demerits also.	**6**
		OR	
		Drugs A and B show one compartment and two compartment distribution characteristics respectively, upon being administered intra-orally. Explain the differences in the pharmacokinetic profile of these drugs. Derive the relationship for the estimation of K_a, α and β for the drug B using method of residuals.	
3	**a.**	Write a note on the assessment of drug transport using cell line studies.	**6**
	b.	Discuss various pharmaceutical factors which affect the absorption of drugs across biological membrane.	**6**

OR

Write a detailed note on approaches to solubilization of hydrophobic drugs.

SECTION 2

4. a. Explain the considerations of pH-partition hypothesis of drug absorption across the gastro-intestinal membrane. **4**

b. Describe biopharmaceutical classification system. **4**

OR

Discuss the objectives of performing *in vitro* dissolution studies.

c. State the inclusion and exclusion criteria for the recruitment of volunteers in BE studies. **3**

5. a. Write a detailed note on bracketing technique for carrying out stability studies of drug products. **6**

b. What are the methods for establishing an IVIVC? Explain level A correlation. **6**

OR

Discuss the challenges in the development of herbal pharmaceutical products.

6. a. How does atmospheric oxygen affect the stability of a formulation? Discuss the techniques for its stabilization against the effect of oxygen. **6**

OR

Discuss the objectives and approaches for developing *in vitro-in vivo* correlation.

b. Discuss various official equipments (as per USP) available to perform in vitro dissolution studies of pharmaceutical products. **6**