UKA TARSADIA UNIVERSITY

M. Pharm. (I Semester) (Pharmaceutics)

Subject: 040040102 Pharmaceutical Formulation Development & Bio-pharmaceutics

Time : **2.30 p**m to **5.30** pm Date : **21/05/**20**14**

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.**	Discuss the methods to characterize the flow properties of a drug powder. Highlight the importance of flow property characterization.	**4**
		OR	
		Write a note on physiological pharmacokinetic models. Explain their merits and demerits over compartment models.	
	b.	Discuss the methods of estimation of volatile organic impurities in drug formulations.	**4**
	c	Explain polymorphism, amorphism and pseudopolymorphism with appropriate examples.	**3**
2	**a.**	What do you understand by intrinsic dissolution rate? Explain its significance and procedure of measurement.	**6**
	b.	What are the methods for thermal characterization of drugs? Discuss differential scanning calorimetry.	**6**
		OR	
		What are the objectives of carrying out drug-excipient compatibility studies? Describe the methods to perform drug-excipient compatibility studies.	
3	**a.**	Discuss the estimation of K_a by the method of residuals for a drug following one compartment open model characteristics (extra-vascular administration). Explain the occurrence of flip-flop phenomena	**6**
	b.	Write a detailed note on approaches to solubilization of hydrophobic drugs.	**6**
		OR	
		Write a detailed note on non-compartmental drug analysis. What are the pharmacokinetic parameters which can be determined through this method? Discuss its merits over compartment modeling.	

SECTION 2

4.	**a.**	Discuss the objectives of performing stability studies of drug formulations.	**4**

b. Write a note on the applications of microcalorimetry in stability studies of formulations. **4**

OR

Discuss various model-independent methods for comparison of dissolution profile of two formulations.

c. What do you understand by sink condition? Explain the importance of maintaining sink conditions during *in vitro* dissolution studies. **3**

5. a. Explain pH-partition theory. Predict the degree of ionization and absorption of very weak, weak and strong acidic and basic drugs from stomach and intestine on the basis of pH-partition theory. **6**

b. Describe USP dissolution apparatus type II with its principle, design, applications advantages and disadvantages. **6**

OR

Write a note on formulation and evaluation of dental cones.

6. a. Discuss the parameters which should be taken into account while selecting a dissolution medium. **6**

OR

Discuss the importance of *in vitro* dissolution studies in formulation-development.

b. Discuss the objectives and approaches for developing *in vitro-in vivo* correlation. **6**