UKA TARSADIA UNIVERSITY

M. Pharm. (II Semester) (Pharmaceutics and Pharmaceutical Technology)

Subject: 040040203 - Global Regulatory Requirements & Validation

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 contents of Investigator's Brochure.	**4**
		OR	
		Write a note on Common Technical Document (CTD).	
	b.	Write a note on World Health Organization.	**4**
	c.	Write a note on CMC data.	**3**
2	**a.**	Explain the review procedure of a new drug application (NDA) by US-FDA.	**6**
	b.	Discuss the content and format of Form 356 H.	**6**
		OR	
		Discuss SUPAC guidelines in context to modified release formulations.	
3	**a.**	What do you understand by abbreviated new drug application? Why is it called 'abbreviated'? Discuss ANDA Para Certification system in detail.	**6**
	b.	Discuss the organization, structure and responsibilities of US-FDA.	**6**
		OR	
	b.	Discuss the content and format of IND application.	

SECTION 2

4.	**a.**	Discuss the considerations which justify the choice and conduct of a clinical study.	**4**
		OR	
		What do you understand by an inactive ingredient? Discuss the purpose of providing Inactive Ingredient Database. Can inactive ingredient ever be considered an active ingredient? Explain such cases, if any.	
	b.	Discuss the cases where bioequivalence between test and reference product may be considered to be self-evident.	**4**
	c.	What are the pharmacokinetic parameters utilized for demonstrating bioequivalence (BE) between two pharmaceutical products? What is the general criterion of acceptance of BE? Discuss the specific cases wherein acceptance interval can be narrowed or tightened.	**3**
5.	**a.**	What do you mean by Orange Book? Discuss its content. Explain the	**6**

criteria and objectives of including drug products into orange book. How often is it updated? How could one get certain specific information on a drug which is not provided in the orange book?

OR

Discuss the key factors which should be considered during the selection of volunteers/patients in a bioequivalence study. Explain various designs utilized to perform such studies. Highlight their merits and demerits.

b. Explain the importance of developing analytical methods at different stages of drug development. Discuss the parameters which guide the selection of analytical methods. **6**

6. a. Discuss the important elements of a cleaning validation program. **6**

OR

What do you understand by validation? Explain the principles of prospective and retrospective validation.

b. Describe the qualification of a blender. **6**