UKA TARSADIA UNIVERSITY

M. Pharm. (Pharmaceutics/Pharmaceutical Technology) (2nd Semester)

Subject: 040040203 - Global Regulatory Requirements & Validation

Time : **2**:**3**0 **p**m to **5**:**3**0 pm Date : **0****2**/**1****2**/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.**	What does USFDA regulate and what does it not regulate? Support your answer with suitable examples.	**4**
		OR	
		Write a note on data exclusivity and patent term extension.	
	b.	Discuss the role of drug regulatory bodies.	**4**
	c.	Discuss the structure and activities of MHRA.	**3**
2	**a.**	What do you understand by SUPAC? Write the history of SUPAC guidelines. What are the different SUPAC guidelines available for industry?	**6**
	b.	Discuss the pre-clinical phase of drug development. What are the challenges before the drug development team during this phase?	**6**
		OR	
		Discuss the NDA regulations regarding review time frame, filing time, foreign data and meetings with FDA.	
3	**a.**	What do you understand by Para IV certification? Discuss the procedure of approval of a drug product filed under Para IV.	**6**
	b.	Describe NDA amendments and supplements.	**6**
		OR	
	b.	Discuss the need of ICH guidelines. Describe the functions of ICH. Name the constituent bodies of ICH.	

SECTION 2

4.	**a.**	Discuss the purpose of conducting food intervention and multiple dose studies. How does the conduct of multiple dose studies differ from single dose studies? Explain with proper illustrations.	**4**
		OR	
		Explain the importance of developing analytical methods at different stages of drug development.	
	b.	Define the following terms: Validation, Revalidation, Critical process parameters, Scale-up, Validation protocol, Open label study, Supra-	**4**

bioavailability, Mean residence time

c. Discuss the key factors which should be considered during the selection of volunteers/patients in a bioavailability study. **3**

5. a. What do you understand by absolute and relative bioavailability? Discuss the importance and need for conducting bioavailability studies. What are the key parameters estimated during such studies. **6**

OR

Discuss the contents of orange book. Discuss the therapeutic equivalence codes assigned to multi-source drug products in the orange book. Describe the procedure of modifying such codes by US-FDA.

b. Describe the qualification of an Autoclave. **6**

6. a. Define a drug master file (DMF). Enlist the types of DMF along with their typical contents. Discuss the process of reviewing a DMF submission by the US-FDA. What are the situations which may lead to closure of an existing DMF? **6**

OR

Describe the process validation of a tablet manufacturing process.

b. Describe the principles of retrospective validation. Give suitable examples. **6**