Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM. - SEMESTER – II • EXAMINATION – WINTER 2012

Subject code: 2920202 Date: 12-01-2013

Subject Name: Global Regulatory Requirements

Time: 10.30 am - 01.30 pm Total Marks: 80

Instructions:

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1	(a)	Define validation. Give essentials and major phases of validation.	**06**
	(b)	Write a note on ERP with advantages and disadvantages.	**05**
	(c)	Write a note on step wise validation of Hot air oven.	**05**
Q.2	(a)	What are Orange Book, Green Book and Blue Book? Discuss the coding system for Therapeutic Equivalence Evaluation and how it can be changed giving suitable illustration?	**06**
	(b)	Differentiate INDA and ANDA. Write a note on Hatchwaxman ammendments.	**05**
	(c)	What is the objective of IIG? Explain general description of IIG.	**05**
Q.3	(a)	What are clinical trials? How are they organised as the part of drug discovery process?	**06**
	(b)	Write a note on Supplemental new drug application.	**05**
	(c)	Explain the scope of USFDA. Discuss the preparations required for facing USFDA audit.	**05**
Q.4	(a)	Give organisation of ICH. What is the role of ICH in improving pharmaceutical product quality?	**06**
	(b)	Describe basic functions and steps for new drug registration at ANVISA.	**05**
	(c)	Write a note on computer system validation.	**05**
Q.5	(a)	What is CTD? What are technical requirements of e-CTD?	**06**
	(b)	Write a short note on TGA.	**05**
	(c)	Describe various components of FDA.	**05**
Q. 6	(a)	Define Pharmaceutical packaging. Discuss the objectives, importance and functions of packaging.	**06**
	(b)	What are the disadvantages of glass as a packaging material? Write a note on packaging for pediatrics and geriatrics.	**05**
	(c)	How is SMF prepared for MCC guidelines?	**05**
Q.7	(a)	What are the main functions of WHO? Enlist different WHO guidelines available for pharmaceutical products.	**06**
	(b)	Write a note on DMF.	**05**
	(c)	Discuss SUPAC guidelines for modified release dosage forms with reference to the site changes.	**05**

****