Seat No.: _____ **Enrolment No._____**

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm Semester –II Examination Dec. - 2011

Subject code: 920202 **Date: 12/12/2011**
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)	What is validation? Discuss its scope and rational in pharmacy.	**06**
	(b)	Describe various activity regulated by TGA.	**05**
	(c)	What are the disadvantages of glass as a packaging material? Explain PET as a packaging material.	**05**
Q.2	(a)	Describe stepwise validation programme for fluid bed dryer.	**06**
	(b)	Define: Orange book, Green book. Describe coding system for therapeutic equivalence evaluation.	**05**
	(c)	Write a note on child resistant container.	**05**
Q.3	(a)	Differentiate INDA and ANDA. Describe various type of INDA.	**06**
	(b)	What is ERP? Discuss merit and demerits of ERP.	**05**
	(c)	What is objective of IIG? Explain general description of IIG.	**05**
Q.4	(a)	Why computer system validation is required? Explain validation of electronic spread sheet.	**06**
	(b)	What is change control? How is it carried out?	**05**
	(c)	Describe various components of FDA.	**05**
Q.5	(a)	How to make a FOIA request? Enlist records withheld by FOIA.	**06**
	(b)	Write a note on Hatchwaxman Amendments.	**05**
	(c)	Enlist parameters of analytical method validation. Describe Accuracy, Ruggedness, and Robustness.	**05**
Q.6	(a)	Describe in brief about SUPAC guidelines for Immediate release dosage forms.	**06**
	(b)	Write a note on DMF.	**05**
	(c)	Describe basic functions and steps for new drug registration at ANVISA.	**05**
Q.7	(a)	What is CTD? Describe various modules of CTD.	**06**
	(b)	What are the main functions of WHO? Enlist various WHO guidelines available for pharmaceutical products.	**05**
	(c)	Write a note on Systems Applications and Products in Data Processing.	**05**

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