Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-II Examination July 2010

Subject code: 920202

Subject Name: Global Regulatory Requirements

Date: 07 /07 /2010 **Time: 11.00 am – 02.00 pm**

Instructions: **Total Marks: 80**

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

Q.1	(a)	Define Pharmaceutical Packaging. What are the conditions pertaining to containers as per USP? Discuss the objectives, importance and functions of packaging.	**06**
	(b)	What are the innovations in tamperproof packaging and coding systems? What are package integrity tests for Parenterals?	**05**
	(c)	Comment on suitability of APIs with packaging material. Write a note on packages for pediatrics and geriatrics.	**05**
Q.2	(a)	What is cleaning validation? What are current regulatory requirements for it? What ICH talks about Analytical methods development and validation?	**06**
	(b)	Why the computer system needs to be validated? How entrepreneur resource planning make use of computers?	**05**
	(c)	Write a note on qualifications of Pharma. Process equipment and write a note on validation of an autoclave.	**05**
Q.3	(a)	What is the need for Orange book? Suggest equivalence related terms and statistical criteria for bio-equivalence. How to use cumulative supplement?	**06**
	(b)	Discuss the historical aspects of drug development and approval. Which information can be obtained as per FOIA?	**05**
	(c)	Write a note on IIG.	**05**
Q.4	(a)	Differentiate IND, NDA and ANDA. Which are the four pillers for timely approval of NDAs/ ANDAs?	**06**
	(b)	Write a note on ANDA. Discuss Drug Price Competition and Patent restoration act of 1984 and WAXMAN-HATCH ACT are the same and its economics on the society is important.	**05**
	(c)	Write a note on supplemental new drug application.	**05**
Q.5	(a)	What USFDA does and does not regulate? How will you prepare for USFDA inspection?	**06**
	(b)	How is SMF prepared for MCC guideline?	**05**
	(c)	Which medicines are not accepted as generics- as per ANVISA?	**05**
Q. 6	(a)	Define CTD and e-CTD. What are technical requirements for e-CTD?	**06**
	(b)	Write a note on EMEA implementation of New EU Pharma. legislation.	**05**
	(c)	Write a note on export certificates as per MHRA. Discuss legal status and reclassification of medicinal products.	**05**
Q.7	(a)	Discuss the TGA's risk management approach.	**06**
	(b)	Categorize ICH activities. Write a note on evaluation of stability data.	**05**
	(c)	How herbal medicinal products are regulated as per WHO?	**05**

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