Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – WINTER • 2014

Subject Code: 2920202 Date: 26-12-2014

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)	Describe in brief about SUPAC guidelines for immediate release dosage forms.	**06**
	(b)	Differentiate NDA and ANDA. Explain the concept of PARA I to IV filing.	**05**
	(c)	Define prospective, concurrent and retrospective validation. Explain in brief validation of rotary tablet machine.	**05**
Q.2	(a)	Discuss role of CDRH, CDER & CFSAN in USFDA guidelines.	**06**
	(b)	Define 'Orange Book', 'Green Book' and 'Blue Book'. Explain statistical criteria for Bio-equiavalence in context to orange book.	**05**
	(c)	Write in brief about freedom of information (FOIA).	**05**
Q.3	(a)	Discuss the WHO certification scheme for pharmaceutical products.	**06**
	(b)	Explain various phases of drug development and approval.	**05**
	(c)	Explain Supplemental New Drug Application with recent examples.	**05**
Q.4	(a)	Discuss the phases of investigation in context to IND.	**06**
	(b)	Describe strategy for analytical method development for a new solid dosage formulation and discuss its validation parameters as per ICH guidelines.	**05**
	(c)	Write a note on computer system validation.	**05**
Q.5	(a)	Define TGA & therapeutic good. Discuss the TGA's risk management approach.	**06**
	(b)	Describe package integrity tests for Parenterals. Write a note on packages for pediatrics and geriatrics.	**05**
	(c)	Describe Enterprise Resource Planning (ERP) system in detail.	**05**
Q. 6	(a)	Define CTD & eCTD. Explain modules of CTD and write in brief technical requirements of eCTD.	**06**
	(b)	Describe evaluation of the stability data as per ICH guidelines.	**05**
	(c)	Write a note on Hatchwaxman ammendments.	**05**
Q.7	(a)	Write a note on MHRA.	**06**
	(b)	Describe IIG in detail.	**05**
	(c)	Explain DMF in brief.	**05**

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