Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2015

Subject Code: 2920202 Date: 16-05-2015

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 are Orange book, Green book and Blue book? Define Therapeutic equivalent and Pharmaceutical alternative.	**06**
	(b)	Write a note on validation of Autoclave.	**05**
	(c)	What is CTD? Discuss structure of CTD. How it differs from eCTD	**05**
Q.2	**(a)**	Describe in brief SUPAC guidelines for modified release dosage forms	**06**
	(b)	Write a note on Hatch-Waxman Amendments and its impact on Pharmaceutical industry.	**05**
	(c)	What is DMF write a short note on Type-I DMF.	**05**
Q.3	**(a)**	What is supplemental NDA. Explain with examples.	**06**
	(b)	Discuss MED WATCH and Dear Doctor Letter.	**05**
	(c)	Explain ERP. Discuss merit and demerits of ERP.	**05**
Q.4	**(a)**	Discuss IIG. How it differs from GRAS?	**06**
	(b)	How to make a FOIA request? Which information cannot be obtained by FOIA?	**05**
	(c)	What is CDSCO? Explain its function in detail.	**05**
Q.5	**(a)**	What are main functions of WHO? What is significance of WHO guidelines?	**06**
	(b)	Discuss matrixing and bracketing methods of sampling as per ICH.	**05**
	(c)	Discuss MERCOSUL and REBLAS as per ANVISA.	**05**
Q. 6	**(a)**	Discuss historical evaluation of USFDA. Discuss CDER in detail.	**06**
	(b)	Write a note on TGA.	**05**
	(c)	What is exclusivity with respect to NDA and ANDA filing?	**05**
Q.7	**(a)**	Write a brief note on MHRA.	**08**
	(b)	Explain various phases of Drug Development and Approval process as per USFDA.	**08**

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