Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM - SEMESTER II– • EXAMINATION – WINTER-2016

Subject Code: 2920202 **Date: 02/12/2016**

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 process validation? Discuss the advantages and disadvantages of organizational structures for process validation.	**06**
	(b)	Write a note on ERP with advantages and disadvantages.	**05**
	(c)	Write a note on validation of Autoclave.	**05**
Q.2	**(a)**	Enumerate key parameters of the analytical method validation and discuss any two.	**06**
	(b)	Write a note on Enterprise Resource Planning (ERP) system.	**05**
	(c)	Write a note on computer system validation.	**05**
Q.3	**(a)**	What is the objective of IIG? Explain general description of IIG.	**06**
	(b)	Define 'Orange Book', 'Green Book' and 'Blue Book'. Explain statistical criteria for Bio-equivalence in context to orange book.	**05**
	(c)	What is DMF? Write a short note on Type-I DMF.	**05**
Q.4	**(a)**	Write a note on ANDA. Explain the concept of PARA I to IV filling.	**06**
	(b)	Mention the goals of NDA. Discuss the general requirements for filing NDA.	**05**
	(c)	Define and explain INDA, stating its objectives.	**05**
Q.5	**(a)**	Write a note on Hatch-Waxman Amendments and its impact on pharmaceutical industry.	**06**
	(b)	Write a note on ANVISA.	**05**
	(c)	Write a note on Post Marketing Surveillance.	**05**
Q. 6	**(a)**	Define CTD & eCTD. Explain modules of CTD.	**06**
	(b)	Describe in brief about SUPAC guidelines for immediate release dosage forms.	**05**
	(c)	What is TGA? Discuss TGA's risk management approach.	**05**
Q.7	**(a)**	Write a note on MHRA.	**06**
	(b)	Explain various phases of Drug Development and Approval process as per USFDA.	**05**
	(c)	Describe evaluation of the stability data as per ICH guidelines.	**05**

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