Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920202 **Date: 09-12-2015**

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 is SAP? Discuss merits and demerits of SAP	**06**
	(b)	Write a note on computer system validation	**05**
	(c)	Explain the parameters for analytical method development validation	**05**
Q.2	**(a)**	What is process validation? Discuss the advantages and disadvantages of organizational structures for process validation	**06**
	(b)	Explain the types of equipment validation	**05**
	(c)	Describe stepwise validation programme for dissolution apparatus	**05**
Q.3	**(a)**	Write a note on ANDA. Explain the concept of PARA I to IV filling	**06**
	(b)	Write a note on Post Marketing Surveillance	**05**
	(c)	Write a note on NDA	**05**
Q.4	**(a)**	Explain the scope of TGA regulations. Discuss the TGA guidelines for OTC product	**06**
	(b)	Describe various activity regulated by CDER	**05**
	(c)	Describe various modules of CTD	**05**
Q.5	**(a)**	Define: Orange book. Describe the codes for therapeutic equivalence evaluation	**06**
	(b)	Describe various components of FDA	**05**
	(c)	Write a note on DMF	**05**
Q. 6	**(a)**	Write the importance of ICH. Explain the ICH guidelines for stability study	**06**
	(b)	How is SMF prepared for MCC guidelines	**05**
	(c)	Write a note on IIG	**05**
Q.7	**(a)**	What is SUPAC? Discuss the SUPAC guidelines for Immediate release dosage forms.	**06**
	(b)	Describe the activity regulated by MHRA	**05**
	(c)	Discuss the WHO certification scheme for pharmaceutical products	**05**

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