Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – WINTER 2013

Subject Code: 2920202 Date: 30-11-2013

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)**	Explain Generic Drug Application and discuss the guidance documents to help prepare the said application.	**06**
	(b)	Discuss "Process Validation" and enlist the benefits of Process Validation.	**05**
	(c)	Discuss various classes of Recalls in context to MCC.	**05**
Q.2	**(a)**	Define Drug Development and write a note on New Chemical Entity development.	**06**
	(b)	Write a note on ICH.	**05**
	(c)	Mention the goals of NDA. Discuss the general requirements for filing NDA.	**05**
Q.3	**(a)**	Discuss Concurrent validation and Revalidation.	**06**
	(b)	State the object of FOIA and discuss the procedure for making FOIA requests.	**05**
	(c)	Write a note on QbD.	**05**
Q.4	**(a)**	Define and explain CTD. Write its significance, general principles and organization.	**06**
	(b)	Define and explain INDA, stating its objectives. Discuss sponsor, investigator and sponsor-investigator in context to the same.	**05**
	(c)	Explain the term ERP and mention various components/modules of the same.	**05**
Q.5	**(a)**	Discuss Dissolution test apparatus validation.	**06**
	(b)	Give brief introduction of ANVISA and enlist various regulations covered by the said agency.	**05**
	(c)	Define DMF. Enumerate types of DMF and write a note on LOA.	**05**
Q. 6	**(a)**	Write a note on CMC in context to INDA.	**06**
	(b)	Discuss various levels of changes under distinct headings of any two changes in context to SUPAC - Immediate Release Solid Oral Dosage Form.	**05**
	(c)	Enumerate key parameters of the Analytical method validation and discuss any two.	**05**
Q.7	**(a)**	Discuss the historical aspect of drug development and its approval.	**06**
	(b)	Discuss various facets of equipment validation.	**05**
	(c)	Give full form of: (i) CANDA (ii) USFDA (iii) OTC(iv) SMF (v) ADEC (vi) MHRA (vii) ANDA (viii) SAP (ix) TGA and (x) IIG	**05**

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