Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920202 **Date: 21/05/2016**

Subject Name: Global Regulatory Requirements

Time: 10:30 AM To 1:30 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)**	Which are the objectives of Process validation? Discuss in detail Retrospective validation.	**06**
	(b)	Write note on validation of "Autoclave"	**05**
	(c)	What is ERP? Give detail account of Computer validation.	**05**
Q.2	**(a)**	Discuss elements of Equipment validation, illustrate you answer with suitable example.	**06**
	(b)	Write not on validation Master plan.	**05**
	(c)	Discuss the components of Analytical method validation.	**05**
Q.3	**(a)**	Give the concept of ANDA & prepare flow chart showing ANDA review process.	**06**
	(b)	Differentiate INDA and ANDA. Describe various type of INDA.	**05**
	(c)	What is "Orange Book"? Give brief discussion on therapeutic codes in orange book.	**05**
Q.4	**(a)**	Give the organization of ICH, & it's objective, Discuss th role of ICH in improving pharmaceutical product quality.	**06**
	(b)	Write note on MHRA.	**05**
	(c)	Write note on ANVISA.	**05**
Q.5	**(a)**	Discuss TGA's risk management approach.	**06**
	(b)	Write note on IIG.	**05**
	(c)	Define CTD and e-CTD, which are the technical requirements for e-CTD.	**05**
Q. 6	**(a)**	What is SUPAC? Give SUPAC guidelines for modified release dosages form..	**06**
	(b)	Define Drug Master File, Holder, Agent and Application. Give difference between Application and DMFs.	**05**
	(c)	Write note on "USFDA".	**05**
Q. 7	**(a)**	What are the clinical trials? How are they organized as a part of drug discovery?	**06**
	(b)	Write note on "FOI".	**05**
	(c)	What are the main functions of WHO? Enlist various WHO guidelines available for pharmaceutical products.	**05**

****