Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920208 Date: 16-05-2015

Subject Name: Industrial Pharmacy - IV

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 the scope of USFDA regulations. Discuss the preparations required for facing USFDA audit.	**06**
	(b)	Write a note on electronic records.	**05**
	(c)	What is validation? Discuss its scope and rational in pharmacy.	**05**
Q.2	**(a)**	Write a note on export certificates as per MHRA. Discuss legal status and Re-classification of medicinal products.	**06**
	(b)	What is objective of IIG? Explain general description of IIG.	**05**
	(c)	Write a note on CDER.	**05**
Q.3	**(a)**	Write a short note on TGA.	**06**
	(b)	Define process validation and explain its importance in pharmaceutical industry.	**05**
	(c)	Write a note on validation of dry heat sterilizer.	**05**
Q.4	**(a)**	What is CTD? Describe various modules of CTD.	**06**
	(b)	Write in brief about regulatory issues in Indian pharmaceutical industry.	**05**
	(c)	Write in brief regulatory aspects of pharmaceutical excipients.	**05**
Q.5	**(a)**	Explain quality assurance and quality audit in detail.	**06**
	(b)	Write in detail of requirements of GLP.	**05**
	(c)	Write short note on OHSAS.	**05**
Q.6	**(a)**	Write a detailed note on new drug application approval process.	**06**
	(b)	Write a note on statistical hypothesis testing.	**05**
	(c)	Write about statistical procedure in assay development.	**05**
Q.7	**(a)**	What is Orange Book? Give a brief discussion on therapeutic codes in Orange Book.	**06**
	(b)	How a monograph for a bulk drug substance is developed in USP?	**05**
	(c)	Write in brief of study of parts of compendia.	**05**

****