Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – WINTER • 2014

Subject Code: 2920208 **Date: 26-12-2014**

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: QC and QA. Describe basic concepts involved in quality assurance.	**06**
	(b)	Write note on ISO 9000 series.	**05**
	(c)	Describe quality audits in pharmaceutical manufacturing with significance.	**05**
Q.2	(a)	Explain: Precision, Acuuracy and Bias with suitable examples.	**06**
	(b)	Describe the statistical procedures that could be used in assay development.	**05**
	(c)	What is USFDA? What does FDA regulate?	**05**
Q.3	(a)	Describe the regulatory aspects of MHRA.	**06**
	(b)	How the TGA regulates over-the-counter medicines?	**05**
	(c)	Summarize the different quality guidelines provided by ICH.	**05**
Q.4	(a)	Describe the basic concepts of Good Clinical Practice.	**06**
	(b)	What is validation? Describe its importance in pharmaceutical manufacturing.	**05**
	(c)	Discuss the approaches for process validation.	**05**
Q.5	(a)	Discuss the validation of analytical equipments.	**06**
	(b)	Give brief information about orange book and inactive ingredient guide.	**05**
	(c)	Describe the codes of therapeutic equivalency.	**05**
Q. 6	(a)	Write note on drug master file (DMF).	**06**
	(b)	Differentiate: CDER and CBER	**05**
	(c)	What biological products does FDA regulate?	**05**
Q.7	(a)	What is draft monograph? State the contents of tablet monograph.	**06**
	(b)	Which is the latest addition of IP? How it differs from an earlier addition?	**05**
	(c)	Describe the evolution of USP.	**05**

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