Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920208 **Date: 09-12-2015**

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)**	Define Quality assurance. Give the Requirements of cGMP.	**06**
	(b)	Write brief note about Quality audits.	**05**
	(c)	Define Validation. Enlist different types of validation and explain in brief.	**05**
Q.2	**(a)**	Write note on general requirements of ANVISA.	**06**
	(b)	Write brief note on TGA.	**05**
	(c)	Write short not on ICH guidelines.	**05**
Q.3	**(a)**	Give basic concepts of good clinical practice.	**06**
	(b)	Write note on Statistical procedure in assay development.	**05**
	(c)	Discuss Accuracy & Precision in detail.	**05**
Q.4	**(a)**	Give the importance of Process validation in pharma industry.	**06**
	(b)	Write the function of MCC.	**05**
	(c)	Differentiate NDA and ANDA.	**05**
Q.5	**(a)**	Write short note on Electronic records (21CFR11).	**06**
	(b)	Write a short note on validation of Rotary tablet compression machine.	**05**
	(c)	What is Orange Book? Discuss in detail.	**05**
Q. 6	**(a)**	Write a short note on Inactive Ingredient Guide (IIG).	**06**
	(b)	Discuss in brief about MHRA.	**05**
	(c)	Write brief note on Drug Master File (DMF).	**05**
Q.7	**(a)**	Give regulatory requirements of biotechnology based product.	**06**
	(b)	Discuss regulatory requirements of manufacturing of pharmaceutical products.	**05**
	(c)	Give a brief of development of a bulk drug substance monograph in Indian pharmacopoeia.	**05**

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