Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920208 **Date: 21/05/2016**

Subject Name: INDUSTRIAL PHARMACY - IV

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)**	Give the general description of GLP.	**06**
	(b)	Define ISO and give brief note on ISO 9000.	**05**
	(c)	Give the requirement of cGMP.	**05**
Q.2	**(a)**	Differentiate accuracy and precision.	**06**
	(b)	Give the concepts of good clinical practice.	**05**
	(c)	Write note on EMEA implementation of new EU Pharma. Legislation.	**05**
Q.3	**(a)**	Define CTD and eCTD. Give technical requirement for eCTD.	**06**
	(b)	Write note on ANVISA.	**05**
	(c)	Discuss the TGA's risk management approach.	**05**
Q.4	**(a)**	Discuss the WHO certification scheme for pharmaceutical product.	**06**
	(b)	Explain scope of USFDA regulation and discuss preparation required for USFAD audit.	**05**
	(c)	Write note on MHRA.	**05**
Q.5	**(a)**	Define CIP and SIP system. Explain cleaning validation parameters.	**06**
	(b)	Write note on validation of dry heat sterilizer.	**05**
	(c)	Differentiate prospective and retrospective validation.	**05**
Q. 6	**(a)**	Explain IIG.	**06**
	(b)	Write note on CDER.	**05**
	(c)	What is ERP? Give merits and demerits of ERP.	**05**
Q.7	**(a)**	Categorize ICH activities and write note on evaluation of stability data.	**06**
	(b)	Give importance of orange book and explain stastical criteria for bioequivalence.	**05**
	(c)	Write note on quality audited.	**05**

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