Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920207 **Date: 31-05-2014**

Subject Name: Quality Control And Quality Assurance

Time: 02:30 pm - 05:30 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)**	What is GLP regulation? Describe protocol for non-clinical laboratory study.	**08**
	(b)	Describe the factors affecting the selection of premises for Pharm. Industry.	**08**
Q.2	**(a)**	Discuss GMP guidelines for packaging and labelling operations.	**08**
	(b)	Describe GLP guidelines for sub part C (building and facilities).	**08**
Q.3	**(a)**	Explain the terms INDA, NDA and ANDA.	**06**
	(b)	What is an Investigator Brochure (IB)? Describe the FDA requirements for the IB.	**10**
Q.4	**(a)**	What is Bioequivalence and bioavailability? Describe importance of bioequivalence study.	**06**
	(b)	Discuss briefly the ICH Good Clinical Practice (GCP) guidelines.	**10**
Q.5	**(a)**	What do you mean by climatic zones? Describe various climatic zones with their storage conditions.	**08**
	(b)	Describe the process of WHO certification.	**08**
Q. 6	**(a)**	What is documentation? Describe statutory requirements and procedure for documentation.	**08**
	(b)	Discuss briefly the ICH guidelines for performing the stability studies of a new drug product.	**08**
Q.7	**(a)**	Discuss CMC part of NDA.	**08**
	(b)	Application of computers in quality control laboratory	**08**

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