Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM. - SEMESTER– I. EXAMINATION – SUMMER 2016

Subject Code: 1911601 **Date: 27/05/2016**

Subject Name: cGMP & Documentation

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)**	Describe interrelationship between QA and GMP.	**06**
	(b)	Explain different type of complaints and GMP procedure for handling of complaints.	**05**
	(c)	Explain in detail selection and purchase specification for equipment.	**05**
Q.2	**(a)**	Explain the WHO certification scheme.	**06**
	(b)	Explain various testing procedures for glass packaging materials.	**05**
	(c)	Short note on solid waste disposal.	**05**
Q.3	**(a)**	Explain good warehousing practice.	**06**
	(b)	Short note on purchase specification for raw materials	**05**
	(c)	Explain the packaging and labeling control guidelines for Pharmaceutical industry.	**05**
Q.4	**(a)**	Short note on Quality audit.	**06**
	(b)	Explain the specification for materials & intermediates for pharmaceutical formulation.	**05**
	(c)	What is SOP? Explain its objectives and criteria for preparation of SOP.	**05**
Q.5	**(a)**	Short note on GLP.	**06**
	(b)	Explain the IPQC test for Aerosols preparation.	**05**
	(c)	Explain the SOP’s for sterile class 100 and membrane filtration.	**05**
Q. 6	**(a)**	Short note on BMS.	**06**
	(b)	Explain the maintenance of finished product release document.	**05**
	(c)	Explain the GMP guidelines for distribution and distribution records	**05**
Q. 7	**(a)**	Explain in detail importance of personnel training and hygiene in pharmaceutical industry.	**06**
	(b)	Explain Factors to be considered for maintenance of sterile areas and control of contamination in Pharmaceutical Industry.	**05**
	(c)	Discuss about strategic sampling plan techniques.	**05**

****