Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1911601 Date: 07-01-2015

Subject Name: cGMP and Documentation

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)**	What is product Recall? Classify their types and explain the procedure to be followed for a recalling a product.	**06**
	(b)	What are reserve samples? Discuss their significance in brief.	**05**
	(c)	Write down general guidelines given for personnel selection and training.	**05**
Q.2	**(a)**	Define Quality Assurance, GMP, GLP and explain their interrelationship.	**06**
	(b)	Write a note on waste & scrap disposal.	**05**
	(c)	Write a note on purpose & procedure of vendor selection.	**05**
Q.3	**(a)**	Write a note on In Process Quality Controls of various dosage forms.	**06**
	(b)	Describe GMP guideline regarding expiry of drug product.	**05**
	(c)	Write a note on testing of packaging material	**05**
Q.4	**(a)**	What are the objectives of GLP guideline?	**06**
	(b)	Define SOPs. Discuss guideline for preparing SOP and give blank format for SOP.	**05**
	(c)	Discuss production and process controls according to guideline. Discuss in detail master formula and batch formula records.	**05**
Q.5	**(a)**	Discuss in Detail Quality Audits.	**06**
	(b)	Write a note on objectives and provision for WHO certification.	**05**
	(c)	Enlist and discuss all requirements for design and construction of Warehousing.	**05**
Q. 6	**(a)**	Write a note on Specifications for Intermediate and Finished Product.	**06**
	(b)	What do you mean by Quality Control? Explain the importance of Quality Control in Industry.	**05**
	(c)	What is packing line clearance and reconciliation of label?	**05**
Q.7	**(a)**	Write SOP for any one unit operation used in production.	**06**
	(b)	Write a note on Good Distribution Practices.	**05**
	(c)	Write a short note on cleaning maintenance and sterilization of equipment.	**05**

****