Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 910204 **Date: 02-01-2016**

Subject Name: Good Manufacturing and Good Laboratory Practice

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, GMP, GLP and explain how they are interrelated?	**06**
	(b)	Describe the objectives of GLP guideline.	**05**
	(c)	Discuss the general guidelines for Personnel selection.	**05**
Q.2	(a)	Discuss the principles of plant layout and construction with reference to manufacture of tablet dosage form giving labeled plan diagram.	**06**
	(b)	Discuss the requirements for design and construction of warehousing.	**05**
	(c)	Describe documentation for maintenance and cleaning procedure for equipments.	**05**
Q.3	(a)	Discuss the factors considered while selecting and purchasing of equipments for pharma manufacturing units.	**06**
	(b)	What are standard operating procedures? Discuss the factors considered during writing of SOP.	**05**
	(c)	Write a note on: In process quality controls of compression.	**05**
Q.4	(a)	Describe the importance of purchase specifications and maintenance of stores for raw materials.	**06**
	(b)	Write a note on: Selection of Vendors.	**05**
	(c)	Write SOP for membrane filtration.	**05**
Q.5	(a)	Discuss the importance of Line Clearing and describe how it is practiced during packing process.	**06**
	(b)	Explain reconciliation of labels.	**05**
	(c)	Write a note on: Tests carried out on plastic packaging materials.	**05**
Q. 6	(a)	Describe the tests used for printed packing materials.	**06**
	(b)	What is product recall? Describe the procedures to be followed for recalling a product.	**05**
	(c)	Wrote a note on: Audits of quality control facilities.	**05**
Q.7	(a)	Describe Self Inspection and Quality Audit in details.	**06**
	(b)	Discuss the provision and objectives of WHO certification.	**05**
	(c)	Write a note on: Specifications for finished product.	**05**

****