Seat No.: _____ **Enrolment No._____**

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm Semester–I Examination Feb. - 2012

Subject code: 910204 **Date: 15/02/2012**

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)	Describe concepts of QA, GMP and GLP in brief.	**06**
	(b)	Enumerate different guidelines of GMP.	**05**
	(c)	Write general guidelines given for personnel selection and training.	**05**
Q.2	(a)	Explain plant layout and construction with reference to parentral dosage form manufacturing.	**06**
	(b)	Write short note on cleaning maintenance and sterilization of equipment.	**05**
	(c)	Describe selection of vendor and vendor certification.	**05**
Q.3	(a)	Write note on master batch documents for tablet dosage form.	**06**
	(b)	Write in process quality controls of various dosage forms.	**05**
	(c)	Discuss line clearance regarding packaging and labeling control.	**05**
Q.4	(a)	Note on quality audits.	**06**
	(b)	Discuss design construction and maintenance of ware house.	**05**
	(c)	Describe evaluation of complaints and recall procedures.	**05**
Q.5	(a)	Describe waste and scrap disposal procedures.	**06**
	(b)	Write note on testing of packaging material.	**05**
	(c)	Explain sampling of raw and finished products.	**05**
Q. 6	(a)	What are retain samples and describe its importance.	**06**
	(b)	Describe GMP guideline regarding expiry of drug product.	**05**
	(c)	Write a note on Good Distribution Practices.	**05**
Q.7	(a)	Write SOP for any one unit operation used in production.	**06**
	(b)	Write note on Good Documentation Practices.	**05**
	(c)	Describe GMP guidelines for quality control laboratory.	**05**

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