Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 910204 **Date: 25-05-2015**

Subject Name: Good Manufacturing and Good Laboratory Practice

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)	How market complains regarding pharmaceutical formulation handled? Explain the procedures for recalling a product.	**06**
	(b)	What is the requirement of quality review and quality audit of finished goods? Classify Quality audits.	**05**
	(c)	What is acceptable method for detecting residues of contaminants in evaluating cleansing validation?	**05**
Q.2	(a)	Enlist pharmaceutical waste? Describe disposal procedures and the records to be kept for Biological waste.	**06**
	(b)	Describe the general guidelines to be observed for labeling and packaging of finished product?	**05**
	(c)	What are cGMP guidelines for recruitment of technical staff in pharmaceutical manufacturing area?	**05**
Q.3	(a)	Enlist SOP for Q.C. laboratory. Give the name of routine control instruments and reagents used in Quality Control Laboratory.	**06**
	(b)	Explain briefly the important elements of the WHO Certification scheme.	**05**
	(c)	Enumerate the tests carried out on plastic packaging materials.	**05**
Q.4	(a)	Discuss design and maintenance of warehouse of a pharmaceutical company.	**06**
	(b)	What are GMP guidelines for testing of drug product containers and closures?	**05**
	(c)	Write a note on Vendor Certification.	**05**
Q.5	(a)	Outline GLP guideline for animal house facility and animal care in a non-clinical testing laboratory.	**06**
	(b)	Write note on phases of equipment qualification.	**05**
	(c)	What are the guidelines given regarding use of automatic and electronic equipment?	**05**
Q. 6	(a)	Describe briefly a good sampling procedure for sampling of starting materials.	**06**
	(b)	What are reserve samples? Discuss briefly its significance and norms.	**05**
	(c)	Describe the in-process quality checks performed for sterile dosage forms.	**05**
Q.7	(a)	Give the regulatory guidelines for reprocessing of materials.	**06**
	(b)	Describe the key elements of a master manufacturing record.	**05**
	(c)	Explain in brief the IPQC parameters observed during the production of Controlled release Tablet.	**05**

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