Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 910204 **Date: 26-05-2014**

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)**	Write a note on purpose & procedure of vendor selection	**06**
	(b)	What is importance of Line Clearing and describe how it is practiced during Production and packing process?	**05**
	(c)	Define Quality Assurance, GMP, GLP and explain their interrelationship	**05**
Q.2	**(a)**	Discuss the general guidelines given for Personnel selection and training.	**06**
	(b)	Write the contents & interrelationship between Master Manufacturing , Batch Manufacturing & Batch Packing records.	**05**
	(c)	Describe the in-process quality checks performed on solid oral dosage forms.	**05**
Q.3	**(a)**	Explain the principles of plant layout and construction with reference to manufacture of tablet dosage form giving plan diagram.	**06**
	(b)	Describe briefly a good sampling procedure for sampling of starting materials	**05**
	(c)	What are reserve samples? Discuss briefly their significance.	**05**
Q.4	**(a)**	Write a note on WHO Certification Scheme	**06**
	(b)	Define Calibration, Qualification, Validation & Verification. Illustrate these terms referring to any one laboratory instrument.	**05**
	(c)	Write a note on cleaning, sanitization & sterilization of equipments	**05**
Q.5	**(a)**	Write a note on GLP.	**06**
	(b)	Write an account of Good Warehouse Practices	**05**
	(c)	Testing of packaging materials.	**05**
Q. 6	**(a)**	Write an SOP for any one unit operation used in production.	**06**
	(b)	Write a note on Self Inspection & Quality Audit.	**05**
	(c)	Write note on waste & scrap disposal.	**05**
Q.7	**(a)**	Write an account of Good Distribution Practices	**06**
	(b)	Write note on complaint & product recall.	**05**
	(c)	Write an account of Good Documentation Practices	**05**

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