Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 910204 Date: 09-01-2015

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 the terms GMP, Quality control & Quality assurance and explain their interrelationship.	**06**
	(b)	Enumerate GLP guidelines practiced in India and briefly explain scope of GLP activities.	**05**
	(c)	Enumerate different GMP guidelines for Drug Substance and Drug product.	**05**
Q.2	**(a)**	Define the followings in relation to pharmaceutical manufacturing facility: Plant Layout, Environment Control, Clean Area, Sanitation, Cross Contamination, Utilities.	**06**
	(b)	Explain the terms Clean-in-place (CIP) and Sterilize-in-place (SIP).	**05**
	(c)	Enumerate different documents related to production of drugs and enlist in-process tests for tablet dosage form.	**05**
Q.3	**(a)**	What is meant by SOP? Write names of five SOPs used in production department for different unit operations and describe any one of them.	**06**
	(b)	Explain Line clearance and Reconciliation of printed packaging materials in relation to Packaging and labeling operations.	**05**
	(c)	Explain role of production, QC and QA in batch release procedure.	**05**
Q.4	**(a)**	Define the followings with respect to QC operations : Sampling, Standard Test Procedure, Retention Samples.	**06**
	(b)	Enlist various sections of warehouse and Good warehouse practices.	**05**
	(c)	Write a note on Vendor approval.	**05**
Q.5	**(a)**	Describe the objective, scope and procedure for WHO certification scheme for pharmaceutical products.	**06**
	(b)	Write a note on self-inspection and quality audit.	**05**
	(c)	Give specifications for any one raw material and work-in-process material.	**05**
Q. 6	**(a)**	Define the following terms in relation to GLP: Sponsor, Quality Assurance Unit, Animal care, Protocol for conduct of study.	**06**
	(b)	How will you determine the specifications of Non-pharmaceutical product?	**05**
	(c)	Write a note on complaint and recall.	**05**
Q.7	**(a)**	Write different tests and methods for testing of primary packing materials.	**06**
	(b)	Enlist different documents related to QC laboratory testing.	**05**
	(c)	Explain importance and different types of Training imparted to an employee in pharmaceutical plant.	**05**

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