Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM. - SEMESTER – I • EXAMINATION – WINTER 2012

Subject code: 910204 **Date: 11/01/2013**

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)	Discuss WHO guideline for premises for manufacture of pharmaceuticals.	**06**
	(b)	Describe equipment maintenance and cleaning guidelines according to GMP.	**05**
	(c)	Discuss the general guidelines given for Personnel selection and training.	**05**
Q.2	(a)	Write in short about GLP.	**06**
	(b)	Discuss how records and reports generated, maintained and audited in quality control laboratory.	**05**
	(c)	Briefly describe finished product release procedure and documentation for release.	**05**
Q.3	(a)	Write in brief about WHO certification.	**06**
	(b)	Discuss testing of packaging materials.	**05**
	(c)	What are Quality audits? Classify their various types. Describe the purpose of carrying out Internal audits.	**05**
Q.4	(a)	Discuss distribution and distribution records, handling of returned goods, recovered materials and reprocessing.	**06**
	(b)	Write in short about waste product disposal.	**05**
	(c)	Discuss batch manufacturing records in detail.	**05**
Q.5	(a)	What do you mean by SOP? Which things to be considered while designing a SOP.	**06**
	(b)	Write in short about raw material purchase specification, vender selection and maintenance of store of raw material.	**05**
	(c)	What do you mean by IPQC? Give importance of it.	**05**
Q. 6	(a)	What is product recall? Classify their types and explain the procedures to be followed for recalling a product.	**06**
	(b)	Discuss issuance and record of packaging and labeling material and line clearance.	**05**
	(c)	What is a pharmaceutical warehouse? Discuss briefly the good warehousing procedures.	**05**
Q.7	(a)	Discuss the guidelines given for issuing of printed labels to prevent possible labeling errors and mix-ups.	**06**
	(b)	Discuss importance of following GMP in a pharmaceutical industry.	**05**
	(c)	Write in short about finish product specification.	**05**

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