Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER 2013

Subject Code: 910204 Date: 26-12-2013

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)	Describe Good Laboratory Practices guideline for drug testing laboratory in India.	**06**
	(b)	Describe the basic elements of quality management: I. Quality Assurance II. GMP	**05**
	(c)	Write a brief account on Waste disposal procedure with records.	**05**
Q.2	(a)	Define Recall strategy, Discuss recall strategy with its elements; Discuss the various reasons of recall.	**06**
	(b)	Write short note on Quality Audit	**05**
	(c)	Describe the advantages and disadvantages plastic containers with that of glass container. Discuss tests carried out on plastic containers.	**05**
Q.3	(a)	What are SOPs? Give objectives of SOP. Enumerate the topics of SOP. Describe the general format for SOP.	**06**
	(b)	What are complains? Discuss types, handling of complains with general format of record.	**05**
	(c)	What is importance of label control in pharmacy? What are statutory labeling requirements?	**05**
Q.4	(a)	Describe the raw material specifications with suitable examples.	**06**
	(b)	What is the aim of warehousing? Describe good warehousing practices for raw material and finished product.	**05**
	(c)	Write a note on Testing and release of finished product.	**05**
Q.5	(a)	Describe the elements with significance of WHO certification scheme.	**06**
	(b)	Write a note on selection and purchase specifications of equipments for manufacturing.	**05**
	(c)	Discuss selection and purchase specifications of an equipments for manufacturing.	**05**
Q. 6	(a)	Describe the master formula record and batch manufacturing record in detail.	**06**
	(b)	Describe in detailed general consideration for factory premises.	**05**
	(c)	What are the sources of particulate contamination? Describe the in process quality controls for sterile dosage forms briefly.	**05**
Q.7	(a)	Write brief note on Selection of vendor	**06**
	(b)	Discuss sampling plans and sampling procedure for raw material.	**05**
	(c)	Describe responsibilities and training guideline for personnel.	**05**

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