Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1911601 **Date: 23-12-2013**

Subject Name: cGMP and Documentation

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 philosophy of good manufacturing as per WHO GMP.	**06**
	(b)	Define Quality Assurance, GMP, GLP and explain their interrelationship.	**05**
	(c)	Discuss the general guideline for personnel selection, training and hygiene.	**05**
Q.2	**(a)**	Explain plant layout and construction with reference to parenteral dosage form manufacturing.	**06**
	(b)	What is importance of purchase specifications and maintenance of store for raw materials ?	**05**
	(c)	How you will select and purchase equipments as per guideline? Describe documentation for maintenance and cleaning procedure for equipments.	**05**
Q.3	**(a)**	Write the contents & interrelationship between Master Formula, Batch Manufacturing & Batch Packing records.	**06**
	(b)	Write an SOP for Compression machine.	**05**
	(c)	What is packing line clearance and reconciliation of label.	**05**
Q.4	**(a)**	Write short note on sampling plans.	**06**
	(b)	Note on quality audits.	**05**
	(c)	What is a pharmaceutical warehouse? Discuss briefly the maintenance and sanitation of warehouse.	**05**
Q.5	**(a)**	Write short note on scrap disposal procedures and its records	**06**
	(b)	Write short note on handling of returned goods.	**05**
	(c)	Explain complaints and recalls. Discuss procedure for recalls.	**05**
Q. 6	**(a)**	Define GLP. Discuss sub part C- Facilities as described in GLP guideline.	**06**
	(b)	Discuss briefly about Quality Audit.	**05**
	(c)	What are the Specifications for materials and finished product.	**05**
Q.7	**(a)**	Write short note on WHO certification scheme for pharmaceutical products.	**06**
	(b)	Discuss the tests carried for parenteral packaging material like glass bottles and vials.	**05**
	(c)	Describe the control of contamination.	**05**

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