Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1911601 Date: 23-05-2014

Subject Name: cGMP and Documentation

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)**	Briefly explain about Quality Assurance, cGMP and cGLP.	**06**
	(b)	Explain the general guidelines for plant location and its layout.	**05**
	(c)	Write a note on the maintenance and control of contamination in sterile areas.	**05**
Q.2	**(a)**	Describe the importance of equipment selection and purchase specification for any machine.	**06**
	(b)	Explain the terms: clean in place (CIP) and sterilize in place (SIP).	**05**
	(c)	Write a note on the management of packaging and raw materials store.	**05**
Q.3	**(a)**	Differentiate MFR and BMR. Write a note on BMR.	**06**
	(b)	What do you understand by SOP? Write a SOP of rotary tablet punching machine.	**05**
	(c)	Describe in details about the quality audits of manufacturing processes and facilities.	**05**
Q.4	**(a)**	What is the need of IPQC? Describe the different IPQC tests for the sterile dosage forms.	**06**
	(b)	Give importance of packaging and labeling control. Explain about the reconciliation of labels, cartons and other packaging materials.	**05**
	(c)	Give the importance of quality control documents for retention samples and audits records.	**05**
Q.5	**(a)**	Write a note on batch release and finished product release documents.	**06**
	(b)	Give the legal importance of handling of returned goods, recovered materials and reprocessing.	**05**
	(c)	Company needs which types of documents for the evaluation of complaints and recall procedures? Explain interrelations about these documents.	**05**
Q. 6	**(a)**	Write a note on GLP.	**06**
	(b)	Write a short note on waste and scrap disposal procedures with its supporting records.	**05**
	(c)	Write a short note on Sampling plans for raw materials, packaging materials and finished products.	**05**
Q.7	**(a)**	Discuss the important tests carried for parenteral packaging materials like glass ampoules and rubber stoppers.	**06**
	(b)	Write a note on WHO certification scheme for pharmaceutical products.	**05**
	(c)	Describe about the specifications for intermediates materials and finished product.	**05**

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