Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1921502 **Date: 31-05-2014**

Subject Name: GMP, GLP and Validation

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)**	Explain the importance and role of Quality Assurance in Pharma industry.	**06**
	(b)	Explain the purchase specification and vendor selection of raw materials.	**05**
	(c)	Define Quality audit. Classify and explain quality audit Pharmaceutical industry.	**05**
Q.2	**(a)**	Explain the guidelines regarding organizational and personnel in Pharmaceutical industry.	**06**
	(b)	Explain the waste and scrap disposal procedure in Pharmaceutical industry.	**05**
	(c)	Short note on cleaning validation.	**05**
Q.3	**(a)**	Define and classify recall of pharmaceutical product. Explain recall procedure of Pharmaceutical product in detail.	**06**
	(b)	Short note on Good Warehousing Practice.	**05**
	(c)	Define process validation and explain its types in detail.	**05**
Q.4	**(a)**	Shortnote on good laboratory practice.	**06**
	(b)	Explain different types of Qualification and Maintenance of equipment.	**05**
	(c)	Explain the calibration of HPLC.	**05**
Q.5	**(a)**	Explain process validation of coated tablets.	**06**
	(b)	Explain the specification regarding packaging and labeling control.	**05**
	(c)	Write down the SOP of coating and sterilization operation.	**05**
Q. 6	**(a)**	Define calibration, validation and verification. Explain each term with example	**06**
	(b)	Write a note sampling criteria in Pharmaceutical industry.	**05**
	(c)	Write a note on Good Distribution Practice.	
Q.7		Write short notes **(any two)**	**16**

1. Computer system validation.
2. Validation master plan
3. Calibration of UV-Visible spectroscopy.

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