Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1921502 **Date: 26-12-2014**

Subject Name: GMP, GLP and Validation

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)**	Explain the difference between quality assurance and quality control.	**06**
	(b)	Discuss the responsibilities of personnel and facilities to be provided to them.	**05**
	(c)	Who are vendors? How are raw materials stored and issued?	**05**
Q.2	**(a)**	Discuss the guidelines for purchase, use and maintenance of equipments.	**06**
	(b)	Write the in-process controls required in manufacture of solid dosage forms.	**05**
	(c)	Discuss the considerations in selection of premises for pharmaceutical manufacturing unit.	**05**
Q.3	**(a)**	What is line clearance? Describe the GMP guidelines followed for packaging and labeling operations.	**06**
	(b)	Describe the different functions of quality control department.	**05**
	(c)	Write a brief note on quality audits.	**05**
Q.4	**(a)**	What are complaints? How are they handled? What records are maintained regarding complaints?	**06**
	(b)	Discuss the responsibilities of QA unit as per Good Laboratory Practices.	**05**
	(c)	Write a note on Good Warehousing Practice.	**05**
Q.5	**(a)**	Define validation. Discuss its advantages.	**06**
	(b)	Describe the content of validation master plan.	**05**
	(c)	Differentiate between retrospective and prospective process validation.	**05**
Q. 6	**(a)**	Describe the validation of tablet manufacturing process.	**08**
	(b)	Explain the important elements in cleaning validation.	**08**
Q.7	**(a)**	Describe the different parameters of analytical method validation.	**08**
	(b)	Why should computer systems be validated? Explain the principles of computer system validation.	**08**

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