Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2015

Subject Code: 1921502 Date: 16-05-2015

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)**	Define validation. Discuss its advantages.	**06**
	(b)	Explain line clearance in detail.	**05**
	(c)	Write about retrospective & revalidation.	**05**
Q.2		Write short notes on following:	
	(a)	Validation of HPLC	**08**
	(b)	Validation of Dissolution test apparatus	**08**
Q.3	**(a)**	Write about design, construction, maintenance and sanitation of warehousing.	**06**
	(b)	Write a note on Good Distribution Practice.	**05**
	(c)	Write down the SOP of compression and coating operation.	**05**
Q.4	**(a)**	Write on cleaning validation in respect of equipment's and facilities.	**08**
	(b)	Describe the process validation of liquid orals.	**08**
Q.5	**(a)**	Explain the importance and role of Quality Control in Pharma industry.	**06**
	(b)	Explain the control on raw materials and finished dosage forms.	**05**
	(c)	Write the in-process controls required in manufacture of sterile dosage forms.	**05**
Q. 6	**(a)**	Describe Location, design, Plant Layout and Construction of premise of pharmaceutical manufacturing unit.	**06**
	(b)	Write a brief note on audits of quality control facilities.	**05**
	(c)	Write about reconciliation of labels, cartons and other packaging materials.	**05**
Q.7	**(a)**	Write short note on Good Laboratory Practice.	**06**
	(b)	Explain Installation Qualification, Operational Qualification and Performance Qualification.	**05**
	(c)	What are complaints? How are they evaluated?	**05**

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