Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM. - SEMESTER– II EXAMINATION – SUMMER 2016

Subject Code: 1921502 **Date: 21/05/2016**

Subject Name: GMP, GLP & Validation

Time: 10:30 AM To 1:30 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 types of process validation.	**06**
	(b)	Explain in detail manufacturing requirements for solid dosage form.	**05**
	(c)	Explain in detail Good distribution Practice.	**05**
Q.2	**(a)**	Write a short note on Quality audit.	**06**
	(b)	Explain batch release document for finished products.	**05**
	(c)	Explain various types of Recall. Explain Various GMP guidelines for recall related Procedures.	**05**
Q.3	**(a)**	Explain GMP guidelines for Packaging and labeling operation.	**06**
	(b)	Explain roles and responsibilities of QA and QC in pharmaceutical industries.	**05**
	(c)	Write a note on responsibilities of personnel in pharmaceutical organization.	**05**
Q.4	**(a)**	Explain in detail SOP for Compression and Cleaning operations in pharmceutical industries.	**06**
	(b)	Explain the process of clean in place and sterilize in place techniques.	**05**
	(c)	Give a note on GMP guidelines for selection of vendors of raw materials.	**05**
Q.5	**(a)**	Explain Various Parameters for analytical method validation.	**06**
	(b)	Write a short note on GLP.	**05**
	(c)	Give brief account on Master Formula record.	**05**
Q. 6	**(a)**	Explain in detail Computer System Validation.	**06**
	(b)	Write a note any two 1. Parenteral process validation 2. Cleaning validation 3. Liquid oral dosage forms process validation.	**10**
Q.7	**(a)**	Write short notes **(any two)** 1. Validation of HPLC. 2. Validation of dissolution test apparatus. 3. Validation of UV-Visible spectroscopy.	**16**

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