Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm – SEMESTER-VII–EXAMINATION – SUMMER-2016

Subject Code:2270014 Date: 13/05/2016

Subject Name: Instrumental and Process Validation

Time: 2:30 PM to 5:30 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)**	Describe validation of GC system.	**06**
	(b)	Describe different types of Process validation with their advantages.	**05**
	(c)	Write a note on validation of manufacturing process for sterile products.	**05**
Q.2	**(a)**	Enlist detectors used in GC. Discuss selection of the detector in GC methods.	**06**
	(b)	Define the following terms. i) Column resolution, ii) Plate number, iii) Plate height, iv) Selectivity factor, v) Capacity factor.	**05**
	(c)	Discuss the steps involved in qualification of Dry powder mixers.	**05**
Q.3	**(a)**	Give importance of Pharmaceutical Process Validation as quality assurance tool.	**06**
	(b)	Explain cleansing validation methods used in pharmaceutical formulation industry.	**05**
	(c)	Explain in brief about LC-MS.	**05**
Q.4	**(a)**	Describe instrumentation for High performance liquid chromatography.	**06**
	(b)	Write in short about mobile phase selection and optimization in RP-HPLC method.	**05**
	(c)	Describe columns and column packing materials used in GC.	**05**
Q.5	**(a)**	Draw Schematic diagram of HPTLC. Give applications of HPTLC.	**06**
	(b)	Discuss detectors used in HPLC.	**05**
	(c)	Write in short about Equipment qualification.	**05**
Q. 6	**(a)**	Discuss methods of extraction of biological fluid samples.	**06**
	(b)	How we can validate the bio analytical HPLC method.	**05**
	(c)	What is pharmaceutical validation and validation master plan?	**05**
Q.7	**(a)**	Describe Laboratory Automation.	**06**
	(b)	Describe flow injection analysis.	**05**
	(c)	What are objectives and stages of cleaning validation?	**05**

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