Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2270014 Date: 29/11/2016

Subject Name: INSTRUMENTAL AND PROCESS 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)**	Discuss scope, types and advantages of validation.	**06**
	(b)	Describe different types of process validation with their advantages.	**05**
	(c)	What is validation master plan.	**05**
Q.2	**(a)**	Discuss design qualification and installation qualification of equipment.	**06**
	(b)	Describe validation of HPLC system.	**05**
	(c)	Discuss steps involved in qualification of Dry powder mixers.	**05**
Q.3	**(a)**	Explain cleansing validation methods used in Pharmaceutical formulation industry.	**06**
	(b)	Explain LC-MS.	**05**
	(c)	Write note on laboratory automation.	**05**
Q.4	**(a)**	Describe instrumentation for High Performance liquid chromatography.	**06**
	(b)	Discuss detectors used in GC.	**05**
	(c)	Explain mobile phase selection and optimization in RP-HPLC.	**05**
Q.5	**(a)**	Draw schematic diagram of HPTLC. Give application of HPTLC.	**06**
	(b)	Give advantages of UPLC over HPLC.	**05**
	(c)	Explain resolution and plate number.	**05**
Q. 6	**(a)**	Explain extraction of biological fluid samples.	**06**
	(b)	Discuss column and column packing material used in GC.	**05**
	(c)	How we can validate the bio analytical HPLC method.	**05**
Q.7	**(a)**	Discuss performance qualification for validation of Autoclave.	**06**
	(b)	Describe flow injection analysis.	**05**
	(c)	Explain validation of manufacturing process for sterile products.	**05**

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