Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM – SEMESTER – VII • EXAMINATION – WINTER • 2015

Subject Code: 2270014 **Date: 16-12-2015**

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)	Define pharmaceutical validation. Discuss "Validation master plan".	**10**
	(b)	Discuss scope, types and advantages of validation.	**06**
Q.2	(a)	Outline objectives and principle of equipment validation. Discuss Design qualification and Installation qualification of equipment.	**10**
	(b)	Describe validation of HPLC system.	**06**
Q.3	(a)	Discuss validation of dry powder mixing, wet granulation and drying of granules for tablet manufacturing.	**10**
	(b)	Write note on laboratory automation.	**06**
Q.4	(a)	What are objectives and stages of cleaning validation? Explain cleansing validation methods used in pharmaceutical formulation industry.	**10**
	(b)	Discuss performance qualifications for the validation of Autoclave?	**06**
Q.5	(a)	Enlist desirable qualities of critical components of HPLC system. How is UPLC better than HPLC?	**10**
	(b)	Discuss steps for optimization of mobile phase with Three Organic Solvents for RP-HPLC.	**06**
Q. 6	(a)	How is Resolution and Plate Number calculated from a chromatogram? What is minimum requirement of these parameters as per ICH guidelines? How are these parameters optimized?	**10**
	(b)	Classify detectors used in HPLC. Discuss selection of the detector in HPLC methods.	**06**
Q.7	(a)	Discuss methods of precipitation of protein from biological fluid and methods for sample clean up in bio-analytical HPLC method.	**10**
	(b)	Write note on LC-MS.	**06**

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