Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm - SEMESTER–VII • EXAMINATION – SUMMER-2017

Subject Code: 2270014 Date: 10/05/2017

Subject Name: Instrumental and Process Validation

Time: 02:30 PM to 05:30 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 types and advantage of validation.	**06**
	(b)	Discuss DQ and IQ in process validation.	**05**
	(c)	Describe Validation Master Plan and its content.	**05**
Q.2	**(a)**	Define D value and F value Describe OQ and PQ steps involved in validation of Autoclave.	**06**
	(b)	Describe validation of HPLC system.	**05**
	(c)	Differentiate instrumentation of HPLC and HPTLC.	**05**
Q.3	**(a)**	Describe system suitability and explain its significance in HPLC analysis.	**06**
	(b)	What are the acceptance criteria used in cleaning validation?	**05**
	(c)	Describe the prospective validation of Tablet manufacturing process.	**05**
Q.4	**(a)**	What are different detectors used in GC.	**06**
	(b)	What is the role of pH value in method development in HPLC?	**05**
	(c)	What is hyphenated technique? write note on LC-MS.	**05**
Q.5	**(a)**	Describe validation of wet granulation process and powder mixing for tablet manufacturing.	**06**
	(b)	What is selectivity factor, Capacity factor and resolution? Elaborate their role in HPLC method development.	**05**
	(c)	What are different column and column material used in GC.	**05**
Q. 6	**(a)**	Discuss liquid – liquid extraction in biological fluid sample.	**06**
	(b)	Write note on Flow Injection Analysis.	**05**
	(c)	Write note on Lab Automation.	**05**
Q.7	**(a)**	Explain DQ and IQ and explain the criteria for requalification of instrument.	**06**
	(b)	Highlight steps for validation of Fluidized Bed Drier.	**05**
	(c)	Describe parameters to be validated for parenteral dosage form.	**05**

****