

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
