

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm – SEMESTER VII • EXAMINATION – WINTER 2017

Subject Code: 2270014

Date: 16-11-2017

Subject Name: Instrumental and process validation

Time: 10:30 am to 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) Describe cleaning validation in pharmaceutical industry.	06
	(b) Explain laboratory automation.	05
	(c) Write a note on LC-MS.	05
Q.2	(a) What is scope, types and advantages of validation?	06
	(b) Explain process validation.	05
	(c) Explain Validation Master Plan.	05
Q.3	(a) Discuss methods of extraction of biological fluid samples.	06
	(b) Explain validation of bioanalytical HPLC method.	05
	(c) Describe Flow injection analysis.	05
Q.4	(a) Describe validation of manufacturing process for sterile products.	06
	(b) Explain performance qualification for validation of Autoclave.	05
	(c) Explain column and column packing material used in GC.	05
Q.5	(a) What is design qualification and installation qualification of equipment?	06
	(b) Give advantages of UPLC over HPLC.	05
	(c) Discuss steps involved in qualification of Dry powder Mixer.	05
Q. 6	(a) Write a note on HPTLC.	06
	(b) Explain mobile phase selection and optimization in RP-HPLC.	05
	(c) Describe validation of HPLC.	05
Q.7	(a) Discuss instrumentation of HPLC.	06
	(b) Explain detectors used in GC.	05
	(c) Describe resolution and plate number.	05
