GUJARAT TECHNOLOGICAL UNIVERSITY B.Pharm - SEMESTER VII - EXAMINATION – WINTER-2016

Subject Code: 2270014Date: 29/11/2016Subject Name: INSTRUMENTAL AND PROCESS VALIDATIONTime: 10.30 am - 01.30 pmTotal Marks: 80

Instructions:

1. 2. 3. Q.1	I v		
	(a) (b) (c)	Discuss scope, types and advantages of validation. Describe different types of process validation with their advantages. What is validation master plan.	06 05 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) (b) (c)	Explain cleansing validation methods used in Pharmaceutical formulation industry. Explain LC-MS. Write note on laboratory automation.	06 05 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
