GUJARAT TECHNOLOGICAL UNIVERSITY M. Pharm - SEMESTER- III • EXAMINATION – SUMMER 2017

Subject Code: 930104Date: 29/04Subject Name: Validation and Product DevelopmentTotal MarTime: 02:30 PM to 05:30 PMTotal Mar				
Instru 1. 2. 3.	Atte Mal	s: empt any five questions. ke suitable assumptions wherever necessary. ares to the right indicate full marks.		
Q.1	(a)	Describe validation of UV spectrophotometer.	06	
	(b)	Write a short note on vendor certification.	10	
Q.2	(a)	Write a short note on various elements of Validation master plan.	06	
	(b)	Describe validation of Pharmaceutical Water system.	05	
	(c)	Write a note on In-Process control parameters of capsule.	05	
Q.3	(a) (b)	Explain validation of Tablet compression machine. Explain In-Process controls required in manufacturing process and design of Aerosol.	06 10	
Q.4	(a)	Explain the terms : Accuracy, Specificity, Robustness	06	
	(b)	Describe in detail various aspects of cleaning validation.	10	
Q.5	(a)	Explain Process validation parameters of cream and ointment formulations.	06	
	(b)	Discuss about Computer system validation.	05	
	(c)	What is validation? Explain scope and advantages of Validation.	05	
Q. 6	(a)	Explain validation of HPLC.	06	
	(b)	Define and explain: Operational Qualification and Calibration	05	
	(c)	Explain validation of Autoclave.	05	
Q.7	(a)	Write a short note on validation of HVAC system.	06	
	(b)	Explain validation of fluidized bed and try dryer.	05	
	(c)	Discuss SUPAC guideline in brief.	05	
