Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. - SEMESTER–III • EXAMINATION – SUMMER-2016

Subject Code:930104 **Date: 27/05/2016**

Subject Name: Validation and Product Development

Time:2:30 PM to 5:30 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 the following terms : Calibration, Commissioning, Qualification, Validation protocol & report, Worst case, Verification	**06**
	(b)	Describe Validation Master Plan and its contents	**05**
	(c)	Explain approach to validation with special reference to process validation	**05**
Q.2	**(a)**	Explain the concepts of URS, DQ, IQ,OQ and PQ with respect to Fluid Bed Dryer OR Tablet Compression Machine	**06**
	(b)	Write a note on validation of integrated line by Media Fill Test.	**05**
	(c)	Explain the significance of vendor certification and SOP thereof.	**05**
Q.3	**(a)**	Enumerate different HVAC system parameters used in qualification of pharmaceutical facility	**06**
	(b)	Draw a diagram of AHU showing different components and state their functions	**05**
	(c)	Explain the relationship between Action Limit and Alert Limit, Requalification and Change Control	**05**
Q.4	**(a)**	Enlist different types of pharmaceutical waters. Draw a diagram of purified water generation, storage and distribution system	**06**
	(b)	Explain three phases of pharmaceutical water system validation	**05**
	(c)	Describe acceptance criteria used in cleaning validation	**05**
Q.5	**(a)**	Enumerate different parameters used for Analytical Method Validation of assay and impurity tests	**06**
	(b)	Enlist different parameters used for calibration/qualification of UV Visible spectrophotometer stating acceptance criteria	**05**
	(c)	Define system suitability and explain its significance in HPLC analysis	**05**
Q. 6	**(a)**	Write a protocol for process validation of coating stage of film coated tablets	**06**
	(b)	Write a note on validation parameters of dissolution test apparatus.	**05**
	(c)	Enumerate In-process control tests used during development and manufacture of tablets and injectable preparations	**05**
Q.7	**(a)**	Write a note on Technology Transfer and Scale-up operation.	**06**
	(b)	Enlist different types of changes to be submitted post approval to licensing authority as per SUPAC guidelines	**05**
	(c)	Explain various aspects of Computer System Validation	**05**

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