Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 930104 Date: 23/11/2016

Subject Name: Validation and Product Development

Time: 10.30 am – 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)**	Define the followings:- Calibration, Verification, Action and Alert Limit, Operating and Maintenance Manual, Good Engineering Practice, Worst Case	**06**
	(b)	Describe the significance and key elements of Validation Master Plan	**05**
	(c)	Enumerate advantages of validation and explain the regulatory import of validation	**05**
Q.2	**(a)**	Explain how Qualification is a part of Validation. Describe the stages of Qualification	**06**
	(b)	Explain relationship between Requalification and Change control	**05**
	(c)	Write a note on vendor certification describing criteria and methods used	**05**
Q.3	**(a)**	Explain the components and functions of Air Handling Unit installed in pharmaceutical manufacturing facility with a diagram	**06**
	(b)	Enlist various parameters for qualification of HVAC system with reference to Manufacturing environment, Airflow and Air cleanliness	**05**
	(c)	Mention types of pharmaceutical waters and Three phase PQ approach to validation of water system	**05**
Q.4	**(a)**	Explain Qualification protocol vs Qualification report. Write a protocol for qualification of Fluid Bed Dryer	**06**
	(b)	What is meant by validation of Sterilization process and Aseptic processing? Describe the important steps in qualification of Dry Heat Sterilizer/tunnel	**05**
	(c)	Enlist the parameters used for qualification of different modules of HPLC system	**05**
Q.5	**(a)**	Describe the types of process validation. What is current regulatory guidance on the subject?	**06**
	(b)	Write a protocol for validation of process for ointment /cream manufacturing	**05**
	(c)	Describe the acceptance criteria for cleanliness in cleaning validation	**05**
Q. 6	**(a)**	What is meant by Analytical Method Validation? What should be the approach for validation of pharmacopoeial methods? Enlist characteristics for validation of assay and impurity testing.	**06**
	(b)	What is the significance of system suitability? What are the parameters used for system suitability of HPLC test method?	**05**
	(c)	Enlist aspects of computer system validation with respect to hardware and software.	**05**
Q.7	**(a)**	Give full form of SUPAC as per USFDA guidance. What is meant by Level 1, 2 and 3 changes with respect to components and composition?	**06**
	(b)	How stability and dissolution tests are performed to establish pharmaceutical equivalence between currently used formulation and proposed change	**05**
	(c)	Enlist in-process tests performed during design and manufacture of solid oral and sterile preparations.	**05**

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