Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm – SEMESTER II • EXAMINATION – WINTER 2016

Subject Code: 1921502 Date: 02/12/2016

Subject Name: GMP, GLP AND VALIDATION

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)**	Describe equipment maintenance and cleaning guidelines according to GMP	**06**
	(b)	What is process validation? Discuss operational and performance qualification in detail.	**05**
	(c)	Write a short note on Quality review and Quality audit.	**05**
Q.2	**(a)**	Explain in detail IPQC tests of Parenteral pharmaceutical products.	**06**
	(b)	Explain in detail location, layout and design of Pharmaceutical Plant.	**05**
	(c)	Explain in detail validation of Dissolution test apparatus	**05**
Q.3	**(a)**	Write a note on specific manufacturing requirements for semisolid dosage forms.	**06**
	(b)	Write a short note on current GLP requirements.	**05**
	(c)	Explain in detail Master formula record.	**05**
Q.4	**(a)**	Explain in detail vendor selection and vendor certification process.	**06**
	(b)	What is SOP? Describe in detail key aspects of writing SOP.	**05**
	(c)	Write a short note on validation master plan	**05**
Q.5	**(a)**	Write a note on process validation of Semisolid dosage forms.	**06**
	(b)	Discuss in detail medical waste disposal and scrap disposal procedures.	**05**
	(c)	Write a note on Good Warehousing Practice in pharmaceutical industry.	**05**
Q. 6	**(a)**	Explain the process and importance of Sterilize in Place.	**06**
	(b)	Write a short note on computer system validation.	**05**
	(c)	Explain in detail different factors of Analytical Method validation.	**05**
Q.7	**(a)**	Explain packaging and labeling control requirements as per GMP. What is the importance of line clearance?	**06**
	(b)	Explain handling and processing of returned goods in Pharmaceutical organization.	**05**
	(c)	Explain the process of cleaning validation in detail.	**05**

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