Seat No.: _____ Enrolment No._____

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

Subject code: 1921502 **Date: 31/05/2017**
Subject Name: GMP, GLP AND VALIDATION
Time: 10:30 AM to 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)	Write a note on analytical method validation parameters as per ICH	**06**
	(b)	Write a note on vendor selection and certification.	**05**
	(c)	Write note on complaint & product recall.	**05**
Q.2	(a)	Define validation. Write advantages , disadvantages, limitation of validation and explain various type of validation.	**08**
	(b)	Write a note on following (any two) i) Validation of HPLC ii) Validation of Dissolution test apparatus iii) Validation of U.V./Visible spectrophotometer	**08**
Q.3	(a)	Describe the GMP guidelines for personnel selection, training and responsibilities.	**06**
	(b)	Write a note on in process control in manufacturing design and development of ophthalmic preparation.	**05**
	(c)	Explain roles and responsibilities of QA and QC in pharmaceutical industries.	**05**
Q.4	(a)	What is IPQC? Explain in brief the IPQC parameters observed during the production of tablets.	**08**
	(b)	What are SOPs? Give objectives of SOP. Enumerate the topics of SOP. Describe the general format for SOP in detail.	**08**
Q.5	(a)	Write an account of Good Distribution Practices.	**08**
	(b)	Write a detail note on GLP	**08**
Q. 6	(a)	Write a note on cleaning validation.	**06**
	(b)	Write a note on computer system validation.	**05**
	(c)	Write note on validation master plan(VMP)	**05**
Q. 7	(a)	Write an account of Good Warehouse Practices.	**08**
	(b)	Describe details of in-process quality checks performed for sterile dosage forms.	**08**

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