Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. - SEMESTER– I • EXAMINATION – SUMMER-2018

Subject Code: 910204 Date: 07/05/2018
Subject Name: Good Manufacturing and Good Laboratory Practice
Time: 02:30PM TO 05:30PM 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)**	What is SOP? What is the purpose of SOP? What are the factors that must be considered while writing a SOP?	**06**
	(b)	Write standard operating procedure for tablet compression machine.	**05**
	(c)	Give sampling plans and sampling procedure for raw material.	**05**
Q.2	**(a)**	Describe the objective, scope and procedure for WHO certification scheme for pharmaceutical products.	**06**
	(b)	What is master formula record? Discuss briefly key elements of master formula record.	**05**
	(c)	Write a note on purpose and procedure for vendor selection.	**05**
Q.3	**(a)**	Why GMP in pharmaceutical plant is required? How to prepare and developed GMP documents?	**06**
	(b)	Explain: GLP. Discuss in brief the key points in GLP.	**05**
	(c)	What is pharmaceutical waste? Describe the waste disposal procedures and the records to be kept for them.	**05**
Q.4	**(a)**	What is product recall? Classify their types and explain the procedures to be followed for recalling a product.	**06**
	(b)	Write a note on in – process quality control of sterile dosage form.	**05**
	(c)	Discuss handling of returned goods with suitable examples.	**05**
Q.5	**(a)**	What are Quality audits? Why quality audit is required in pharmaceutical plant? Discuss the purpose of carrying out internal audits.	**06**
	(b)	Write a note on purchase specifications for equipments.	**05**
	(c)	What is importance of line clearance? Discuss in brief about packing line clearance and reconciliation of label.	**05**
Q. 6	**(a)**	Discuss different types of glass used in packaging. Discuss tests for glass containers.	**06**
	(b)	Explain the principles of plant layout with respect to pharmaceutical manufacturing unit for oral solid dosage forms.	**05**
	(c)	Describe specifications for intermediates and finished products.	**05**
Q.7	**(a)**	Explain: Storage. Discuss briefly good warehousing procedure for different material used in pharmaceutical industry.	**06**
	(b)	Write briefly on distribution records.	**05**
	(c)	Write in brief about responsibilities and training guideline for personnel.	**05**

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