

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm. – SEMESTER– I • EXAMINATION – SUMMER-2016****Subject Code: 910204****Date: 30/05/2016****Subject Name: Good Manufacturing and Good Laboratory Practices****Time: 10:30 AM to 1:30 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)	What is quality assurance? Describe the activities of quality assurance department.	06
	(b)	What is GMP? Why do we have GMP regulations? Enumerate major risks in pharmaceutical production.	05
	(c)	Why was GLP created? Discuss objectives of GLP.	05
Q.2	(a)	Enlist various benefits of quality audit. Write a note on auditing procedure.	06
	(b)	What are SOPs? Why SOPs are needed? Prepare SOP for cleaning of tablet compression machine.	05
	(c)	Write a note on good warehousing procedure.	05
Q.3	(a)	Write on in-process quality controls for various dosage forms.	06
	(b)	Define quality control. What is difference between quality control and quality assurance? Describe the responsibilities and activities of quality control laboratory.	05
	(c)	Enlist various types of pharmaceutical product recalls and explain the procedure for recalling product.	05
Q.4	(a)	Give GMP guidelines for manufacturing premises.	06
	(b)	Write a note on WHO certification scheme.	05
	(c)	Describe the components of batch manufacturing records.	05
Q.5	(a)	Discuss important factors to be considered while selecting & purchasing equipments for pharmaceutical manufacturing.	06
	(b)	Explain good sampling procedure for starting materials. Give significance of reserve samples.	05
	(c)	Describe in brief various tests for plastic packaging materials.	05
Q. 6	(a)	Describe the GMP guidelines for personnel selection, training and responsibilities.	06
	(b)	Discuss in brief the GMP regulations regarding packaging and labeling controls.	05
	(c)	Write a note on fundamentals of GLP.	05
Q.7	(a)	Enumerate various records to be maintained for finished product release, distribution of drug product, and waste disposal.	06
	(b)	Describe in brief purchase specifications, maintenance of store and selection of vendor for raw materials.	05
	(c)	Explain in brief ten principles of GMPs.	05
