Seat No.:	Enrolment No.
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GUJARAT TECHNOLOGICAL UNIVERSITY				
a		M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2015		
•		le: 910204 Date: 02-01-20	J16	
-		ne: Good Manufacturing and Good Laboratory Practice		
Time	e: 10.30	am - 01.30 pm Total Marks:	80	
Instru	actions:			
		empt any five questions.		
		ke suitable assumptions wherever necessary.		
	3. Fig	ures to the right indicate full marks.		
Q.1	(a)	Define Quality Assurance, GMP, GLP and explain how they are interrelated?	06	
	(b)	Describe the objectives of GLP guideline.	05	
	(c)	Discuss the general guidelines for Personnel selection.	05	
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Q.2	(a)	Discuss the principles of plant layout and construction with reference to manufacture of tablet dosage form giving labeled plan diagram.	06	
	(b)	Discuss the requirements for design and construction of warehousing.	05	
	(c)	Describe documentation for maintenance and cleaning procedure for equipments.	05	
Q.3	(a)	Discuss the factors considered while selecting and purchasing of equipments for pharma manufacturing units.	06	
	(b)	What are standard operating procedures? Discuss the factors considered during writing of SOP.	05	
	(c)	Write a note on: In process quality controls of compression.	05	
Q.4	(a)	Describe the importance of purchase specifications and maintenance of stores for raw materials.	06	
	(b)	Write a note on: Selection of Vendors.	05	
	(c)	Write SOP for membrane filtration.	05	
Q.5	(a)	Discuss the importance of Line Clearing and describe how it is practiced during packing process.	06	
	(b)	Explain reconciliation of labels.	05	
	(c)	Write a note on: Tests carried out on plastic packaging materials.	05	
Q. 6	(a) (b)	Describe the tests used for printed packing materials. What is product recall? Describe the procedures to be followed for	06 05	
	(c)	recalling a product. Wrote a note on: Audits of quality control facilities.	05	
Q.7	(a)	Describe Self Inspection and Quality Audit in details.	06	

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Discuss the provision and objectives of WHO certification.

Write a note on: Specifications for finished product.

(b)

(c)