Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. IST Semester Examination – June- 2011

Subject code: 910204

Subject Name: Good manufacturing and Good Laboratory Practice

Date:24/06/2011 **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)**	Discuss philosophy of good manufacturing as per WHO GMP.	**08**
	(b)	Discuss general requirements, environmental control, utilities and services like gas, water, maintenance of sterile areas and control of contamination.	**08**
Q.2	**(a)**	How you will select and purchase equipments as per guideline? Describe documentation for maintenance and cleaning procedure for equipments.	**06**
	(b)	What is importance of purchase specifications and maintenance of store for raw materials?	**05**
	(c)	Discuss production and process controls accordingly to guideline discuss in detail master formula and batch formula records	**05**
Q.3		Write short note on followings:	
	(a)	In process quality controls and SOP of coating.	**06**
	(b)	WHO certification: Its provision and objectives.	**05**
	(c)	Testing of packaging materials	**05**
Q.4	**(a)**	Discuss general requirments for control of components and drug product container and closure.	**06**
	(b)	Enlist and discuss all requirements for design and construction of warehousing.	**05**
	(c)	Define SOPs. Discuss guideline for preparing SOP and give blank format for SOP.	**05**
Q.5	**(a)**	Explain complaints and recalls. Discuss procedure for recalls.	**08**
	(b)	Discuss qualifications, training, requirements and responsibilities of personnel in pharma organizations.	**08**
Q. 6	**(a)**	What are the objectives of GLP guideline?	**06**
	(b)	Discuss sub part B-organization and personnel as described in GLP guideline	**05**
	(c)	Discuss sub part C- Facilities as described in GLP guideline	**05**
Q.7		Discuss in detail	
	(a)	Quality audit	**06**
	(b)	Specifications for intermediate and finished product	**05**
	(c)	Waste disposal and scrap disposal procedures	**05**

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