Seat No.: _____ **Enrolment No._____**

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-I Examination January 2010

Subject code: 910204

Subject Name: Good Manufacturing And Good Laboratory Practice

Date: 30 / 01 / 2010 **Time:12.00 – 3.00 pm**

Instructions: **Total Marks: 80**

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1	(a)	What is GLP? Describe the responsibilities of the Quality assurance unit of a non-clinical testing laboratory.	**06**
	(b)	What are the important factors considered while selecting and purchasing an equipment for manufacturing?	**05**
	(c)	What are the guidelines given regarding use of automatic, mechanical and electronic equipment.	**05**
Q.2	(a)	Discuss the GMP guidelines for testing and approval / rejection of components, drug product containers and closures.	**06**
	(b)	Write a note on Vendor Certification.	**05**
	(c)	What is a pharmaceutical warehouse? Discuss briefly the good warehousing procedures.	**05**
Q.3	(a)	Enlist the various records required to be maintained in pharmaceutical manufacturing , control and distribution of drug products.	**06**
	(b)	Describe the key components of a master manufacturing record.	**05**
	(c)	Explain the significance and the GMP regulations regarding expiration dating of drug products.	**05**
Q.4	(a)	Describe the in-process quality checks performed on various dosage forms.	**06**
	(b)	Describe briefly a good sampling procedure for sampling of starting materials.	**05**
	(c)	What are reserve samples? Discuss briefly their significance.	**05**
Q.5	(a)	Discuss the guidelines given for issuing of printed labels to prevent possible labeling errors and mix-ups.	**06**
	(b)	Enumerate the tests carried out on plastic packaging materials.	**05**
	(c)	Explain briefly the important elements of the WHO Certification scheme.	**05**
Q. 6	(a)	What is product recall? Classify their types and explain the procedures to be followed for recalling a product.	**06**
	(b)	What are standard operating procedures? What are the factors that must be considered while writing a SOP?	**05**
	(c)	What are Quality audits? Classify their various types. Describe the purpose of carrying out Internal audits.	**05**
Q.7	(a)	Discuss the general guidelines given for Personnel selection and training.	**06**
	(b)	Describe the general guidelines to be followed for design and use of documents. What minimum information must a finished product label bear?	**05**
	(c)	What is pharmaceutical waste? Describe the waste disposal procedures and the records to be kept for them.	**05**

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