Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-I Regular / Remedial Examination January/February 2011

Subject code: 910204

Subject Name: Good Manufacturing and Good Laboratory Practice

Date: 03 /02 /2011 **Time: 10.30 am – 01.30 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)	Define Quality Assurance, GMP, GLP and explain their interrelationship	**06**
	(b)	Enlist different guidelines for GMP and GLP	**05**
	(c)	Write a note on WHO Certification Scheme & CPP	**05**
Q.2	(a)	Explain the principles of plant layout and construction with reference to manufacture of tablet dosage form giving plan diagram	**06**
	(b)	Write a note on cleaning, sanitization & sterilization of equipments	**05**
	(c)	Write a note on purpose & procedure of vendor selection	**05**
Q.3	(a)	Write the contents & interrelationship between Master Formula, Batch Manufacturing & Batch Packing records	**06**
	(b)	Write an SOP for any one unit operation used in production	**05**
	(c)	Describe In-process tests in manufacture of oral solids, oral liquids, liquid and powder injectables	**05**
Q.4	(a)	What is importance of Line Clearing and describe how it is practiced during Production and packing process?	**06**
	(b)	Explain importance & method for reconciliation of packing materials	**05**
	(c)	Describe Sampling of raw & packing materials & finished products	**05**
Q.5	(a)	Write an account of Good Warehouse Practices	**06**
	(b)	Write an account of Good Documentation Practices	**05**
	(c)	Write an account of Good Distribution Practices	**05**
Q. 6	(a)	Define Calibration, Qualification, Validation & Verification. Illustrate these terms referring to any one laboratory instrument	**06**
	(b)	Tests used for printed packing materials, glass bottles & Vials	**05**
	(c)	Write a note on Self Inspection & Quality Audit	**05**
Q.7	(a)	Write specifications generally employed for Drug Substance & drug products	**06**
	(b)	Write note on complaint & product recall	**05**
	(c)	Write note on waste & scrap disposal	**05**

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