

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.

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|------------|---|-----------|
| <b>Q.1</b> | (a) Define Quality Assurance, GMP, GLP and explain their interrelationship  | <b>06</b> |
|            | (b) Enlist different guidelines for GMP and GLP   | <b>05</b> |
|            | (c) Write a note on WHO Certification Scheme & CPP  | <b>05</b> |
| <b>Q.2</b> | (a) Explain the principles of plant layout and construction with reference to manufacture of tablet dosage form giving plan diagram | <b>06</b> |
|            | (b) Write a note on cleaning, sanitization & sterilization of equipments  | <b>05</b> |
|            | (c) Write a note on purpose & procedure of vendor selection   | <b>05</b> |
| <b>Q.3</b> | (a) Write the contents & interrelationship between Master Formula, Batch Manufacturing & Batch Packing records                      | <b>06</b> |
|            | (b) Write an SOP for any one unit operation used in production  | <b>05</b> |
|            | (c) Describe In-process tests in manufacture of oral solids, oral liquids, liquid and powder injectables                            | <b>05</b> |
| <b>Q.4</b> | (a) What is importance of Line Clearing and describe how it is practiced during Production and packing process?                     | <b>06</b> |
|            | (b) Explain importance & method for reconciliation of packing materials   | <b>05</b> |
|            | (c) Describe Sampling of raw & packing materials & finished products  | <b>05</b> |
| <b>Q.5</b> | (a) Write an account of Good Warehouse Practices  | <b>06</b> |
|            | (b) Write an account of Good Documentation Practices  | <b>05</b> |
|            | (c) Write an account of Good Distribution Practices   | <b>05</b> |
| <b>Q.6</b> | (a) Define Calibration, Qualification, Validation & Verification. Illustrate these terms referring to any one laboratory instrument | <b>06</b> |
|            | (b) Tests used for printed packing materials, glass bottles & Vials   | <b>05</b> |
|            | (c) Write a note on Self Inspection & Quality Audit   | <b>05</b> |
| <b>Q.7</b> | (a) Write specifications generally employed for Drug Substance & drug products  | <b>06</b> |
|            | (b) Write note on complaint & product recall  | <b>05</b> |
|            | (c) Write note on waste & scrap disposal  | <b>05</b> |

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