

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER • 2014

Subject Code: 910204

Date: 26-05-2014

Subject Name: Good Manufacturing and Good Laboratory Practice

Time: 02:30 pm - 05:30 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) Write a note on purpose & procedure of vendor selection | 06 |
| | (b) What is importance of Line Clearing and describe how it is practiced during Production and packing process? | 05 |
| | (c) Define Quality Assurance, GMP, GLP and explain their interrelationship | 05 |
| Q.2 | (a) Discuss the general guidelines given for Personnel selection and training. | 06 |
| | (b) Write the contents & interrelationship between Master Manufacturing , Batch Manufacturing & Batch Packing records. | 05 |
| | (c) Describe the in-process quality checks performed on solid oral dosage forms. | 05 |
| Q.3 | (a) Explain the principles of plant layout and construction with reference to manufacture of tablet dosage form giving plan diagram. | 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.4 | (a) Write a note on WHO Certification Scheme | 06 |
| | (b) Define Calibration, Qualification, Validation & Verification. Illustrate these terms referring to any one laboratory instrument. | 05 |
| | (c) Write a note on cleaning, sanitization & sterilization of equipments | 05 |
| Q.5 | (a) Write a note on GLP. | 06 |
| | (b) Write an account of Good Warehouse Practices | 05 |
| | (c) Testing of packaging materials. | 05 |
| Q.6 | (a) Write an SOP for any one unit operation used in production. | 06 |
| | (b) Write a note on Self Inspection & Quality Audit. | 05 |
| | (c) Write note on waste & scrap disposal. | 05 |
| Q.7 | (a) Write an account of Good Distribution Practices | 06 |
| | (b) Write note on complaint & product recall. | 05 |
| | (c) Write an account of Good Documentation Practices | 05 |
