

GUJARAT TECHNOLOGICAL UNIVERSITY
M. PHARM - SEMESTER- II EXAMINATION – SUMMER 2016

Subject Code: 2920207**Date: 21/05/2016****Subject Name: Quality Control & Quality Assurance****Time: 10:30 AM To 1:30 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) What are the activities of ICH and its constitution? | 06 |
| | (b) Describe procedure for filing of INDA for approval and registration. | 05 |
| | (c) Give procedure for documentation. | 05 |
| Q.2 | (a) Explain regulatory aspect for manufacturing of biotechnologically derived products. | 06 |
| | (b) Write a note on: determination of shelf life. | 05 |
| | (c) Application of computers in Quality control laboratory. | 05 |
| Q.3 | (a) Write in detail about quadrants of GLP. | 06 |
| | (b) Differentiate GLP and GCP. | 05 |
| | (c) Explain WHO certification. | 05 |
| Q.4 | (a) Give statutory requirements and importance of documentation. | 06 |
| | (b) How to present, record and interpret stability data. | 05 |
| | (c) Write a note on: Patenting of Pharmaceuticals. | 05 |
| Q.5 | (a) Write the procedure for filing a New Drug Application. | 06 |
| | (b) What are the recent advances in the stability testing equipment? | 05 |
| | (c) What are the GMP norms for packaging and labeling of pharmaceuticals? | 05 |
| Q. 6 | (a) Protocol for stability testing under different climatic zones and conditions. | 06 |
| | (b) What are the norms and controls on animal house facility? | 05 |
| | (c) What are the norms for container and closures? | 05 |
| Q.7 | (a) Discuss management's responsibilities in light of GLP. | 06 |
| | (b) Explain CMC section in regulatory submissions. | 05 |
| | (c) Write a note on : (i) Vendor qualification (ii) Master batch packing formula. | 05 |
