

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. – SEMESTER – II • EXAMINATION – WINTER • 2014

Subject Code: 2920207**Date: 26-12-2014****Subject Name: Quality Control and Quality Assurance****Time: 10:30 am - 01:30 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 care and handling of animals as per GLP guidelines **06**
(b) Discuss the application of computers in quality control laboratories **05**
(c) What are the general provisions for building and manufacturing facilities as per GLP guidelines **05**
- Q.2** (a) What do GLP guidelines suggest for the control of records and reports? **06**
(b) What are the current GMP guidelines for manufacturing and processing of drugs **05**
(c) Write a note on guidelines of GMP concerning finished products. **05**
- Q.3** (a) What are the Process validation guidelines as per cGMP? **06**
(b) What are the responsibilities of quality control unit? **05**
(c) Enlist GMP guidelines for packaging and labeling of pharmaceuticals. **05**
- Q.4** (a) For which drug does company file ANDA? What are its steps? **06**
(b) Write a note on NDA submission. **05**
(c) Discuss exploratory IND studies. **05**
- Q.5** (a) What are different drug degradation pathways? Write a note on chemical stability of a drug molecule. **06**
(b) Discuss different methods for the determination of shelf life of a product. **05**
(c) Write a note on bracketing and matrixing design guidelines for stability testing of a new drug substance. **05**
- Q.6** (a) Write a note on ICH guidelines for the stability testing of a new drug substance and dosage forms. **06**
(b) Discuss equipments used for the stability testing of new drug entities. **05**
(c) Discuss the importance of documentation. **05**
- Q.7** (a) Write a note on guidelines on the implementation of the WHO certification scheme **06**
(b) How can shelf life be determined based on stability studies. **05**
(c) Write a note on structure of ICH. **05**
