

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2015****Subject Code: 2920207****Date: 16-05-2015****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) What are the responsibilities of quality control unit? **06**
(b) What is documentation? Describe statutory requirements and procedure for documentation. **05**
(c) Explain the following terms: SOPs, Study Director, Regulatory study, Raw data, Line clearance. **05**
- Q.2** (a) Describe the process of WHO certification. **06**
(b) Discuss in detail about the application of computers in quality control laboratory. **05**
(c) Discuss the principles of ICH Good Clinical Practices. **05**
- Q.3** (a) Describe the content of CMC section in NDA submission. **06**
(b) Describe the structure of ICH. **05**
(c) Discuss Management's responsibilities in the light of GLP principles. **05**
- Q.4** (a) How does bracketing and matrixing is useful in stability study? Give guidelines for the same. **06**
(b) Discuss the following terms in association with ICH : (i) EWG (ii) Concept Paper (iii) Final Business Plans **05**
(c) Discuss exploratory IND studies. **05**
- Q.5** (a) Write a note on: (i) Vendor qualification (ii) Master batch packing formula. **06**
(b) Give content of study plan and discuss in brief conduct of study as per GLP regulations. **05**
(c) Give an account of guidelines for photostability testing of new drug substance. **05**
- Q. 6** (a) Explain the terms INDA, NDA and ANDA in brief. **06**
(b) Discuss in detail process validation as per CGMP. **05**
(c) What is shelf life? Explain shelf life determination performed for a drug? **05**
- Q.7** (a) Discuss building and manufacturing facilities for pharmaceuticals. **06**
(b) Describe the different climatic zones as per ICH guideline. What is meant by 'significant change'? **05**
(c) What is Bioequivalence and bioavailability? Describe importance of bioequivalence study. **05**
