Seat No.: _____ Enrolment No._____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2014**

**Subject Code: 1911502** **Date: 09-01-2015**

**Subject Name: Basic Concepts of Regulatory Affairs**

**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.**

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|---|---|---|---|
| **Q.1** | (a) | Compare organization and role of QA and QC in Pharmaceutical industry. | **06** |
| | (b) | What is mean by quality product? Explain concept of TQM for dosage form. | **05** |
| | (c) | What are key elements of GMP? Enlist risk involved in bypassing GMP. | **05** |
| **Q.2** | (a) | Outline historical background of GLP. Enlist Objectives, SOPs and Certification requirements of GLP. | **06** |
| | (b) | Discuss GLP guidelines for disqualification of laboratory facilities. | **05** |
| | (c) | What are the salient features of consumer protection act? | **05** |
| **Q.3** | (a) | What are objectives and technical data requirement for product registration at international level? | **06** |
| | (b) | Write note on "Abusive Practices -- Federal Trade Commission Act" | **05** |
| | (c) | Explain functions of center for drug evaluation and Research. | **05** |
| **Q.4** | (a) | Discuss self life of cosmetics. | **04** |
| | (b) | Does FDA require animal testing for cosmetics? Explain. | **04** |
| | (c) | What precautions should you take if you dye your hairs? Why? | **04** |
| | (d) | What ingredients are prohibited from use in cosmetics? | **04** |
| **Q.5** | (a) | What is CPCB? Outline objectives of the environment pollution control act. | **06** |
| | (b) | Discuss powers and functions of CPCB. | **05** |
| | (c) | What is tort law about? Discuss various offences covered under the tort law? | **05** |
| **Q. 6** | (a) | What was reason for introduction of Federal Food and drug control Act 1938? Discuss the scope of the Act. | **06** |
| | (b) | What was Durham Humphrey amendment 1951? How was it enforced? | **05** |
| | (c) | Give chart of step involved in new drug development process. | **05** |
| **Q.7** | (a) | What is GATT? How did it affect economy of Indian pharmaceutical industry? | **04** |
| | (b) | Correlate Patent and R & D. | **04** |
| | (c) | Discuss WHO certification in export import of drug. | **04** |
| | (d) | Discuss Trade mark dispute. | **04** |

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