

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER 2013

Subject Code: 1911502

Date: 26-12-2013

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 & role of QA & 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 & 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 & 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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