

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. - SEMESTER– I • EXAMINATION – SUMMER-2016

Subject Code: 1911502

Date: 30/05/2016

Subject Name: Basic concepts of Regulatory Affairs

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.**

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|-------------|------------|--|-----------|
| Q.1 | (a) | Give a brief note on ISO 9001. | 06 |
| | (b) | What is CPCB? Outline objectives of the environment pollution control act | 05 |
| | (c) | What was Durham Humphrey amendment 1951? How was it enforced? | 05 |
| Q.2 | (a) | Explain loan licensing in Pharmaceutical industry. | 06 |
| | (b) | Discuss WHO certification in export import of drug. | 05 |
| | (c) | Explain in detail about GATT. | 05 |
| Q.3 | (a) | Prescription Drug Marketing act 1987. | 06 |
| | (b) | Describe the history and organization structure of USFDA. | 05 |
| | (c) | How is manufacture and sale of cosmetics regulated in India? | 05 |
| Q.4 | (a) | Write the objectives of Drug Listing Act and Prescription Drug Marketing Act. | 06 |
| | (b) | Explain the aim, purpose, general provisions of the Hatch Waxman act, 1984 along with its amendments | 05 |
| | (c) | Write a short note on Copyrights. | 05 |
| Q.5 | (a) | Write a short note on Factory Act. | 06 |
| | (b) | Write a short note on Kefauver-Harris amendment 1962 | 05 |
| | (c) | Write a note on WTO. | 05 |
| Q. 6 | (a) | Write a brief note on sale and import of drug according to Drugs and Cosmetic Act | 06 |
| | (b) | Explain different types of Trademark with suitable examples | 05 |
| | (c) | Explain the role of Total Quality Management in Pharmaceutical industry. | 05 |
| Q.7 | (a) | Give the salient features of the Consumer Protection Act | 06 |
| | (b) | What is tort law about? Discuss various offences covered under the tort law? | 05 |
| | (c) | Write a short note on ICH guidelines. | 05 |
