

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm. - SEMESTER- III • EXAMINATION – SUMMER-2016****Subject Code:1931601****Date: 27/05/2016****Subject Name: Regulatory Affairs-II****Time: 2:30 PM to 5:30 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) | Discuss the regulatory aspects that affect drug product design, manufacture and distribution in Brazil. | 06 |
| | (b) | What are Bolar exemptions? Give a brief account on recent developments relating to the bolar exemptions. | 05 |
| | (c) | Write a note on: Hatch Waxman Act. | 05 |
| Q.2 | (a) | Discuss in brief the regulatory requirements for pharmaceutical and bulk drug manufacture. | 06 |
| | (b) | Explain the procedures for certification and licensing of a pharmaceutical product. | 05 |
| | (c) | Give a brief account on importance of regulatory drug analysis. | 05 |
| Q.3 | (a) | Explain herbal drug regulations in India. State the differences of the same from the regulatory aspects of other countries. | 06 |
| | (b) | Which are the most recent regulations laid for the contract manufacturing in India? | 05 |
| | (c) | Discuss in brief the most recent amendments to Drugs and Cosmetics Act, 1940. | 05 |
| Q.4 | (a) | Describe in brief the distribution records, batch release documents and complaints & recalls documents. | 06 |
| | (b) | What are the quality and safety aspects for the cosmetic products? | 05 |
| | (c) | Write a note on: BOP Analysis. | 05 |
| Q.5 | (a) | Explain PCT. Discuss the advantages and procedure of PCT. | 06 |
| | (b) | What is the importance of investigator's brochure? Give a brief outline of clinical research protocols. | 05 |
| | (c) | Discuss the salient features of FDA guidelines for clinical trials in India. | 05 |
| Q. 6 | (a) | Write a note on specific requirements, content and format of NDA. | 06 |
| | (b) | Discuss the new trends in patenting biotechnology based products. | 05 |
| | (c) | Give a brief outline of the procedure for importing and exporting the pharmaceutical goods. | 05 |
| Q.7 | (a) | Discuss the different factors affecting the international business environment. | 06 |
| | (b) | Explain in brief exporting to US and prelitigation considerations. | 05 |
| | (c) | Write a note on: Effective Pharma Patent Drafting. | 05 |
