Seat No.: _____ Enrolment No._____

# GUJARAT TECHNOLOGICAL UNIVERSITY

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

**Subject Code: 1931601** **Date: 06-12-2014**

**Subject Name: Regulatory Affairs - II**

**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)** | How regulatory affect the drug product design in USA. | **06** |
| | **(b)** | Write brief note on Hatch Waxmann Act. | **05** |
| | **(c)** | Short note: Regulatory Drug Analysis. | **05** |
| **Q.2** | **(a)** | What is Loan license? Explain guide line for Loan license. | **06** |
| | **(b)** | Explain recent amendments to drugs and cosmetic act. | **05** |
| | **(c)** | What is licensing procedures in India? | **05** |
| **Q.3** | **(a)** | What is NDA? How it is filed and reviewed? | **06** |
| | **(b)** | Describe in brief the various types of NDA. | **05** |
| | **(c)** | Brief on New Chemical Entity (NCE). | **05** |
| **Q.4** | **(a)** | Waht is the procedure for documentation in retention samples? | **06** |
| | **(b)** | How can maintain the documentation in complaints and recalls? | **05** |
| | **(c)** | Short note: Batch Release documents. | **05** |
| **Q.5** | **(a)** | Brief the safety parameters in Herbal Products. | **06** |
| | **(b)** | What is IND? Draw the format of IND. | **05** |
| | **(c)** | Explain the clinical research Protocols. | **05** |
| **Q. 6** | **(a)** | What is the procedure for exporting the goods? | **06** |
| | **(b)** | How the marketing factors and labor factors affect the foreign trade. | **05** |
| | **(c)** | Short note: foreign exchange control. | **05** |
| **Q.7** | **(a)** | Brief on Emerging Trends in Biotechnology Patenting. | **06** |
| | **(b)** | Write the strategies for effective patent Drafting. | **05** |
| | **(c)** | Short note: IP Issues in contract Manufacturing. | **05** |

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