

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 |
