

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. – SEMESTER – II • EXAMINATION – WINTER 2013

Subject Code: 2920204

Date: 30-11-2013

Subject Name: Regulatory Affairs and New Drug Applications

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) | Write a note on review process of NDA. | 06 |
| | (b) | What is IND? List out different types of IND and explain each in brief. | 05 |
| | (c) | What is ICH? Write in brief about responsibilities of ICH. | 05 |
| Q.2 | (a) | Give brief account on sale of drug according to Drug and Cosmetic Act 1940. | 06 |
| | (b) | Write a note on quality safety of herbal products. | 05 |
| | (c) | What is MSDS? Give purpose and scope of each section of MSDS. | 05 |
| Q.3 | (a) | Describe Drug Master File in detail. | 06 |
| | (b) | Give brief account on Indian Pharmacopoeia. | 05 |
| | (c) | Describe salient features of Consumer Protection Act. | 05 |
| Q.4 | (a) | Write a note on standard institute and certification agency US-FDA. | 06 |
| | (b) | Give salient feature of Pollution Control act. | 05 |
| | (c) | Describe in brief regulatory aspects of bulk drug and pharmaceutical products. | 05 |
| Q.5 | (a) | Briefly describe the format & content of IND. | 06 |
| | (b) | Give brief account on guidelines for filing in USA. | 05 |
| | (c) | Write a brief note on objectives of The Pharmacy Act 1948. | 05 |
| Q. 6 | (a) | Write a brief note on regulatory aspects of biotechnology derived products. | 06 |
| | (b) | Give objectives of industrial safety and health. | 05 |
| | (c) | Describe in brief WHO as a certification agency. | 05 |
| Q.7 | (a) | Give brief account on content and format of NDA. | 06 |
| | (b) | Describe salient features of Prevention of Food Adulteration Act. | 05 |
| | (c) | Write in brief about functions of pharmacy council of India. | 05 |
