

GUJARAT TECHNOLOGICAL UNIVERSITY
M. PHARM. - SEMESTER – II • EXAMINATION – WINTER 2012

Subject code: 2920204**Date: 12-01-2013****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 the objectives of the Pharmacy Act. Describe the functions of Pharmacy Council of India. | 06 |
| | (b) Discuss the constitution and functions of Central Drugs Laboratory. | 05 |
| | (c) Describe the content of MSDS. | 05 |
| Q.2 | (a) Write a note on the drug regulatory agency of India. | 06 |
| | (b) Explain the objectives of the Pollution Control Act. | 05 |
| | (c) Name the classes of drugs prohibited to import as per Drugs and Cosmetics Act. | 05 |
| Q.3 | (a) Explain the different types of Drug Master Files. | 06 |
| | (b) What is a NDA? Write the content of the CMC section of NDA. | 05 |
| | (c) Explain the different types of IND applications. | 05 |
| Q.4 | (a) Write briefly about the certification system of Bureau of Indian Standards. | 06 |
| | (b) Discuss the salient features of Prevention of Food Adulteration Act. | 05 |
| | (c) Compare and contrast IP with USP. | 05 |
| Q.5 | (a) Discuss the composition and powers of the District Forum under the Consumer Protection Act. | 06 |
| | (b) Explain the importance of industrial health and safety. | 05 |
| | (c) Discuss the WHO GMP guidelines given regarding premises for manufacturing of herbal medicines. | 05 |
| Q. 6 | (a) Describe the composition and responsibilities of the ICH. | 06 |
| | (b) Discuss the guidelines for personnel involved in manufacturing biotechnology-derived products. | 05 |
| | (c) Describe in brief the content of investigator's brochure. | 05 |
| Q.7 | (a) Write briefly about the Industrial Development and Regulation Act. | 06 |
| | (b) Discuss the guidelines for packaging and labeling of API and intermediates. | 05 |
| | (c) How is manufacture and sale of cosmetics regulated in India? | 05 |
