

**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.

- 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**

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