Seat No.:	Enrolment No
GUJARAT TECHNOLOGICAL UNIVERSITY M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014	

Subject Code: 2920204 Date: 31-05-2014 **Subject Name: Regulatory Affairs and New Drug Applications** Time: 02:30 pm - 05:30 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 objectives of the Pharmacy Act. Describe the functions of Pharmacy 06 Council of India. **(b)** Write a note on quality and safety of herbal products. 05 (c) Describe the composition and responsibilities of the ICH. 05 (a) Write a note on the drug regulatory agency of India. 06 Q.2**(b)** Compare and contrast IP with USP. 05 (c) Give objectives of industrial safety and health. 05 **O.3** (a) Give brief account on sale of drug according to Drug and Cosmetic Act 1940. **06 (b)** Describe features of Prevention of Food Adulteration Act. 05 (c) Describe in brief regulatory aspects of bulk drug and pharmaceutical products. 05 0.4 (a) Write a note on standard institute and certificate agency US-FDA. **06 (b)** Describe features of Consumer Protection Act. 05 (c) Describe in brief the content of investigator's brochure. 05 0.5 (a) Is DMF mandatory? What are advantages of it? Write details of it. 06 (b) What is IND? List out different types of IND and explain each in detail. 05 (c) Discuss CTD and e-CTD. 05 (a) Write a note on review process of NDA. 06 Q.6 **(b)** Describe the content of MSDS. 05 (c) Give brief account on guidelines for filing in USA. 05 **Q.7** (a) Write briefly about the Industrial Development and Regulation Act. 06 **(b)** How is manufacture and sale of cosmetics regulated in India? 05

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(c) Discuss the constitution and functions of Central Drugs Laboratory.