

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-II-EXAMINATION – JULY 2012

Subject code: 2920204

Date: 09/07/2012

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) | Give constitution of PCI. How does Pharmacy Act 1948 regulate the profession of pharmacy? | 08 |
| | (b) | Give objectives of Drug and cosmetics ACT? Who are members of DTAB .How Drug and cosmetics ACT regulates import of Drug and cosmetics? | 08 |
| Q.2 | (a) | Discuss format and process for NDA. | 08 |
| | (b) | Enumerate quality, safety and legislation for herbal products. | 08 |
| Q.3 | (a) | Define and classify environment pollution. Name Pollution control Acts. Give functions and powers of State Boards. | 08 |
| | (b) | What is Material Safety Data Sheet (MSDS)? Describe different sections of MSDS. | 08 |
| Q.4 | (a) | Write note on Prevention of Food Adulteration Act 1954. | 08 |
| | (b) | Discuss mandatory provisions of Factory act for safety and health of workers in pharmaceutical industry? | 08 |
| Q.5 | (a) | Enlist Standard institutes & certification agencies. Discuss objectives of such organizations? | 08 |
| | (b) | Give organization structure, activities & responsibilities of Drug Regulatory Agency of India. | 08 |
| Q. 6 | (a) | What is Drug Master File (DMF)? Discuss different type of DMFs. | 08 |
| | (b) | What is MSDS? Describe purpose and scope of each section of MSDS. | 08 |
| Q.7 | | Give regulatory requirements for Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure. | 16 |
