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**

****