Seat No.: _____ **Enrolment No._____**

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm Semester –II Examination Dec. - 2011

Subject code: 920204 **Date: 12/12/2011**
Subject Name: Regulatory Affairs and New Drug Application
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.**

1.	a	Describe salient features of consumer protection act.	[08]
	b	Write notes on pollution control act.	[08]
2.	a	Describe content of Drug Master File.	[08]
	b	Describe qualifications, duties and powers of food inspector.	[08]
3.		What is MSDS? Describe purpose and scope of each section of MSDS.	[16]
4		Discuss regulatory requirements for pharmaceutical products.	[16]
5.	a	Discuss general considerations of new drug NDA.	[08]
	b	Describe CMC requirements of NDA.	[08]
6		Describe following standard institutes and certification agencies. a. WHO b. US-FDA	[16]
7		Write notes on (any two) a. Import of drugs and cosmetics. b. Guideline for manufacture of herbal drugs. c. Industrial safety and health.	[16]
