Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-II Examination July 2010

Subject code: 920204

Subject Name: Regulatory Affairs and New Drug Applications

Date: 07 /07 /2010 **Time: 11.00 am – 02.00 pm**

Instructions: **Total Marks: 80**

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1		Discuss regulatory requirements for biotechnology derived products.	**16**
Q.2		What is Drug Master File? Describe types of DMFs in detail.	**16**
Q.3		What is MSDS? Describe purpose and scope of each section of MSDS.	**16**
Q.4	(a)	Describe the investigator's brochure for IND.	**08**
	(b)	Describe specific requirements and contents of an NDA.	**08**
Q.5		What is the purpose of ' The pharmacy Act 1948' ? Describe a functions of pharmacy council of India. B. registration of pharmacist.	**16**
Q. 6	(a)	Describe the functions of Central Drug Laboratory.	**08**
	(b)	Sale of drugs according to drugs and cosmetic Act.	**08**
	(c)		
Q.7		Write note on any two:	**16**
	(a)	Indian standard Institute.	
	(b)	ASTM	
	(c)	US-FDA	

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