Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. Semester – IIND Examination –June/July- 2011

Subject code: 920204

Subject Name: Regulatory Affairs and New Drug Applications

Date:04/07/2011 **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)**	What is Investigational New Drug (IND) application? Give content of investigator's broucher.	**06**
	(b)	Give brief account on Indian Pharmacopoeia.	**05**
	(c)	Give quality safety for cosmetic products.	**05**
Q.2	**(a)**	Write in brief about review process of New Drug Application (NDA).	**06**
	(b)	Describe in brief the responsibilities of International Conference on Harmonisation (ICH).	**05**
	(c)	Write in brief about standard institute and certification agency – US FDA.	**05**
Q.3	**(a)**	Write in brief about aims, objects and salient features of Pollution Act	**06**
	(b)	Enlist Different Types of IND and explain each in brief.	**05**
	(c)	What is Material Safety Data Sheet (MSDS)? Enlist different sections of MSDS.	**05**
Q.4	**(a)**	Give brief comparative picture of guidelines for filing in US & EU	**06**
	(b)	Write objectives of industrial safety and health.	**05**
	(c)	What are the salient features of consumer protection act?	**05**
Q.5	**(a)**	Write on sale of drug according to Drug and Cosmetic Act.	**08**
	(b)	Explain, how pharmacy profession is regulated in India?	**08**
Q. 6	**(a)**	What is Drug Master File (DMF)? Enlist different type of DMFs, and describe each in detail.	**08**
	(b)	Write in brief about content and format of NDA.	**08**
Q.7	**(a)**	What are biotechnology derived products? Describe regulatory aspects of biotechnology derived products in detail.	**16**

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