Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014

Subject Code: 2920204 Date: 31-05-2014

Subject Name: Regulatory Affairs and New Drug Applications

Time: 02:30 pm - 05:30 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)**	Write objectives of the Pharmacy Act. Describe the functions of Pharmacy Council of India.	**06**
	(b)	Write a note on quality and safety of herbal products.	**05**
	(c)	Describe the composition and responsibilities of the ICH.	**05**
Q.2	**(a)**	Write a note on the drug regulatory agency of India.	**06**
	(b)	Compare and contrast IP with USP.	**05**
	(c)	Give objectives of industrial safety and health.	**05**
Q.3	**(a)**	Give brief account on sale of drug according to Drug and Cosmetic Act 1940.	**06**
	(b)	Describe features of Prevention of Food Adulteration Act.	**05**
	(c)	Describe in brief regulatory aspects of bulk drug and pharmaceutical products.	**05**
Q.4	**(a)**	Write a note on standard institute and certificate agency US-FDA.	**06**
	(b)	Describe features of Consumer Protection Act.	**05**
	(c)	Describe in brief the content of investigator's brochure.	**05**
Q.5	**(a)**	Is DMF mandatory? What are advantages of it? Write details of it.	**06**
	(b)	What is IND? List out different types of IND and explain each in detail.	**05**
	(c)	Discuss CTD and e-CTD.	**05**
Q.6	**(a)**	Write a note on review process of NDA.	**06**
	(b)	Describe the content of MSDS.	**05**
	(c)	Give brief account on guidelines for filing in USA.	**05**
Q.7	**(a)**	Write briefly about the Industrial Development and Regulation Act.	**06**
	(b)	How is manufacture and sale of cosmetics regulated in India?	**05**
	(c)	Discuss the constitution and functions of Central Drugs Laboratory.	**05**

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