Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920204 Date: 26-12-2014

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)**	What is the purpose of 'The Pharmacy Act 1948'? Write note on Constitution of Pharmacy Council of India.	**06**
	(b)	Write short note on industrial safety and health.	**05**
	(c)	Describe in detail content of type II Drug Master File.	**05**
Q.2	**(a)**	Write note on Quality control of standardized herbal products.	**06**
	(b)	Define the following terms: 1. Drug 2. Cosmetics 3. Letter of authorization 4. Adulterated drug 5. Spurious drug	**05**
	(c)	Explain in detail CTD Vs eCTD.	**05**
Q.3	**(a)**	Write note on USFDA.	**06**
	(b)	Write detail note on Central Drug Laboratory.	**05**
	(c)	Write in brief about standard institute and certification agency – TGA.	**05**
Q.4	**(a)**	How Drug and cosmetics ACT regulates sale of Drug and cosmetics?	**06**
	(b)	Give brief comparative picture of IP, USP, BP and EP.	**05**
	(c)	Describe qualifications, duties and powers of food inspector.	**05**
Q.5	**(a)**	Give organization structure, activities and responsibilities of Drug regulatory Agency of Japan.	**06**
	(b)	Write short note on Consumer Protection Act.	**05**
	(c)	Explain IND. Enlist Different Types of IND and explain each in brief.	**05**
Q. 6	**(a)**	What is material safety data sheet? Describe different sections of MSDS in detail as per ANSI.	**08**
	(b)	Describe regulatory aspects of biotechnology derived products in detail.	**08**
Q.7	**(a)**	Describe general consideration, specific requirements and contents of an NDA.	**08**
	(b)	Describe the investigator's brochure for IND.	**08**

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