Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. PHARM. - SEMESTER – II EXAMINATION – SUMMER 2017

Subject Code: 2920204 **Date: 31/05/2017**
Subject Name: Regulatory Affairs and New Drug Applications
Time: 10:30 AM to 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)**	Describe Drug Master File in detail.	**06**
	(b)	What is MSDS? Give purpose and scope of each section of MSDS.	**05**
	(c)	Give brief account on Indian Pharmacopoeia.	**05**
Q.2	**(a)**	Describe regulatory aspects of biotechnology derived products in detail.	**06**
	(b)	Describe qualifications, duties and powers of food inspector.	**05**
	(c)	Describe the composition and responsibilities of the ICH.	**05**
Q.3	**(a)**	Give brief account on content and format of NDA.	**06**
	(b)	Discuss the constitution and functions of Central Drugs Laboratory.	**05**
	(c)	Describe in brief WHO as a certification agency.	**05**
Q.4	**(a)**	Write briefly about the certification system of Bureau of Indian Standards.	**06**
	(b)	Describe salient features of Prevention of Food Adulteration Act.	**05**
	(c)	Explain the different types of IND applications	**05**
Q.5	**(a)**	Give brief account on sale of drug according to Drug and Cosmetic Act 1940.	**06**
	(b)	Describe salient features of Consumer Protection Act.	**05**
	(c)	Describe in brief the content of investigator's brochure.	**05**
Q. 6	**(a)**	Discuss CTD and e-CTD.	**06**
	(b)	Discuss the guidelines for packaging and labeling of API and intermediates.	**05**
	(c)	Write a brief note on objectives of The Pharmacy Act 1948.	**05**
Q.7	**(a)**	Write note on USFDA.	**06**
	(b)	Write a note on quality and safety of herbal products.	**05**
	(c)	How is manufacture and sale of cosmetics regulated in India?	**05**

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