Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm – SEMESTER II • EXAMINATION – WINTER-2016

Subject Code: 2920204 **Date: 02/12/2016**

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 do you understand by drug master file? Describe types of DMFs in detail.	**06**
	(b)	Describe in brief the responsibilities of International Conference on Harmonization (ICH).	**05**
	(c)	Discuss Standard institute and certificate agency- USFDA.	**05**
Q.2	**(a)**	Describe briefly the format & content of IND.	**06**
	(b)	Give brief account on Indian Pharmacopoeia.	**05**
	(c)	What is MSDS? Describe purpose and scope of MSDS.	**05**
Q.3	**(a)**	Explain in detail the content & format of NDA.	**06**
	(b)	Write the quality safety regulation for herbal product.	**05**
	(c)	Describe constitution & objectives of The Pharmacy Act 1948.	**05**
Q.4	**(a)**	Discuss salient features of Consumer Protection Act.	**06**
	(b)	Describe in brief WHO as a certification agency.	**05**
	(c)	Write in brief about functions of pharmacy council of India.	**05**
Q.5	**(a)**	Write briefly about the certification system of Bureau of Indian Standards.	**06**
	(b)	Give objectives of industrial safety and health.	**05**
	(c)	Describe various activity regulated by TGA.	**05**
Q. 6	**(a)**	Discuss the constitution and functions of Central Drugs Laboratory.	**06**
	(b)	Describe in brief regulatory aspects of bulk drug and pharmaceutical products.	**05**
	(c)	Write short note on ASTM.	**05**
Q.7	**(a)**	Describe the main features of Industrial Development & Regulation Act.	**06**
	(b)	Discuss the salient features of Prevention of Food Adulteration Act.	**05**
	(c)	Give salient feature of Pollution Control act.	**05**

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