Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – WINTER • 2015

Subject Code: 2920204 **Date: 09-12-2015**

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 MSDS? Describe purpose and scope of each section of MSDS.	**06**
	(b)	Write brief note on Consumer protection Act.	**05**
	(c)	Write the quality safety regulation for herbal product	**05**
Q.2	**(a)**	What are the main functions of WHO? Enlist various WHO guidelines available for pharmaceutical products.	**06**
	(b)	Write brief note on Prevention of Food Adulteration Act 1954	**05**
	(c)	Write short note on pollution control act.	**05**
Q.3	**(a)**	Describe in brief the responsibilities of International Conference on Harmonization (ICH).	**06**
	(b)	Describe various activity regulated by TGA.	**05**
	(c)	What is regulation for industrial development?	**05**
Q.4	**(a)**	What is drug master file? Describe types of DMFs in detail.	**06**
	(b)	Give brief account on Indian Pharmacopoeia.	**05**
	(c)	What is regulatory aspect for manufacturing of biotechnology derived product?	**05**
Q.5	**(a)**	Standard institute and certificate agency- USFDA.	**06**
	(b)	Write short note on ISI.	**05**
	(c)	Write Industrial Safety & Health Guide lines for filing in US.	**05**
Q. 6	**(a)**	Short not on ASTM.	**06**
	(b)	How the import, manufacture and distribution of the drugs regulate in India	**05**
	(c)	Describe the functions of Central Drug Laboratory.	**05**
Q.7	**(a)**	Explain in detail the content & format of NDA.	**06**
	(b)	Write short note on BSS.	**05**
	(c)	Describe the investigator's brochure for IND.	**05**

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