Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. - SEMESTER– I • EXAMINATION – SUMMER 2015

Subject Code: 1911502 Date: 25-05-2015

Subject Name: Basic Concepts of Regulatory Affairs

Time: 02:30 pm to 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)**	Explain the main principles of TQM system.	**06**
	(b)	Explain the concept of GMP. What is cGMP?	**05**
	(c)	Discuss the concept of quality assurance and quality control.	**05**
Q.2	**(a)**	What are the objectives and scope of Good Laboratory Practices?	**06**
	(b)	What is ISO? What are the advantages of ISO certification?	**05**
	(c)	Write the objectives of Drug Listing Act and Prescription Drug Marketing Act.	**05**
Q.3	**(a)**	Discuss the provisions of the Environment Pollution Control Act.	**06**
	(b)	Give the salient features of the Consumer Protection Act.	**05**
	(c)	Write a brief note on the Factory Act.	**05**
Q.4	**(a)**	Define: Patents, Trademarks and Copyrights.	**06**
	(b)	Explain the different rights obtained through patent registration.	**05**
	(c)	Explain the impact of WTO on trade of pharmaceuticals.	**05**
Q.5	**(a)**	Describe the history and organization structure of USFDA.	**06**
	(b)	What are the different functions of USFDA?	**05**
	(c)	Write the composition of ICH. Discuss the various activities of ICH.	**05**
Q. 6	**(a)**	Discuss the recent amendments of the Drugs and Cosmetics Act, 1940.	**08**
	(b)	Describe the main provisions for manufacture and import of drugs in the D&C Act.	**08**
Q.7	**(a)**	Write the advantages of WHO certification. Explain the different certificates under the certification scheme.	**08**
	(b)	How is manufacture and sale of cosmetics regulated in India?	**08**

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