Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM. - SEMESTER– I - EXAMINATION – WINTER 2016

Subject Code: 1911502 Date: 04/01/2017

Subject Name: Basic concepts of Regulatory Affairs

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)**	Explain the Role of QA and GMP and GLP in Pharmaceutical Industry.	**06**
	(b)	Explain the procedure to resolve the consumer disputes.	**05**
	(c)	Explain the role of Total Quality Management in Pharmaceutical industry.	**05**
Q.2	**(a)**	Write a note on Kefauver-Harris amendment 1962.	**06**
	(b)	Explain the Prescription drug marketing act 1987.	**05**
	(c)	Explain the Durham-Humphrey amendment 1951.	**05**
Q.3	**(a)**	Explain the control of Water pollution as per legislative act.	**06**
	(b)	Give the requirement of Loan Licensing as per CDSCO.	**05**
	(c)	Explain Trademark with Suitable Examples.	**05**
Q.4	**(a)**	Writa a short note on ICH guidelines.	**06**
	(b)	Explain in detail patentable and non-patentable matter with suitable Examples.	**05**
	(c)	What is the difference between contract and agreement? Explain elements of contract law with examples.	**05**
Q.5	**(a)**	Write a short note on Organization and functions of Federal food and drug administration.	**06**
	(b)	Explain in detail Drug listing act as per USFDA.	**05**
	(c)	Explain In detail Factory act.	**05**
Q. 6	**(a)**	Write a note on WHO certification.	**06**
	(b)	Explain the general Import and manufacturing requirements for Pharmaceutical Drugs as per D & C act.	**05**
	(c)	Write a note on Tort Law with suitable example.	**05**
Q.7	**(a)**	Write a short note on ISO 9001	**06**
	(b)	Explain in detail about GATT and WTO.	**05**
	(c)	Explain in detail current Globalization Pharmaceutical Industries	**05**

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