Seat No.:	Enrolment No.
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## **GUJARAT TECHNOLOGICAL UNIVERSITY**

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2015 Subject Code: 1911502 Date: 02-01-2016 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) (b) (c)	Give a brief account on role of GMP in pharmaceutical Industry.  Give a detail note on ICH Guidelines.  Write a note on ISO.	06 05 05
Q.2	(a) (b) (c)	Give a brief note on IPR. What are the different Criteria for factories under factory act? Give brief note on Component of TQM.	06 05 05
Q.3	(a) (b) (c)	Write a note on GATT and WTO. Write a note on WHO certification Scheme on Pharmaceuticals. Give a brief note on Drug Listing Act.	06 05 05
Q.4	(a) (b) (c)	Explain the Durham-Humphrey amendment 1951 Explain the Prescription drug marketing act 1987. Write a note on Kefauver-Harris amendment 1962.	06 05 05
Q.5	(a) (b) (c)	Explain the labeling requirements for Narcotic and Biological Pharmaceutical Drugs as per D & C act. Give a short note on Tort Law. Write a short note on Consumer dispute Redressal Agencies.	06 05 05
Q. 6	(a) (b) (c)	Give a brief note on Different types of Trademark. Write a note on Loan License. Write a note on Import and Export policy for pharmaceutical drugs.	06 05 05
Q.7	(a) (b) (c)	Write a short note on Contract Law with suitable example. Write a note on Globalization of Pharmaceutical Industries. Explain the control of Air pollution as per legislative act.	06 05 05

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