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** 

 $Time: 10.30 \ AM - 01.30 \ PM \qquad \qquad Total \ Marks: 80$ 

## **Instructions:**

1.	Attempt	anv	five	questions.
	LICULIA	CLII Y	1110	questions.

- 2. Make suitable assumptions wherever necessary.
- 3. Figures to the right indicate full marks.

Q.1	(a) (b) (c)	<u>.</u>			
Q.2	(a) (b) (c)				
Q.3	(a) (b) (c)	Explain the control of Water pollution as per legislative act. Give the requirement of Loan Licensing as per CDSCO. Explain Trademark with Suitable Examples.			
Q.4	(a) (b) (c)	Writa a short note on ICH guidelines.  Explain in detail patentable and non-patentable matter with suitable Examples.  What is the difference between contract and agreement? Explain elements of contract law with examples.			
Q.5	(a) (b) (c)	administration.			
Q. 6	(a) (b) (c)	Write a note on WHO certification.  Explain the general Import and manufacturing requirements for Pharmaceutical Drugs as per D & C act.  Write a note on Tort Law with suitable example.	06 05 05		
Q.7	(a) (b) (c)	Write a short note on ISO 9001 Explain in detail about GATT and WTO. Explain in detail current Globalization Pharmaceutical Industries	06 05 05		

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