Seat.	No.: _	Enrolment No	
		GUJARAT TECHNOLOGICAL UNIVERSITY	
		M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER • 2014	
Sub	ject (Code: 1911502 Date: 26-05-2014	
Sub	ject l	Name: Basic Concepts of Regulatory Affairs	
Tim	e: 02	2:30 pm - 05:30 pm Total Marks: 80	
Instr			
		Attempt any five questions.	
		Make suitable assumptions wherever necessary. Figures to the right indicate full marks.	
	<i>J</i> .	rigures to the right indicate run marks.	
Q.1	(a)	Explain the correlation between QA and GMP.	06
	(b)	Explain the Historical development of Pharmaceutical product registration.	05
	(c)	Write a short note on ICH guidelines.	05
Q.2	(a)	Differentiate the term contract and agreement. Explain different element of	06
	(b)	contract law. Short note on Air Pollution act	05
	(b) (c)	Short note on Trademark.	05
0.2			
Q.3	(a) (b)	Explain the Total Quality Management in Pharmaceutical industry. Define Tort law and explain the different types of tort law.	06 05
	(c)	Explain patentable and non patentable matter in detail.	05
Q.4	(a)	Expalin the role of GATT in pharmaceuticals.	06
	(b)	Short note on copy rights	05
	(c)	Give a brief note on ISO 9001.	05
Q.5	(a)	Write a short note on factory act.	06
	(b)	Explain the procedure in case of consumer dispute.	05
	(c)	Explain current export policy of drugs in Pharmaceutical industry.	05
Q. 6	(a)	Explain the labeling requirement of Schedule C ₁ and X drugs	06
	(b)	Explain the organization and personnel of federal food and drug administration.	05
	(c)	Explain in brief world trade organization.	05
Q.7		Write a short note (any two)	
		i) Druham-Humphrey amendment 1951.	16
		ii) Kefauver-Harris amendment 1962.iii) Prescription Drug Marketing act 1987.	
		m, 110001puon Diag Manacang act 1707.	
