Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER 2013

Subject Code: 1911502 Date: 22-05-2013

Subject Name: Basic Concept 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)	Effect of GATT and WTO on commerce of pharmaceuticals.	**06**
	(b)	Organization and functions of federal food and drug administration of USA.	**05**
	(c)	Write about Druham ï Humphrey Amendment 1951.	**05**
Q.2	(a)	Write note on Total Quality Management.	**06**
	(b)	Write in brief about Tort law and Contract law.	**05**
	(c)	What is mean by IPR. Give brief introduction of IPR.	**05**
Q.3	(a)	Write about the federal food drug & cosmetics act 1938.	**06**
	(b)	Kefauver ï Harris Amendment 1962.	**05**
	(c)	Write brief note on GMP.	**05**
Q.4	(a)	Explain the Export import policy of drugs.	**06**
	(b)	Prescription Drug Marketing Act 1987.	**05**
	(c)	What is mean by cGMP. Explain part of cGMP.	**05**
Q.5	(a)	Implementation of Good Laboratory Practice.	**06**
	(b)	Write the steps of WHO certification.	**05**
	(c)	Write in brief about consumer protection act.	**05**
Q. 6	(a)	Recent amendments in licensing of drugs and cosmetics.	**06**
	(b)	Write in detail about Trademarks and copyrights.	**05**
	(c)	Who can go for ISO certification? How.	**05**
Q.7	(a)	ICH guideline for Quality.	**06**
	(b)	Write in brief about Factory act.	**05**
	(c)	How the globalization of drug industries can take place.	**05**

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