Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM. - SEMESTER – I • EXAMINATION – WINTER 2012

Subject code: 1911502 Date: 11-01-2013

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 quality policy and quality system? What are the basic elements of total quality management?	**06**
	(b)	Explain Quality Assurance, GMP and GLP along with their interrelationship.	**05**
	(c)	What is cGMP. What is primary aim of cGMP? Enlist different guidelines for GMP and GLP. Describe various aspects of GLP.	**05**
Q.2	**(a)**	Explain in brief various steps to be taken for prevention and control of environmental pollution under environmental pollution control act.	**06**
	(b)	Explain aims, objectives and formation of central, state and district consumer protection council.	**05**
	(c)	Write a brief note on sale and import of drug according to Drugs and Cosmetic Act.	**05**
Q.3	**(a)**	Explain various amendments for regulation and licensing of drugs and cosmetics under schedule Y.	**06**
	(b)	Explain various historical aspects that led to the evolution of various regulations in drug development and its approval.	**05**
	(c)	Describe the structure, functions, advantages of ISO.	**05**
Q.4	**(a)**	Explain various provisions of Federal food and drugs cosmetics act, 1938. Explain the significance of Durham - Humphrey Amendment 1951 and Kefauver - Harris Amendment 1962.	**06**
	(b)	Describe in detail organizational structure and functions of USFDA.	**05**
	(c)	Explain the objective and various sections of Prescription Drug Marketing Act 1987.	**05**
Q.5	**(a)**	Describe organizational structure of ICH and explain the role of ICH in improving pharmaceutical product quality.	**06**
	(b)	Enlist various ICH quality guidelines and explain stability testing for new drug product.	**05**
	(c)	Explain WHO certification scheme for pharmaceutical products.	**05**
Q. 6	**(a)**	What is PCT, explain its advantages. Explain the significance of IPR for researchers and enlist various amendments in Indian Patent act, 2005.	**06**
	(b)	Describe in detail copyright, trademark and GATT/ TRIPS agreement.	**05**
	(c)	Explain the aim, purpose, general provisions of the Hatch Waxman act, 1984 alongwith its amendments.	**05**
Q. 7	**(a)**	Answer the following: 1. Enlist the differences between quality control and quality assurance activities. 2. Explain loan licensing in pharma industry. 3. What is the origin and significance of tort law?	**06**
	(b)	Describe briefly export import policy for pharmaceutical drug industry.	**05**
	(c)	Explain various aspects of federal trade commission with respect to promotion of export trade and prevention of unfair methods of competition.	**05**

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