Seat N	Ю.:	Enrolment No.	
		GUJARAT TECHNOLOGICAL UNIVERSITY	
		M. Pharm. – SEMESTER – I • EXAMINATION – WINTER 2013	
Subi	ect C	Code: 1911502 Date: 26-12-2013	
•		fame: Basic Concepts of Regulatory Affairs	
-			
		30 am - 01.30 pm Total Marks: 80	
nstru	ction		
		Attempt any five questions. Make suitable assumptions wherever necessary.	
		Figures to the right indicate full marks.	
	J. 1	rigures to the right mulcate run marks.	
Q.1	(a)	Compare organization & role of QA & QC in Pharmaceutical industry.	06
	(b)	What is mean by quality product? Explain concept of TQM for dosage form.	05
	(c)	What are key elements of GMP? Enlist risk involved in bypassing GMP.	05
	` /		
Q.2	(a)	Outline historical background of GLP. Enlist Objectives, SOPs and Certification	06
		requirements of GLP.	
	(b)	Discuss GLP guidelines for disqualification of laboratory facilities.	05
	(c)	What are the salient features of consumer protection act?	05
Q.3	(a)	What are objectives and technical data requirement for product registration at	06
	<i>a</i> .	international level?	
	(b)	Write note on "Abusive Practices Federal Trade Commission Act"	05
	(c)	Explain functions of center for drug evaluation & Research.	05
Q.4	(a)	Discuss self life of cosmetics.	04
	(b)	Does FDA require animal testing for cosmetics? Explain.	04
	(c)	What precautions should you take if you dye your hairs? Why?	04
	(d)	What ingredients are prohibited from use in cosmetics?	04
	(4)	That ingredients are promoted from use in cosmettes.	•
Q.5	(a)	What is CPCB? Outline objectives of the environment pollution control act.	06
	(b)	Discuss powers and functions of CPCB.	05
	(c)	What is tort law about? Discuss various offences covered under the tort law?	05
Q. 6	(a)	What was reason for introduction of Federal Food & drug control Act 1938?	06
		Discuss the scope of the Act.	
	(b)	What was Durham Humphrey amendment 1951? How was it enforced?	05
	(c)	Give chart of step involved in new drug development process.	05
0.7	(2)	What is CATTO How did it offeet economy of Ladian abaneous visal in Justice	Ω4
Q.7	(a)	What is GATT? How did it affect economy of Indian pharmaceutical industry? Correlate Patent and R&D.	04
	(b)	Discuss WHO certification in export import of drug.	04 04
	(c) (d)	Discuss Trade mark dispute.	04
	(u)	Discuss Trade mark dispute.	VT
