Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – WINTER 2013

Subject Code: 1931601 Date: 11-12-2013

Subject Name: Regulatory Affairs - II

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)**	Name most significant recent amendments to Drugs and Cosmetics Act.	**06**
	(b)	What are the recommendations about penalties to tackle the problem of spurious and adulterated drugs as per amendment 2008 of D & C Act (India)?	**05**
	(c)	Give in brief requirements and guidelines prescribed by Government of India for permission to import and/or manufacture of new Drugs to undertake Clinical Trials as per D & C amendment Act 2005.	**05**
Q.2	**(a)**	Throw light on challenges in formulation of regulatory laws in Herbal medicines in USA.	**06**
	(b)	What is the role of India in regulation of Herbal medicines?	**05**
	(c)	Give Salient features of Patent co-operation treaty.	**05**
Q.3	**(a)**	Give elements of Drug quality assurance program by WHO.	**06**
	(b)	Write a short note on emerging trends in Biotechnology patenting.	**05**
	(c)	Write on Good Quality Control practices by WHO.	**05**
Q.4	**(a)**	Write a note on Phase I, II and III trials on humans.	**06**
	(b)	What do you understand by trials in special populations? How is documentation done in bioavailability/bioequivalence studies?	**05**
	(c)	Write a note on Roche-Bolar provisions related to exemptions in research.	**05**
Q.5	**(a)**	Give important provisions of Food and Drugs administration modernization act of USA.	**06**
	(b)	Write on Indian governmental policies about Biotechnology Park.	**05**
	(c)	Explain on documentation related to distribution, complaints and product recalls.	**05**
Q. 6	**(a)**	Classify changes in Drug Manufacturing and give requirements for making and reporting them for an approved NDA and ANDA.	**06**
	(b)	Write a note on recent regulations laid for Contract Manufacture in India.	**05**
	(c)	Give a brief account of certification. Include procedure for Licensing.	**05**
Q.7	**(a)**	Explain in brief on Anti-biotics regulations. Are there exemptions provided from certification for anti-biotics.	**06**
	(b)	Give brief overview of Hatch-Waxman Act.	**05**
	(c)	Write a note on International Good Clinical Practices.	**05**

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