Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – SUMMER • 2015

Subject Code: 1931601 Date: 13-05-2015

Subject Name: Regulatory Affairs - II

Time: 02:30 pm - 05:30 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 PCT. Discuss the advantages and procedure of PCT.	**06**
	(b)	Which are the most recent regulations laid for the contract manufacturing in India?	**05**
	(c)	Discuss the salient features of FDA guidelines for clinical trials in India.	**05**
Q.2	**(a)**	Discuss in brief the regulatory requirements for pharmaceutical and bulk drug manufacture.	**06**
	(b)	Describe the procedures for certification and licensing of a pharmaceutical product.	**05**
	(c)	Give a brief account on importance of regulatory drug analysis.	**05**
Q.3	**(a)**	Explain herbal drug regulations in India. State the differences of the same from the regulatory aspects of European union (EU).	**06**
	(b)	What are the quality and safety aspects for the cosmetic products?	**05**
	(c)	Discuss in brief the most recent amendments to Drugs and Cosmetics Act, 1940.	**05**
Q.4	**(a)**	Describe in brief the disrtibution records, batch release documents and complaints & recalls documents.	**06**
	(b)	Which are the new trends in patenting biotechnology based products?	**05**
	(c)	Give a brief account on: Hatch Waxman Act.	**05**
Q.5	**(a)**	Explain the regulatory aspects that affect drug product design, manufacture and distribution in USA.	**06**
	(b)	Give a brief account on recent developments relating to the bolar exemptions.	**05**
	(c)	Describe the procedure of exporting to US and pre-litigation considerations.	**05**
Q. 6	**(a)**	Discuss the specific requirements, content and format of NDA.	**06**
	(b)	What is the importance of investigator's brochure? Give a brief outline of clinical research protocols.	**05**
	(c)	Write a note on: Effective Pharma Patent Drafting.	**05**
Q.7	**(a)**	Discuss the different factors affecting the international business environment.	**06**
	(b)	Write a note on: BOP Analysis.	**05**
	(c)	Give a brief outline of the procedure for importing and exporting the pharmaceutical goods.	**05**

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