Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM. - SEMESTER– III • EXAMINATION – WINTER 2016

Subject Code: 1931601 **Date: 23/11/2016**

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)	What is PCT? Describe the procedure for filing and processing international applications under PCT.	**06**
	(b)	Discuss the recent developments relating to Bolar exemptions.	**05**
	(c)	State the impact of Hatch-Waxman act on generic companies.	**05**
Q.2	(a)	How do regulatory aspects affect drug product design and manufacturing in a developing country? Explain giving suitable example.	**06**
	(b)	Differentiate between INDA and ANDA. Describe various types of INDA.	**05**
	(c)	Throw light on the recent amendments to Drugs and Cosmetic Act.	**05**
Q.3	(a)	What are the goals of NDA? Discuss the general requirements for filing NDA.	**06**
	(b)	What is the procedure for contract manufacturing in India?	**05**
	(c)	Write a detailed note on FDA guidelines for clinical trials.	**05**
Q.4	(a)	Describe briefly the procedure for obtaining license for manufacturing of drug substance.	**06**
	(b)	Explain on documentation related to manufacturing.	**05**
	(c)	Write a note on: WHO certification.	**05**
Q.5	(a)	Enumerate different parts of a patent and explain claims in detail.	**06**
	(b)	Comment on the issues involved in export of drug products to US.	**05**
	(c)	Write a note on quality and safety aspects for the cosmetic products.	**05**
Q. 6	(a)	Write a note on: Marketing and labor factors affecting foreign trade.	**06**
	(b)	Describe BOP analysis in brief.	**05**
	(c)	What are the policies of Indian Government in biotechnology patenting?	**05**
Q.7	(a)	Discuss the regulatory aspects and approval of herbal drugs in different countries.	**06**
	(b)	Write a note on: Foreign exchange control.	**05**
	(c)	Describe the importance of regulatory drug analysis.	**05**

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