Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1931601 **Date: 08-12-2015**

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)**	Write the full name of Waxman Hatch Act. How did it improve the prospects of branded and generic drugs in USA?	**06**
	(b)	How did Bolar provision give boost to ANDA approval process in USA?	**05**
	(c)	What is Code of Federal Regulation? How is this related to Federal Food Drugs & Cosmetic Act?	**05**
Q.2	**(a)**	Enlist manufacturing license types for Drug Substance and briefly describe procedure for obtaining license and terms of license	**06**
	(b)	Is loan license a manufacturing license? Describe types of loan license based on drug categories in India and responsibilities of loan licensee and parent firm	**05**
	(c)	Briefly describe amendment to Drug & Cosmetic Rules regarding prescription drug and clinical trials	**05**
Q.3	**(a)**	Describe licensing and GMP provision for manufacture of herbal product manufactured as Ayurvedic products	**06**
	(b)	Describe various tests performed on herbal drugs to establish safety	**05**
	(c)	Describe the provisions of manufacturing and GMP for cosmetics	**05**
Q.4	**(a)**	Describe the followings with respect to clinical research: Investigator's brochure, Clinical reserach protocol, Institutional Ethics Committee	**06**
	(b)	Explain the purpose and procedure for IND application to USFDA and similar application in India	**05**
	(c)	What is Common Technical Document? Describe various modules thereof.	**05**
Q.5	**(a)**	Describe various factors affecting international business. What are the advantages for India as investment destination	**06**
	(b)	Explain the following in relation to international business: Globalization, Liberalization and IMF	**05**
	(c)	Briefly describe steps involved in export of drug products from India	**05**
Q. 6	**(a)**	What is the basic objective of Patent Cooperation Treaty? Explain the terms international application and international search with reference to PCT	**06**
	(b)	Describe the parts of a patent and explain significance of Claims therein	**05**
	(c)	Comment on the patent issues in manufacturing and marketing of a drug	**05**
Q.7	**(a)**	What is biological patent? Describe positions of different countries in patentability of natural processes and substances	**06**
	(b)	Give a brief account of biotechnology patent law in EU, US and India	**05**
	(c)	Write a note on FDA guidance for clinical trials	**05**

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