Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014

Subject Code: 1921601 **Date: 29-05-2014**

Subject Name: Regulatory Affairs-I

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)**	Discuss history and ethics of profession of Pharmacy.	**06**
	(b)	Describe in brief events leading to the evolution of drug laws in India.	**05**
	(c)	Describe briefly the manufacture of alcoholic preparations in Bond under the medicinal and toilet preparations act.	**05**
Q.2	**(a)**	Discuss the procedure for calculation of the wholesaler and retailer price as per DPCO?	**06**
	(b)	What are the aims and objectives of Pharmacy Act 1948? Explain in brief the provisions under the education regulations 1991.	**05**
	(c)	Write composition/constitution of and functions of Pharmacy council of India.	**05**
Q.3	**(a)**	What is schedule M? Explain its provision in manufacture of drugs.	**06**
	(b)	Explain the conditions for the issue of license to manufacture schedule C, C1 and X drugs.	**05**
	(c)	Write a note on non-patentable inventions as per Indian Patent Act.	**05**
Q.4	**(a)**	Define magic remedy. Explain exempted advertisements with respect to the drugs and remedies act 1955.	**06**
	(b)	Describe provisions for performance of animal experiments as per prevention of cruelty of Animal Act.	**05**
	(c)	What is copyright? Discuss the various rights availed through copyright act.	**05**
Q.5	**(a)**	Compare and contrast laws pertaining to Patent in USA and India	**06**
	(b)	What are the rules for import, export, and transshipment of narcotic drugs under the Narcotic and psychotropic substances act and rules?	**05**
	(c)	Write a brief note on TRIPS.	**05**
Q. 6	**(a)**	Define: Patent, Geographical indication, Claims, infringement, Intellectual property rights, Compulsory license	**06**
	(b)	Explain Exclusive Marketing Rights (EMR).	**05**
	(c)	Write about Company act with reference to legal environment of business.	**05**
Q.7	**(a)**	Describe provisions for manufacturing and analytical records of drugs as per schedule U.	**06**
	(b)	Discuss various aspects of European Patent Laws.	**05**
	(c)	Discuss the duties and powers of Drug Inspector as per Drugs and Cosmetic Act 1940.	**05**

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