Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1921601 Date: 14-05-2015

Subject Name: Regulatory Affairs-I

Time: 10:30 am to 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)**	Discuss scope, objectives and nature of Pharmaceutical legislation in India.	**06**
	(b)	How is a Pharmacist responsible in handling prescription as per Ethics?	**05**
	(c)	Define Bulk Drugs, Formulation. Discuss the objectives and provisions under the drugs price control order Act 1995	**05**
Q.2	**(a)**	Write composition/constitution of and functions of Pharmacy council of India.	**06**
	(b)	What are the qualifications required for registration of a Pharmacist?	**05**
	(c)	What are the conditions for manufacture schedule C/C1 drugs?	**05**
Q.3	**(a)**	What are the aims and objectives of Pharmacy Act 1948? Explain in brief the provisions under the education regulations 1991.	**06**
	(b)	Describe constitution and function of DTAB.	**05**
	(c)	What is the licensing procedure for manufacturing of alcohol containing preparation?	**05**
Q.4	**(a)**	Discuss Copy Right Act and TRIPS.	**06**
	(b)	Compare and contrast laws pertaining to Patent in USA and India	**05**
	(c)	Discuss IPR.	**05**
Q.5	**(a)**	Write in brief about cruelty of animals act.	**06**
	(b)	What classes of advertisements are prohibited under Drugs and Magic Remedies Act?	**05**
	(c)	What are schedules as per Drugs and Cosmetic Act? Give brief information on Schedule HX and Schedule M	**05**
Q. 6	**(a)**	What are conditions for sale of Drug as per Drug and Cosmetic Act?	**06**
	(b)	Discuss Schedule U requirements for Product development stage documentation.	**05**
	(c)	Write a note on non-patentable inventions as per Indian Patent Act.	**05**
Q.7	**(a)**	Discuss the duties and powers of Drug Inspector as per Drugs and Cosmetic Act 1940.	**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)	Explain Exclusive Marketing Rights (EMR).	**05**

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