Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1921601 **Date: 07-12-2015**

Subject Name: Regulatory Affairs-I

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)**	Define "Registered Pharmacist". Give a brief account on "Registration of pharmacist".	**06**
	(b)	Describe in brief the origin, scope, objectives and nature of pharmaceutical legislation in India.	**05**
	(c)	Explain briefly direct and indirect corporate tax laws.	**05**
Q.2	**(a)**	Describe the licensing procedure for manufacturing of alcoholic preparations under Medicinal and Toilet preparations (Excise Duties) Act, 1955.	**06**
	(b)	What is a trademark? Describe the procedure for the registration of trademark.	**05**
	(c)	Write a note on: Prevention of Cruelty to Animals Act	**05**
Q.3	**(a)**	Give a detailed comparison between Indian, US and EP patent law.	**06**
	(b)	What are intellectual property rights? Discuss in detail different types of intellectual properties.	**05**
	(c)	Give a brief account on: Sale of Goods Act.	**05**
Q.4	**(a)**	What is SOP? Explain objectives, format and content of SOP.	**06**
	(b)	Throw light on advertisements whose publication is prohibited under Drugs and Magic remedies (Objectionable Advertisements) Act, 1955.	**05**
	(c)	Discuss the history and ethics of profession of pharmacy in brief.	**05**
Q.5	**(a)**	Give a brief outline on the prohibition, control and regulation of narcotic drugs under The Narcotic and Psychotropic Substances Act.	**06**
	(b)	Describe in brief the procedure for obtaining an Indian patent.	**05**
	(c)	Discuss the salient features of TRIPS.	**05**
Q. 6	**(a)**	Discuss the provisions of the Drugs & Cosmetics Act 1940, that are applicable to the import, manufacture, sale and labelling of homeopathic medicines.	**06**
	(b)	State the latest amendments of the Drugs & Cosmetics Act, 1940.	**05**
	(c)	Describe the equipments required in manufacture of solid dosage forms as per schedule M of the Drugs & Cosmetics Act 1940.	**05**
Q.7	**(a)**	What is TRIMS? Give a detailed account on the main provisions of TRIMS.	**06**
	(b)	Write a note on: Drugs (Price Control) Order.	**05**
	(c)	Explain the functions, benefits and misunderstandings about WTO.	**05**

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