Seat No.:	Enrolment No.

Subject Code: 1921601

Subject Name: Regulatory Affairs-I

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Date: 07-12-2015

Time		0:30 am - 01:30 pm Total Marks: 80 ons:	
	1. 2.	Attempt any five questions. Make suitable assumptions wherever necessary. 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) (c)	What is a trademark? Describe the procedure for the registration of trademark. Write a note on: Prevention of Cruelty to Animals Act	05 05
(b)	(a) (b)	Give a detailed comparison between Indian, US and EP patent law. What are intellectual property rights? Discuss in detail different types of intellectual properties.	06 05
	(c)	Give a brief account on: Sale of Goods Act.	05
	(a) (b)	What is SOP? Explain objectives, format and content of SOP. Throw light on advertisements whose publication is prohibited under Drugs and Magic remedies (Objectionable Advertisements) Act, 1955.	06 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) (c)	Describe in brief the procedure for obtaining an Indian patent. Discuss the salient features of TRIPS.	05 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) (c)		05 05
Q.7	(a) (b) (c)	What is TRIMS? Give a detailed account on the main provisions of TRIMS. Write a note on: Drugs (Price Control) Order. Explain the functions, benefits and misunderstandings about WTO.	06 05 05
