Seat N	lo.:		
		GUJARAT TECHNOLOGICAL UNIVERSITY	
~		M. PHARM - SEMESTER-II • EXAMINATION – SUMMER-2016	
Subject Code: 1921601			
U		Name: Regulatory Affairs-I	
		:30 AM To 1:30 PM Total Marks: 80	
Instru			
		empt any five questions. ke suitable assumptions wherever necessary.	
		ures to the right indicate full marks.	
Q.1	(a)	Give introduction to Narcotic Drugs and Psychotropic Substances Act 1985 and	06
		Define (i) Hemp (ii) Coca leaf (iii) Psychotropic substances and (iv) Opium.	
	(b)	Define copy rights? Discuss the provisions of TRIPs agreement for Copy	05
	()	rights.	0.5
	(c)	What are the aims and objectives of Pharmacy Act 1948? Describe the role of pharmacy council of India in pharmacy education.	05
Q.2	(a)	Give an account on fixation of retail price of formulations as per drug price	06
		control Order, 1995. Explain the formula used for calculation of retail price of drug formulations.	
	(b)	What are the different forms of Intellectual properties? Explain steps involved	05
	(D)	in Patent application cycle.	US
	(c)	What is Drug Technical Advisory Board? Give its constitution.	05
Q.3	(a)	Differentiate between adulterated and spurious drugs under D& C act, 1940.	06
Ų.S	(a)	What are the penalties for offences related to manufacture, sale and distribution	VV
		of Adulterated and spurious drugs as per D& C act, 1940.	
	(b)	What do you mean by business environment? Write in detail non economical	05
		factors that influence business.	
	(c)	Explain similarities and differences between US and European patent law.	05
Q.4	(a)	Name three conditions that a patent must satisfy. What are the different patents	06
	()	that can be secured under the Indian Patent Act, 1970?	3 3
	(b)	Write short note on corporate taxation. Give brief account on in direct taxes.	05
	(c)	Discuss effect of Privatization and Globalization on Business enterprises.	05
0.5	(a)	State the object of Medicinal and Toilet Preparations Act Discuss the	06

State the object of Medicinal and Toilet Preparations Act. Discuss the procedure required to be followed to obtain license for manufacture of preparations containing alcohol or other narcotic substances. Define Magic Remedy? State the objectives of Drugs and Magic Remedies Act. 05 Mention the classes of Advertisements exempted under the said Act.

(c) Discuss offences and penalties under Narcotic Drugs and psychotropic 05 Substances Act, 1985.

Q. 6 Discuss the duties and powers of Drug Inspector as per Drugs and Cosmetic 06 (a) Act 1940. Discuss in detail the procedures of inspector?

What are schedules as per Drugs and Cosmetic Act? Discuss in brief Schedule 05 **(b)** X and Schedule M.

05

Write provisions of import of drug as per D& C act, 1940. (c)

Q.7 What are the different forms of Intellectual properties? Explain steps involved **06** (a) in Patent application cycle. **05**

Discuss patentable and non patentable inventions as per Indian patent law. **(b)**

What do you understand by word Trademark? How they are protected? 05 (c)
