

GUJARAT TECHNOLOGICAL UNIVERSITY**M. PHARM - SEMESTER-II • EXAMINATION – SUMMER-2016****Subject Code: 1921601****Date: 19/05/2016****Subject Name: Regulatory Affairs-I****Time: 10:30 AM To 1:30 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) Give introduction to Narcotic Drugs and Psychotropic Substances Act 1985 and Define (i) Hemp (ii) Coca leaf (iii) Psychotropic substances and (iv) Opium. **06**
- (b) Define copy rights? Discuss the provisions of TRIPs agreement for Copy rights. **05**
- (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 control Order, 1995. Explain the formula used for calculation of retail price of drug formulations. **06**
- (b) What are the different forms of Intellectual properties? Explain steps involved in Patent application cycle. **05**
- (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. What are the penalties for offences related to manufacture, sale and distribution of Adulterated and spurious drugs as per D& C act, 1940. **06**
- (b) What do you mean by business environment? Write in detail non economical factors that influence business. **05**
- (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 that can be secured under the Indian Patent Act, 1970? **06**
- (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**
- Q.5** (a) 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. **06**
- (b) Define Magic Remedy? State the objectives of Drugs and Magic Remedies Act. Mention the classes of Advertisements exempted under the said Act. **05**
- (c) Discuss offences and penalties under Narcotic Drugs and psychotropic Substances Act, 1985. **05**
- Q. 6** (a) Discuss the duties and powers of Drug Inspector as per Drugs and Cosmetic Act 1940. Discuss in detail the procedures of inspector? **06**
- (b) What are schedules as per Drugs and Cosmetic Act? Discuss in brief Schedule X and Schedule M. **05**
- (c) Write provisions of import of drug as per D& C act, 1940. **05**
- Q.7** (a) What are the different forms of Intellectual properties? Explain steps involved in Patent application cycle. **06**
- (b) Discuss patentable and non patentable inventions as per Indian patent law. **05**
- (c) What do you understand by word Trademark? How they are protected? **05**