

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. – SEMESTER – II • EXAMINATION – WINTER • 2014

Subject Code: 1921601**Date: 24-12-2014****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.**

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| Q.1 | (a) Discuss the history and nature of pharmaceutical legislation in India. | 06 |
| | (b) Which ethics must be followed by a pharmacist in relation to his profession? | 05 |
| | (c) Discuss the development of Indian patent law in brief. | 05 |
| Q.2 | (a) Briefly explain the restrictions imposed by the Narcotic and Psychotropic substances Act on import, export and transshipment of narcotic drugs. | 06 |
| | (b) Discuss Medicinal and Toilet preparations [Excise Duties] Act, 1955 with latest amendments. | 05 |
| | (c) What are the aims and objects of the Pharmacy Act, 1948? What are the educational regulations and how are they implemented by PCI? | 05 |
| Q.3 | (a) Discuss the essential requirements of building, space, equipments etc. outlined in schedule M for the manufacture of drugs. | 06 |
| | (b) Write a note on: Prevention of Cruelty to Animals Act. | 05 |
| | (c) Explain the provisions of Drugs (price control) order in force. | 05 |
| Q.4 | (a) Discuss the provisions of the D&C Act, 1940 that are applicable to the sale of allopathic drugs. | 06 |
| | (b) What are Intellectual Property rights? Explain the different types of intellectual property with examples. | 05 |
| | (c) Write a short note on: Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955. | 05 |
| Q.5 | (a) Discuss the salient features of TRIMS. | 06 |
| | (b) Write a Note on: Copyright Act. | 05 |
| | (c) Describe the procedure for the registration of Trademark. | 05 |
| Q. 6 | (a) What is WTO? Explain scope, functions, benefits and misunderstandings about WTO. | 06 |
| | (b) Describe in brief the main provisions of TRIPS. | 05 |
| | (c) Discuss the standard operating procedures and standard test procedures as per schedule U requirements in brief. | 05 |
| Q.7 | (a) State the differences between Indian, US and EP patent law. | 06 |
| | (b) What is the need for financial regulations in business? Explain the terms SEBI, BIFR and FEMA. | 05 |
| | (c) Write a note on: Corporate Tax Laws. | 05 |
