

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

Subject Code: 1921601**Date: 29-05-2014****Subject Name: Regulatory Affairs-I****Time: 02:30 pm - 05:30 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 history and ethics of profession of Pharmacy. | 06 |
| | (b) | Describe in brief events leading to the evolution of drug laws in India. | 05 |
| | (c) | Describe briefly the manufacture of alcoholic preparations in Bond under the medicinal and toilet preparations act. | 05 |
| Q.2 | (a) | Discuss the procedure for calculation of the wholesaler and retailer price as per DPCO? | 06 |
| | (b) | What are the aims and objectives of Pharmacy Act 1948? Explain in brief the provisions under the education regulations 1991. | 05 |
| | (c) | Write composition/constitution of and functions of Pharmacy council of India. | 05 |
| Q.3 | (a) | What is schedule M? Explain its provision in manufacture of drugs. | 06 |
| | (b) | Explain the conditions for the issue of license to manufacture schedule C, C1 and X drugs. | 05 |
| | (c) | Write a note on non-patentable inventions as per Indian Patent Act. | 05 |
| Q.4 | (a) | Define magic remedy. Explain exempted advertisements with respect to the drugs and remedies act 1955. | 06 |
| | (b) | Describe provisions for performance of animal experiments as per prevention of cruelty of Animal Act. | 05 |
| | (c) | What is copyright? Discuss the various rights availed through copyright act. | 05 |
| Q.5 | (a) | Compare and contrast laws pertaining to Patent in USA and India | 06 |
| | (b) | What are the rules for import, export, and transshipment of narcotic drugs under the Narcotic and psychotropic substances act and rules? | 05 |
| | (c) | Write a brief note on TRIPS. | 05 |
| Q. 6 | (a) | Define: Patent, Geographical indication, Claims, infringement, Intellectual property rights, Compulsory license | 06 |
| | (b) | Explain Exclusive Marketing Rights (EMR). | 05 |
| | (c) | Write about Company act with reference to legal environment of business. | 05 |
| Q.7 | (a) | Describe provisions for manufacturing and analytical records of drugs as per schedule U. | 06 |
| | (b) | Discuss various aspects of European Patent Laws. | 05 |
| | (c) | Discuss the duties and powers of Drug Inspector as per Drugs and Cosmetic Act 1940. | 05 |
