

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm - SEMESTER-II • EXAMINATION – SUMMER-2017

Subject Code: 1921601

Date: 29/05/2017

Subject Name: Regulatory Affairs - I

Time: 10:30 AM to 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) Describe provisions for performance of animal experiments as per prevention of cruelty of Animal Act. | 06 |
| | (b) Discuss Medicinal and toilet preparation act with latest amendment. | 05 |
| | (c) Discuss about Direct and indirect tax laws. | 05 |
| Q.2 | (a) Describe briefly the manufacture of alcoholic preparations in Bond under the medicinal and toilet preparations act. | 06 |
| | (b) What are the aims and objectives of Pharmacy Act 1948? Describe the role of pharmacy council of India in pharmacy education. | 05 |
| | (c) Compare and contrast laws pertaining to Patent in USA and India. | 05 |
| Q.3 | (a) Discuss about historical perspective of Pharmaceutical Legislation. | 06 |
| | (b) Describe briefly about trade mark act. | 05 |
| | (c) Explain scope, functions and benefits about WTO. | 05 |
| Q.4 | (a) Discuss role of SEBI as financial instrument regulator. | 06 |
| | (b) What is copyright? Discuss the various rights availed through copyright act. | 05 |
| | (c) Discuss the salient features of TRIMS. | 05 |
| Q.5 | (a) Discuss the procedure for calculation of the wholesaler and retailer price as per DPCO. | 06 |
| | (b) Discuss non patentable inventions as per Indian patent law. | 05 |
| | (c) Discuss Schedule U requirements for Product development stage documentation. | 05 |
| Q. 6 | (a) What is SOP? Explain objectives, format and content of SOP. | 06 |
| | (b) Discuss the need of government regulation on financial bodies. | 05 |
| | (c) Describe the procedure for the registration of Trademark. | 05 |
| Q.7 | (a) Discuss the duties and powers of Drug Inspector as per Drugs and Cosmetic Act 1940. | 06 |
| | (b) Discuss the development of Indian patent law in brief. | 05 |
| | (c) Write a brief note on TRIPS. | 05 |
