

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.**

- 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**

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