

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM – SEMESTER – 2- EXAMINATION –WINTER - 2018

Subject Code:2920204

Date: 19/11/2018

Subject Name: Regulatory Affairs and New Drug Applications

Time:02:30 PM TO 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) | Give brief account on manufacture distribution and sale of drug according to Drug and Cosmetic Act 1940. | 06 |
| | (b) | Describe objectives of The Pharmacy Act 1948. | 05 |
| | (c) | Write note on constitution of pharmacy council of India. | 05 |
| Q.2 | (a) | Describe regulatory aspects of pharmaceutical products in detail. | 06 |
| | (b) | Explain in brief about functions of pharmacy council of India. | 05 |
| | (c) | Short note on quality control of herbal products. | 05 |
| Q.3 | (a) | Write short note on Consumer Protection Act. | 06 |
| | (b) | Describe salient features of Prevention of Food Adulteration Act. | 05 |
| | (c) | Give salient feature of Pollution Control act. | 05 |
| Q.4 | (a) | Explain WHO certification agency. | 06 |
| | (b) | Give full form of NDA, IND, MSDS, TGA, UK-MCA | 05 |
| | (c) | Explain DMF in brief. | 05 |
| Q.5 | (a) | Give purpose and scope of each section of MSDS. | 06 |
| | (b) | Give organization structure, activities and responsibilities of drug regulatory Agency of US. | 05 |
| | (c) | Give brief comparative picture of IP, USP, BP and EP. | 05 |
| Q. 6 | (a) | List out different types of IND. Describe the format & content of IND. | 06 |
| | (b) | Describe contents and format of an NDA | 05 |
| | (c) | What is ICH? Write in brief about responsibilities of ICH. | 05 |
| Q.7 | (a) | Write manufacturing control requirement of NDA | 06 |
| | (b) | Describe the investigator's brochure for IND. | 05 |
| | (c) | Define: 1. Drug 2. Cosmetics 3. MSDS 4. Adulterated drug 5. Spurious drug | 05 |
