

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM – SEMESTER – 8 EXAMINATION – SUMMER-2025

Subject Code: BP804TT

Date: 16-05-2025

Subject Name: Pharmaceutical Regulatory science

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) | Explain the regulatory approval process for ANDA. | 06 |
| | (b) | Enlist different drug regulatory body in India. Explain any one from them. | 05 |
| | (c) | Write a note on Preclinical studies as per CDSCO. | 05 |
| Q.2 | (a) | What is CTD and eCTD. Explain the different modules of CTD in detail | 06 |
| | (b) | Discuss the criteria for selection of human volunteers in clinical trials. | 05 |
| | (c) | Differentiate innovator and generic products. | 05 |
| Q.3 | (a) | What is IRB? Describe working and functions of IRB. | 06 |
| | (b) | Explain the regulatory approval process for New Drug Application. | 05 |
| | (c) | Explain in detail about Orange Book. | 05 |
| Q.4 | (a) | Explain the organization and functions of CDSCO. | 06 |
| | (b) | Write a detailed note on Generic Drug Development. | 05 |
| | (c) | Explain the salient features of pharmacovigilance. | 05 |
| Q.5 | (a) | Define clinical trial and explain Phase III. | 06 |
| | (b) | Explain code of federal regulation. | 05 |
| | (c) | Write different modules of ACTD. | 05 |
| Q.6 | (a) | Explain regulatory change over from NDA to ANDA. | 06 |
| | (b) | Explain salient features of Purple Book. | 05 |
| | (c) | Explain code for federal regulation with respect to Part 21. | 05 |
| Q.7 | (a) | What is DMF? Explain the different contents of DMF. | 06 |
| | (b) | Explain the organization structure and functions of Australian drug regulatory body. | 05 |
| | (c) | Write a detailed note on Technical Documentation. | 05 |
