Seat No.: _____ Enrolment No. _____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**B.PHARM - SEMESTER–8 EXAMINATION – WINTER -2023**

**Subject Code: BP804TT** **Date: 08/12/2023**

**Subject Name: Pharmaceutical Regulatory science**

**Time:02.30 p.m. to 5.30 p.m.** **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 the procedure for new drug approval from CDSCO in India. | **06** |
| | **(b)** | Explain Innovator and generics products with suitable example. | **05** |
| | **(c)** | What is Post Marketing Surveillance (PMS)? Give it's important in clinical trials. | **05** |
| **Q.2** | **(a)** | Write a note on ANDA. Explain PARA I to IV filling in ANDA. | **06** |
| | **(b)** | Define IND. Discuss about different types of IND. | **05** |
| | **(c)** | Write about post approved changes in NDA. | **05** |
| **Q.3** | **(a)** | Define CTD & e-CTD. Explain modules of CTD. | **06** |
| | **(b)** | What is DMF? Write a short note on Type of DMF. | **05** |
| | **(c)** | Give details note on MHRA. | **05** |
| **Q.4** | **(a)** | Discuss composition and functions of Institutional Review Board. | **06** |
| | **(b)** | Discuss components and importance of informed consent form. | **05** |
| | **(c)** | Give in details of Pharmacovigilence safety monitoring in Clinical Trials. | **05** |
| **Q.5** | **(a)** | Define 'Orange Book'. Describe the codes for therapeutic equivalence evaluation. | **06** |
| | **(b)** | Explain terms: i) CMC ii) Biowaiver iii) Purple Book iv) ACTD v)EMA | **05** |
| | **(c)** | What are the clinical trials? How are they organized as a part of drug discovery? | **05** |
| **Q. 6** | **(a)** | Describe general consideration, specific requirements and contents of an NDA. | **06** |
| | **(b)** | Write a note on Good Clinical Practices. | **05** |
| | **(c)** | Explain the various components of FDA. | **05** |
| **Q.7** | **(a)** | Discuss about clinical research Protocols. | **06** |
| | **(b)** | Give organization structure, activities and responsibilities of TGA. | **05** |
| | **(c)** | Describe various activity regulated by CDER. | **05** |

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