

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.PHARM - SEMESTER- 8 EXAMINATION – SUMMER -2023**

**Subject Code: BP804TT****Date: 03/07/2023****Subject Name: Pharmaceutical Regulatory science****Time:10.30 a.m. to 1.30 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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|------------|--|-----------|
| <b>Q.1</b> | (a) Describe the procedure for new drug approval from CDSCO in India.                  | <b>06</b> |
|            | (b) Explain Innovator and generics products with suitable example.                     | <b>05</b> |
|            | (c) What is Post Marketing Surveillance (PMS)? Give it's important in clinical trials. | <b>05</b> |
| <b>Q.2</b> | (a) Write a note on ANDA. Explain PARA I to IV filling in ANDA.                        | <b>06</b> |
|            | (b) Define IND. Discuss about different types of IND.                                  | <b>05</b> |
|            | (c) Write about post approved changes in NDA.  | <b>05</b> |
| <b>Q.3</b> | (a) Define CTD & e-CTD. Explain modules of CTD.  | <b>06</b> |
|            | (b) What is DMF? Write a short note on Type of DMF.                                    | <b>05</b> |
|            | (c) Give details note on MHRA.   | <b>05</b> |
| <b>Q.4</b> | (a) Discuss composition and functions of Institutional Review Board.                   | <b>06</b> |
|            | (b) Discuss components and importance of informed consent form.                        | <b>05</b> |
|            | (c) Give in details of Pharmacovigilence safety monitoring in Clinical Trials.         | <b>05</b> |
| <b>Q.5</b> | (a) Define 'Orange Book'. Describe the codes for therapeutic equivalence evaluation.   | <b>06</b> |
|            | (b) Explain terms: i) CMC ii) Biowaiver iii) Purple Book iv) ACTD v)EMA                | <b>05</b> |
|            | (c) What are the clinical trials? How are they organized as a part of drug discovery?  | <b>05</b> |
| <b>Q.6</b> | (a) Describe general consideration, specific requirements and contents of an NDA.      | <b>06</b> |
|            | (b) Write a note on Good Clinical Practices.   | <b>05</b> |
|            | (c) Explain the various components of FDA.   | <b>05</b> |
| <b>Q.7</b> | (a) Discuss about clinical research Protocols.   | <b>06</b> |
|            | (b) Give organization structure, activities and responsibilities of TGA.               | <b>05</b> |
|            | (c) Describe various activity regulated by CDER.                                       | <b>05</b> |

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