

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Ph. – SEMESTER- VIII-EXAMINATION – SUMMER -2022

Subject Code:BP804TT**Date:06/06/2022****Subject Name: Pharmaceutical Regulatory science****Time: 10:30am to 01:30pm****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) Define new drug according to FDA. Explain in detail the new drug development process with the time course for each phase. **06**
(b) Explain the approval process of new drug under 505 (b) (2). **05**
(c) Discuss about various Stages of drug discovery. **05**
- Q.2** (a) Write a note on Preclinical studies as per CDSCO. **06**
(b) Discuss about Organization structure and Overview of regulatory authorities of India. **05**
(c) Describe general consideration, specific requirements and contents of an NDA. **05**
- Q.3** (a) Describe the procedure for Generic drug approval from CDSCO in India. **06**
(b) Explain the purpose and procedure for IND application to USFDA. **05**
(c) Describe Informed Consent process and procedures for clinical trial study. **05**
- Q.4** (a) What is the importance of investigator's brochure? Give a brief outline of clinical research protocols. **06**
(b) What is Common Technical Document? Describe various CTD modules. **05**
(c) Write a note on International Good Clinical Practices. **05**
- Q.5** (a) Describe how Waxman-Hatch Act has simplified and facilitated approval of generic products in US? **06**
(b) What is DMF? Write a note on Type of DMF. **05**
(c) Discuss content of ASEAN Common Technical Document. **05**
- Q. 6** (a) How did Bolar provision give boost to ANDA approval process in USA? **06**
(b) Give the composition, functions and responsibilities of Institutional review board. **05**
(c) Briefly explain about Safety monitoring of medical products. **05**
- Q.7** (a) Write scope and approaches of 21 CFR part 11. **06**
(b) Write note on Purple book. **05**
(c) Discuss the salient features of FDA guidelines for clinical trials in India. **05**
