

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Ph. - SEMESTER-8 • EXAMINATION – SUMMER-2018

Subject Code:2280011

Date: 09/05/2018

Subject Name: Drug Approval Process

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) Explain various phases of drug development. **06**
(b) What is investigational new drug (IND)? Explain types of INDs. **05**
(c) Enlist various section of IND application. Give Format of application. **05**
- Q.2** (a) What is Orange Book ? List the contents of orange book. Describe coding system for therapeutic equivalence evaluation. **10**
(b) Define bioequivalence. How is it performed? State statistical criteria of Bioequivalence? **06**
- Q.3** (a) How to make a FOIA request? Which information is exempted from FOIA? **06**
(b) What is DMF? Enlist type of DMF. Discuss DMF Type II. **05**
(c) Write note on Inactive Ingredients Guidelines. **05**
- Q.4** (a) Write short note on ANVISA. **06**
(b) Discuss the WHO certification scheme for pharmaceutical products. **05**
(c) Write brief note on TGA. **05**
- Q.5** (a) States the goals of NDA. Discuss general requirements of NDA. **06**
(b) Prepare a NDA chart showing NDA review process **05**
(c) Write note on supplement NDA. **05**
- Q. 6** (a) Outline steps taken by CDSCO in February 2015 in making its services responsive, effective and transparent. **06**
(b) Write a note on ANDA. Explain the concept of PARA I to IV filling. **05**
(c) What is SUPAC? Discuss the SUPAC guidelines for Immediate release dosage forms. **05**
- Q.7** (a) What is CTD? Discuss structure of CTD. How it differs from eCTD. **06**
(b) Describe the activity regulated by MHRA. **05**
(c) How approval of bio-similar differs from NDA? **05**
