

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.Pharm - SEMESTER-VIII • EXAMINATION – SUMMER 2017**

**Subject Code: 2280011****Date: 09/05/2017****Subject Name: Drug Approval Process****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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|------------|-----|---|-----------|
| <b>Q.1</b> | (a) | What is CCDSCO? Outline steps taken by CDSCO in 2015 in making its services responsive, effective and transparent.      | <b>06</b> |
|            | (b) | Describe content & steps of ANDA.   | <b>05</b> |
|            | (c) | What is SUPAC? Discuss the SUPAC guidelines for Immediate release dosage forms.   | <b>05</b> |
| <b>Q.2</b> | (a) | How to make a request under FOIA? Which information is exempted from FOIA?  | <b>06</b> |
|            | (b) | Enlist type of Drug Master File and discuss DMF Type II.  | <b>05</b> |
|            | (c) | Write note on CDER guidelines for inclusion of Inactive Ingredients in formulation.                                     | <b>05</b> |
| <b>Q.3</b> | (a) | States the goals of NDA. Discuss general requirements of NDA.   | <b>06</b> |
|            | (b) | Prepare a NDA chart showing NDA review process  | <b>05</b> |
|            | (c) | Explain provisions of supplement NDA.   | <b>05</b> |
| <b>Q.4</b> | (a) | What are common Technical documents required for new drug approval? Discuss structure of CTD. How it differs from eCTD. | <b>06</b> |
|            | (b) | What are Bio-similar? How approval of bio-similar differs from NDA?   | <b>05</b> |
|            | (c) | Describe the activity regulated by USFDA.   | <b>05</b> |
| <b>Q.5</b> | (a) | Define Drug. Outline various phases of drug development.  | <b>06</b> |
|            | (b) | What is investigational new drug (IND)? Explain types of INDs.  | <b>05</b> |
|            | (c) | Enlist various section of IND application. Give Format of application.  | <b>05</b> |
| <b>Q.6</b> | (a) | What is ANVISA? How it differs from ICH guidelines for drug approval.   | <b>06</b> |
|            | (b) | Discuss the WHO certification scheme for pharmaceutical products.   | <b>05</b> |
|            | (c) | Write brief note on TGA.  | <b>05</b> |
| <b>Q.7</b> | (a) | Write note on content and application of Orange Book.   | <b>08</b> |
|            | (b) | What is bioequivalence? How is it performed? State statistical criteria of Bioequivalence?                              | <b>08</b> |

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