

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.PHARM – SEMESTER – 8- EXAMINATION –WINTER - 2018**

**Subject Code: 2280011**

**Date: 28/11/2018**

**Subject Name: Drug Approval Process**

**Time: 02:30 PM TO 05:30 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 SUPAC? Explain the level of changes in SUPAC-MR.                                                                  | <b>06</b> |
|             | (b) Discuss guideline for the post approval changes in SUPAC – IR                                                             | <b>05</b> |
|             | (c) Explain in brief SUPAC – SS.                                                                                              | <b>05</b> |
| <b>Q.2</b>  | (a) Explain the concept of para I to IV and generic exclusivity.                                                              | <b>06</b> |
|             | (b) Explain in brief regulatory agency ICH.                                                                                   | <b>05</b> |
|             | (c) Write a note on CTD.                                                                                                      | <b>05</b> |
| <b>Q.3</b>  | (a) Define new drug according to FDA. Explain in detail the new drug development process with the time course for each phase. | <b>06</b> |
|             | (b) What are Bio – similar? How approval of bio similar differs from NDA.                                                     | <b>05</b> |
|             | (c) Prepare a NDA chart showing NDA review process.                                                                           | <b>05</b> |
| <b>Q.4</b>  | (a) Define DMF. Explain it briefly.                                                                                           | <b>06</b> |
|             | (b) Describe the activity regulated by TGA.                                                                                   | <b>05</b> |
|             | (c) Write note on Purple book.                                                                                                | <b>05</b> |
| <b>Q.5</b>  | (a) Discuss special emphasis on approval under 505 (b) (2).                                                                   | <b>06</b> |
|             | (b) What is INDA? Give the contents of investigation broucher of INDA.                                                        | <b>05</b> |
|             | (c) Explain registration process of new drug under ANVISA.                                                                    | <b>05</b> |
| <b>Q. 6</b> | (a) What is CDSCO? Outline steps taken by CDSCO in 2015 in making its services responsive, effective and transparent.         | <b>06</b> |
|             | (b) Explain in detail the sources of new drug.                                                                                | <b>05</b> |
|             | (c) What is bioequivalence? State statistical criteria of Bioequivalence.                                                     | <b>05</b> |
| <b>Q.7</b>  | (a) Write note on freedom of Information.                                                                                     | <b>06</b> |
|             | (b) Discuss the WHO certification scheme for pharmaceutical products.                                                         | <b>05</b> |
|             | (c) Describe content and steps of ANDA.                                                                                       | <b>05</b> |

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