

GUJARAT TECHNOLOGICAL UNIVERSITY**B.PHARM - SEMESTER- VIII- EXAMINATION – SUMMER-2016****Subject Code:2280011****Date:10/05/2016****Subject Name: Drug Approval Process****Time:10:30am.- 1:30pm.****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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|-------------|-----|---|-----------|
| 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 in detail the sources of new drug. | 05 |
| | (c) | Enlist and explain methods of drug discovery. | 05 |
| Q.2 | (a) | Define DMF. Enlist and explain types of DMF. | 06 |
| | (b) | Write short note on orange book. | 05 |
| | (c) | Write short note on inactive ingredient guide and FOI. | 05 |
| Q.3 | (a) | Explain the concept of para I to IV filing. | 06 |
| | (b) | Explain the approval process of new drug under 505 (b) (2). | 05 |
| | (c) | What is INDA? Give the contents of investigation broucher of INDA. | 05 |
| Q.4 | (a) | Define the following: | 06 |
| | | 1. Purple book | |
| | | 2. ICH | |
| | | 3. MCA | |
| | | 4. Biosimilarity | |
| | | 5. WHO | |
| | | 6. MHRA | |
| | (b) | Explain registration process of new drug under ANVISA. | 05 |
| | (c) | What is TGA? Give the structure of TGA. | 05 |
| Q.5 | (a) | What is CTD? Write in brief about CTD. | 06 |
| | (b) | Write short note on US- FDA. | 05 |
| | (c) | Write short note on WHO. | 05 |
| Q. 6 | (a) | What is SUPAC? Explain the level of changes in SUPAC- MR. | 06 |
| | (b) | Guideline for the post approval changes in SUPAC-IR. | 05 |
| | (c) | Explain in brief SUPAC-SS. | 05 |
| Q.7 | (a) | Explain in brief about content and format of NDA. | 06 |
| | (b) | Write short note on bio-similarity. | 05 |
| | (c) | Enlist and explain different types of IND. | 05 |
