Seat No.: _____ Enrolment No._____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**M. Pharm. – SEMESTER – III • EXAMINATION – WINTER • 2015**

**Subject Code: 1931501 Date: 08-12-2015**

**Subject Name: Drug Regulation and Regulatory Authority**

**Time: 10:30 am - 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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|---|---|---|---|
| **Q.1** | **(a)** | Give a brief account on Drug Master File. | **06** |
| | **(b)** | Give a brief note on WHO certification Scheme on Pharmaceuticals. | **05** |
| | **(c)** | Write note on Good Clinical Practice as per US. | **05** |
| **Q.2** | **(a)** | What are the different regulatory consideration for evaluation of Clinical Parameters? | **06** |
| | **(b)** | Give a note on Harmonization of Pharmaceutical Standards. | **05** |
| | **(c)** | Give in detail criteria for designing clinical trials for Geriatric Population. | **05** |
| **Q.3** | **(a)** | Write a note on NPPA. | **06** |
| | **(b)** | Write a note on recent amendments in D & C Act. | **05** |
| | **(c)** | Write a note on procedure required for New Drug Application as per US. | **05** |
| **Q.4** | **(a)** | Write a note on IP Review Process. | **06** |
| | **(b)** | Give a brief note on Haemovigilance Programme. | **05** |
| | **(c)** | Write in detail ICH E8 guidelines. | **05** |
| **Q.5** | **(a)** | Give in detail parameters to be considered for formation of monograph. | **06** |
| | **(b)** | Give different types of Toxicity Studies. Give a note on Immunotoxicity and Genotoxicity | **05** |
| | **(c)** | Give brief account on Pharmacovigilance Programme in Indian perspective. | **05** |
| **Q. 6** | **(a)** | Give a note on medical device application procedure as per US. | **06** |
| | **(b)** | Give Brief note on electronic CTD. | **05** |
| | **(C)** | Give a note on NDA filling as per Schedule Y. | **05** |
| **Q.7** | **(a)** | Give a current Price fixation Procedure for Pharmaceutical drugs. | **06** |
| | **(b)** | Give a note on Documents required for clinical trial application Schedule Y. | **05** |
| | **(c)** | Give a note on document required for new drug application as per EUDRA guidelines. | **05** |

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