Seat No.: _____ Enrolment No._____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014**

**Subject Code: 2920202 Date: 31-05-2014**

**Subject Name: Global Regulatory Requirements**

**Time: 02:30 pm - 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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|---|---|---|---|
| **Q.1** | (a) | Discuss the phases of investigation in context to IND. | **06** |
| | (b) | Write a note on computer system validation. | **05** |
| | (c) | Explain in brief freedom of information (FOIA). | **05** |
| **Q.2** | (a) | A multinational pharmaceutical company want to change its manufacturing site due to tax waiver. Discuss the SUPAC guidelines for modified release dosage forms with reference to the site changes. | **06** |
| | (b) | Define: Pharmaceutical Equivalents, Pharmaceutical Alternatives and Therapeutic Equivalents. Explain code "A" & code "B" with reference to therapeutic equivalence evaluation code. | **05** |
| | (c) | Discuss Supplemental New Drug Application with recent examples | **05** |
| **Q.3** | (a) | Development of tablet formulation of new anticancer drug "Afatinib" is in process. Discuss the strategy for analytical method development for this tablet dosage form and discuss its validation parameters as per ICH guidelines. | **06** |
| | (b) | Write a note on IIG. | **05** |
| | (c) | Write a note on Enterprise Resource Planning (ERP) system. | **05** |
| **Q.4** | (a) | Write a note on Drug Master File(DMF) in detail | **06** |
| | (b) | Define CTD & eCTD. Explain modules of CTD. | **05** |
| | (c) | Discuss the WHO certification scheme for pharmaceutical products | **05** |
| **Q.5** | (a) | What are the advantages & disadvantages of glass and plastic as a packaging material? Write note on packaging for pediatrics. | **06** |
| | (b) | Explain the concept of revalidation and retrospective validation in pharmaceutical industry with reference to process validation. | **05** |
| | (c) | Define prospective and concurrent validation. Explain in brief step wise validation of fluid bed dryer. | **05** |
| **Q. 6** | (a) | Explain the concept of ANDA and ANDA review process. | **06** |
| | (b) | Explain MHRA in brief | **05** |
| | (c) | Discuss role of CBER in USFDA. | **05** |
| **Q.7** | (a) | Write a note on ANVISA. | **06** |
| | (b) | What is TGA ? Discuss TGA's risk management approach. | **05** |
| | (c) | Differentiate INDA and ANDA. Describe various type of INDA | **05** |

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