

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**M.Pharm Semester –II Examination Dec. - 2011**

**Subject code: 920202**

**Date: 12/12/2011**

**Subject Name: Global Regulatory Requirements**

**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.**

- Q.1** (a) What is validation? Discuss its scope and rational in pharmacy. **06**  
(b) Describe various activity regulated by TGA. **05**  
(c) What are the disadvantages of glass as a packaging material? Explain PET as a packaging material. **05**
- Q.2** (a) Describe stepwise validation programme for fluid bed dryer. **06**  
(b) Define: Orange book, Green book. Describe coding system for therapeutic equivalence evaluation. **05**  
(c) Write a note on child resistant container. **05**
- Q.3** (a) Differentiate INDA and ANDA. Describe various type of INDA. **06**  
(b) What is ERP? Discuss merit and demerits of ERP. **05**  
(c) What is objective of IIG? Explain general description of IIG. **05**
- Q.4** (a) Why computer system validation is required? Explain validation of electronic spread sheet. **06**  
(b) What is change control? How is it carried out? **05**  
(c) Describe various components of FDA. **05**
- Q.5** (a) How to make a FOIA request? Enlist records withheld by FOIA. **06**  
(b) Write a note on Hatchwaxman Amendments. **05**  
(c) Enlist parameters of analytical method validation. Describe Accuracy, Ruggedness, and Robustness. **05**
- Q.6** (a) Describe in brief about SUPAC guidelines for Immediate release dosage forms. **06**  
(b) Write a note on DMF. **05**  
(c) Describe basic functions and steps for new drug registration at ANVISA. **05**
- Q.7** (a) What is CTD? Describe various modules of CTD. **06**  
(b) What are the main functions of WHO? Enlist various WHO guidelines available for pharmaceutical products. **05**  
(c) Write a note on Systems Applications and Products in Data Processing. **05**

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