

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.**

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|------------|--|-----------|
| 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 |
