

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

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

# GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-II Examination July 2010

Subject code: 920202

Subject Name: Global Regulatory Requirements

Date: 07/07/2010

Time: 11.00 am – 02.00 pm

**Instructions:**

**Total Marks: 80**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1** (a) Define Pharmaceutical Packaging. What are the conditions pertaining to containers as per USP? Discuss the objectives, importance and functions of packaging. **06**
- (b) What are the innovations in tamperproof packaging and coding systems? What are package integrity tests for Parenterals? **05**
- (c) Comment on suitability of APIs with packaging material. Write a note on packages for pediatrics and geriatrics. **05**
- Q.2** (a) What is cleaning validation? What are current regulatory requirements for it? What ICH talks about Analytical methods development and validation? **06**
- (b) Why the computer system needs to be validated? How entrepreneur resource planning make use of computers? **05**
- (c) Write a note on qualifications of Pharma. Process equipment and write a note on validation of an autoclave. **05**
- Q.3** (a) What is the need for Orange book? Suggest equivalence related terms and statistical criteria for bio-equivalence. How to use cumulative supplement? **06**
- (b) Discuss the historical aspects of drug development and approval. Which information can be obtained as per FOIA? **05**
- (c) Write a note on IIG. **05**
- Q.4** (a) Differentiate IND, NDA and ANDA. Which are the four pillars for timely approval of NDAs/ ANDAs? **06**
- (b) Write a note on ANDA. Discuss Drug Price Competition and Patent restoration act of 1984 and WAXMAN-HATCH ACT are the same and its economics on the society is important. **05**
- (c) Write a note on supplemental new drug application. **05**
- Q.5** (a) What USFDA does and does not regulate? How will you prepare for USFDA inspection? **06**
- (b) How is SMF prepared for MCC guideline? **05**
- (c) Which medicines are not accepted as generics- as per ANVISA? **05**
- Q. 6** (a) Define CTD and e-CTD. What are technical requirements for e-CTD? **06**
- (b) Write a note on EMEA implementation of New EU Pharma. legislation. **05**
- (c) Write a note on export certificates as per MHRA. Discuss legal status and reclassification of medicinal products. **05**
- Q.7** (a) Discuss the TGA's risk management approach. **06**
- (b) Categorize ICH activities. Write a note on evaluation of stability data. **05**
- (c) How herbal medicinal products are regulated as per WHO? **05**

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