Seat No.:	Enrolment No.

Subject code: 2920202

GUJARAT TECHNOLOGICAL UNIVERSITY M. PHARM. - SEMESTER - II • EXAMINATION - WINTER 2012

Date: 12-01-2013

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) Define validation. Give essentials and major phases of validation. **06** (b) Write a note on ERP with advantages and disadvantages. 05 05 Write a note on step wise validation of Hot air oven. What are Orange Book, Green Book and Blue Book? Discuss the coding system **Q.2** 06 (a) for Therapeutic Equivalence Evaluation and how it can be changed giving suitable illustration? Differentiate INDA and ANDA. Write a note on Hatchwaxman ammendments. 05 05 What is the objective of IIG? Explain general description of IIG. What are clinical trials? How are they organised as the part of drug discovery **Q.3** 06 (a) process? 05 (b) Write a note on Supplemental new drug application. Explain the scope of USFDA. Discuss the preparations required for facing 05 USFDA audit. Give organisation of ICH. What is the role of ICH in improving pharmaceutical **Q.4** (a) 06 product quality? Describe basic functions and steps for new drug registration at ANVISA. 05 Write a note on computer system validation. 05 What is CTD? What are technical requirements of e-CTD? **Q.5** (a) 06 Write a short note on TGA. (b) 05 Describe various components of FDA. 05 (a) Define Pharmaceutical packaging. Discuss the objectives, importance and Q. 6 06 functions of packaging. (b) What are the disadvantages of glass as a packaging material? Write a note on 05 packaging for pediatrics and geriatrics. How is SMF prepared for MCC guidelines? 05 (c) What are the main functions of WHO? Enlist different WHO guidelines available **Q.7** 06 (a) for pharmaceutical products. 05 (b) Write a note on DMF. Discuss SUPAC guidelines for modified release dosage forms with reference to 05 the site changes.
