

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER– II • EXAMINATION – SUMMER 2016

Subject Code: 2920202**Date: 21/05/2016****Subject Name: Global Regulatory Requirements****Time: 10:30 AM To 1:30 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) Which are the objectives of Process validation? Discuss in detail Retrospective validation. | 06 |
| | (b) Write note on validation of “Autoclave” | 05 |
| | (c) What is ERP? Give detail account of Computer validation. | 05 |
| Q.2 | (a) Discuss elements of Equipment validation, illustrate you answer with suitable example. | 06 |
| | (b) Write not on validation Master plan. | 05 |
| | (c) Discuss the components of Analytical method validation. | 05 |
| Q.3 | (a) Give the concept of ANDA & prepare flow chart showing ANDA review process. | 06 |
| | (b) Differentiate INDA and ANDA. Describe various type of INDA. | 05 |
| | (c) What is “Orange Book”? Give brief discussion on therapeutic codes in orange book. | 05 |
| Q.4 | (a) Give the organization of ICH, & it’s objective, Discuss th role of ICH in improving pharmaceutical product quality. | 06 |
| | (b) Write note on MHRA. | 05 |
| | (c) Write note on ANVISA. | 05 |
| Q.5 | (a) Discuss TGA’s risk management approach. | 06 |
| | (b) Write note on IIG. | 05 |
| | (c) Define CTD and e-CTD, which are the technical requirements for e-CTD. | 05 |
| Q. 6 | (a) What is SUPAC? Give SUPAC guidelines for modified release dosages form.. | 06 |
| | (b) Define Drug Master File, Holder, Agent and Application. Give difference between Application and DMFs. | 05 |
| | (c) Write note on “USFDA”. | 05 |
| Q. 7 | (a) What are the clinical trials? How are they organized as a part of drug discovery? | 06 |
| | (b) Write note on “FOI”. | 05 |
| | (c) What are the main functions of WHO? Enlist various WHO guidelines available for pharmaceutical products. | 05 |
