

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**M.PHARM - SEMESTER-2 EXAMINATION – SUMMER-2019**

**Subject Code: 2920202****Date: 31/05/2019****Subject Name: Global Regulatory Requirements****Time: 10:30 AM TO 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 are the objectives of computer system validation? Discuss in brief about ERP. **06**
- (b) Enumerate working area and regulatory guidelines of MHRA. **05**
- (c) Enlist contents of IND. Describe process of withdrawal of IND. **05**
- Q.2** (a) Differentiate calibration and verification. Describe stepwise validation programme for granulation process. **06**
- (b) Explain the scope of TGA. Discuss TGA guidelines in brief. **05**
- (c) What are clinical trials? How are they organized as a part of drug discovery and development process? **05**
- Q.3** (a) What is SAP? Discuss merits and demerits of SAP. **06**
- (b) Define IIG. Describe various modules of IIG database. **05**
- (c) Classify ANDA. Discuss regulatory requirements for ANDA. **05**
- Q.4** (a) Describe in brief about basic criteria for new analytical method development for dosage forms. **06**
- (b) Enumerate types of guidelines provided by ICH. **05**
- (c) What is CTD? Describe various modules of CTD. **05**
- Q.5** (a) Define FOIA. Which types of information can be obtained as per FOIA? **06**
- (b) Discuss various component of FDA. **05**
- (c) Explain Supplemental New Drug Application with recent examples **05**
- Q.6** (a) Describe in brief about SUPAC guidelines for immediate release dosage forms. **06**
- (b) Give brief discussion on therapeutic codes in orange book. **05**
- (c) Write a note on ANVISA. **05**
- Q.7** (a) Discuss the WHO certification scheme for pharmaceutical products. **06**
- (b) Define Drug Master File, Holder, Agent and Application. Give difference between Application and DMFs. **05**
- (c) Write a note on step wise validation of Rotary tablet machine. **05**

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