Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – WINTER 2013

Subject Code: 930104 Date: 11-12-2013

Subject Name: Validation & Product Development

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 Process Validation, discuss its options & explain its importance in Pharmaceutical industry. (6)

(b) Explain the significance of instrument validation & describe the procedure For validation of UV-Visible spectrophotometer. (5)

(c) Discuss the Regulatory Perspectives of analytical method validation and Discuss the type of analytical procedures to be validated. (5)

Q-2 (a) Explain in detail, the Cause & Effect diagram for process of coated tablet Manufacturing. (6)

(b) What is SOP? What is its importance? Describe the SOP for Dissolution Test Apparatus. (5)

(c) Explain the importance & advantages of Vendor Certification. (5)

Q-3 (a) What is Cleaning Validation? Explain in detail the general procedure for Cleaning validation. (6)

(b) Discuss in detail, the methods to determine Accuracy & Precision of any New Instrumental analytical method. (5)

(c) What is Protocol? Give the general protocol format for Prospective Process Validation. (5)

Q-4 (a) Mention the types of water used in Pharmaceutical Industry & Explain the Validation of Water for Injection plant. (6)

(b) Give the flow - chart for Retrospective Process Validation. (5)

(c) Give a brief note on precautions to be taken while performing Scale-up Operation. (5)

Q-5 (a) What is Calibration? What is its importance? Give the Master Plan for Calibration of HPLC system. (6)

(b) Give a brief note on Software System Validation. (5)

(c) Enlist the differences between Validation Protocol & Validation Master Plan. (5)

Q-6 (a) Explain in detail IQ,OQ and PQ for Hot Air Oven. (6)

(b) Describe the Validation Master Plan for Injectable Preparations. (5)

(c) Enlist the differences between Validated & Non-validated manufacturing Process. (5)

Q-7 (a) Give detailed explanation about Product Development steps for Sustained Release tablet formulation. (6)

(b) Draw the detailed Cause & Effect diagram for Ointment manufacturing. (5)

(c) Write a short-note on Aseptic area validation. (5)

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