

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Ph Semester–III Examination Dec. - 2011

Subject code: 930104

Date: 10/12/2011

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) Explain the term Calibration, Qualification & Verification and their interrelationship **06**
(b) Explain different stages of facility & equipment qualification **05**
(c) Write a note on vendor qualification with respect to procurement of materials **05**
- Q.2** (a) Define the Validation Master Plan & explain its importance in setting up of a new manufacturing facility **06**
(b) Describe the types of process validation and role of different technical personnel in executing the same **05**
(c) Explain the terms Validation Protocol and Validation Report. Give Protocol for validation of tablet compression OR coating process **05**
- Q.3** (a) Write a note on validation of Fluid Bed Dryer **06**
(b) Write a note on validation of integrated lines by media fill test **05**
(c) Write a note on qualification of Dissolution test apparatus **05**
- Q.4** (a) Enumerate different parameters used for analytical method validation in Assay and Impurities testing **06**
(b) Explain the terms Robustness and Reproducibility in method validation **05**
(c) Briefly explain the terms System Suitability, Column Qualification & Method Transfer with respect to HPLC use **05**
- Q.5** (a) How will you validate HVAC system installed in sterile product manufacturing facility? **06**
(b) Explain different mechanisms to control cross contaminate in HVAC system **05**
(c) Define the terms As-built, At – rest condition & operational condition with respect to facility design **05**
- Q. 6** (a) Write a note on Performance Qualification of purified water system **06**
(b) Write a note on validation of hardware & software **05**
(c) Enumerate in process controls employed in manufacturing process design of ophthalmic & parenteral preparations **05**
- Q.7** (a) What are SUPAC Guidelines? Explain different levels of changes with respect to Components & composition, Manufacturing equipment & process for immediate release solid oral dosage form **06**
(b) Write a note on scaling up operation in pharmaceutical development **05**
(c) What are current developments in GMP compliance giving reference to ICH guidelines **05**
