

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.

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|-------------|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>Q.1</b>  | (a) | Explain the term Calibration, Qualification & Verification and their interrelationship                                                                                                  | <b>06</b> |
|             | (b) | Explain different stages of facility & equipment qualification                                                                                                                          | <b>05</b> |
|             | (c) | Write a note on vendor qualification with respect to procurement of materials                                                                                                           | <b>05</b> |
| <b>Q.2</b>  | (a) | Define the Validation Master Plan & explain its importance in setting up of a new manufacturing facility                                                                                | <b>06</b> |
|             | (b) | Describe the types of process validation and role of different technical personnel in executing the same                                                                                | <b>05</b> |
|             | (c) | Explain the terms Validation Protocol and Validation Report. Give Protocol for validation of tablet compression OR coating process                                                      | <b>05</b> |
| <b>Q.3</b>  | (a) | Write a note on validation of Fluid Bed Dryer                                                                                                                                           | <b>06</b> |
|             | (b) | Write a note on validation of integrated lines by media fill test                                                                                                                       | <b>05</b> |
|             | (c) | Write a note on qualification of Dissolution test apparatus                                                                                                                             | <b>05</b> |
| <b>Q.4</b>  | (a) | Enumerate different parameters used for analytical method validation in Assay and Impurities testing                                                                                    | <b>06</b> |
|             | (b) | Explain the terms Robustness and Reproducibility in method validation                                                                                                                   | <b>05</b> |
|             | (c) | Briefly explain the terms System Suitability, Column Qualification & Method Transfer with respect to HPLC use                                                                           | <b>05</b> |
| <b>Q.5</b>  | (a) | How will you validate HVAC system installed in sterile product manufacturing facility?                                                                                                  | <b>06</b> |
|             | (b) | Explain different mechanisms to control cross contaminate in HVAC system                                                                                                                | <b>05</b> |
|             | (c) | Define the terms As-built, At – rest condition & operational condition with respect to facility design                                                                                  | <b>05</b> |
| <b>Q. 6</b> | (a) | Write a note on Performance Qualification of purified water system                                                                                                                      | <b>06</b> |
|             | (b) | Write a note on validation of hardware & software                                                                                                                                       | <b>05</b> |
|             | (c) | Enumerate in process controls employed in manufacturing process design of ophthalmic & parenteral preparations                                                                          | <b>05</b> |
| <b>Q.7</b>  | (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 | <b>06</b> |
|             | (b) | Write a note on scaling up operation in pharmaceutical development                                                                                                                      | <b>05</b> |
|             | (c) | What are current developments in GMP compliance giving reference to ICH guidelines                                                                                                      | <b>05</b> |

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