*Seat No.: _____* *Enrolment No._____*

# GUJARAT TECHNOLOGICAL UNIVERSITY

**M. Pharmacy Sem-III Regular Examination January 2011**

## Subject code: 930104
## Subject Name: Validation and Product Development

**Date: 06 / 01 /2011** **Time: 10.30 am – 01.30 pm**

***Instructions:*** **Total Marks: 80**

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) | What is process validation? Discuss design and installation qualification in detail | **08** |
| | (b) | Describe the prospective validation of tablet manufacturing process | **08** |
| **Q.2** | (a) | Explain analytical method validation. Describe precision and accuracy with their evaluation technique | **09** |
| | (b) | Describe the validation of dissolution test apparatus | **07** |
| **Q.3** | | Describe the manufacturing process, in-process controls and finished product specifications in manufacturing of liquid orals. | **16** |
| **Q.4** | (a) | What are the objectives of cleaning validation? Describe the elements of cleaning validation. | **09** |
| | (b) | Describe briefly computer system validation. | **07** |
| **Q.5** | (a) | Define D-value and F-value. Describe OQ and PQ steps involved in the validation of autoclave. | **08** |
| | (b) | Describe validation parameters of HVAC system | **08** |
| **Q. 6** | | Discuss the requirements of scale-up and post-approval changes in immediate release dosage form ( SUPAC-IR ) | **16** |
| **Q.7** | | Write short-notes on the following ( Any Two )<br>(a) Validation protocol. (b) Vendor certification (c) Validation of pharmaceutical water system. | **16** |

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