

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.Pharm - SEMESTER VII - EXAMINATION – WINTER-2016**

**Subject Code: 2270014**

**Date: 29/11/2016**

**Subject Name: INSTRUMENTAL AND PROCESS VALIDATION**

**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) | Discuss scope, types and advantages of validation.                                | <b>06</b> |
|             | (b) | Describe different types of process validation with their advantages.             | <b>05</b> |
|             | (c) | What is validation master plan.   | <b>05</b> |
| <b>Q.2</b>  | (a) | Discuss design qualification and installation qualification of equipment.         | <b>06</b> |
|             | (b) | Describe validation of HPLC system.   | <b>05</b> |
|             | (c) | Discuss steps involved in qualification of Dry powder mixers.                     | <b>05</b> |
| <b>Q.3</b>  | (a) | Explain cleansing validation methods used in Pharmaceutical formulation industry. | <b>06</b> |
|             | (b) | Explain LC-MS.  | <b>05</b> |
|             | (c) | Write note on laboratory automation.  | <b>05</b> |
| <b>Q.4</b>  | (a) | Describe instrumentation for High Performance liquid chromatography.              | <b>06</b> |
|             | (b) | Discuss detectors used in GC.   | <b>05</b> |
|             | (c) | Explain mobile phase selection and optimization in RP-HPLC.                       | <b>05</b> |
| <b>Q.5</b>  | (a) | Draw schematic diagram of HPTLC. Give application of HPTLC.                       | <b>06</b> |
|             | (b) | Give advantages of UPLC over HPLC.  | <b>05</b> |
|             | (c) | Explain resolution and plate number.  | <b>05</b> |
| <b>Q. 6</b> | (a) | Explain extraction of biological fluid samples.                                   | <b>06</b> |
|             | (b) | Discuss column and column packing material used in GC.                            | <b>05</b> |
|             | (c) | How we can validate the bio analytical HPLC method.                               | <b>05</b> |
| <b>Q.7</b>  | (a) | Discuss performance qualification for validation of Autoclave.                    | <b>06</b> |
|             | (b) | Describe flow injection analysis.   | <b>05</b> |
|             | (c) | Explain validation of manufacturing process for sterile products.                 | <b>05</b> |

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