

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.PHARM – SEMESTER – 7- EXAMINATION –WINTER - 2018**

**Subject Code: 2270014**

**Date: 28/11/2018**

**Subject Name: Instrumental and Process Validation**

**Time: 10:30 AM TO 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.**

- |            |   |           |
|------------|---|-----------|
| <b>Q.1</b> | (a) Explain validation of manufacturing process for sterile products.   | <b>06</b> |
|            | (b) Discuss performance qualification for validation of Autoclave.  | <b>05</b> |
|            | (c) Explain cleansing validation methods used in pharmaceutical formulation industry.   | <b>05</b> |
| <b>Q.2</b> | (a) Describe Validation Master Plan and its content.  | <b>06</b> |
|            | (b) Describe validation of wet granulation process and powder mixing for tablet manufacturing.  | <b>05</b> |
|            | (c) Discuss scope, types and advantages of validation.  | <b>05</b> |
| <b>Q.3</b> | (a) What is Process validation? Describe different types of Process validation with their advantages.                                     | <b>06</b> |
|            | (b) Write a note on HPTLC.  | <b>05</b> |
|            | (c) Define the following terms.<br>i) Column resolution, ii) Plate number, iii) Plate height, iv) Selectivity factor, v) Capacity factor. | <b>05</b> |
| <b>Q.4</b> | (a) Differentiate i) HPLC and HPTLC ii) HPLC and GC.  | <b>06</b> |
|            | (b) What is hyphenated technique? Write note on LC-MS.  | <b>05</b> |
|            | (c) Enlist the detectors used in GC. Explain FID in detail.   | <b>05</b> |
| <b>Q.5</b> | (a) How many types of biological fluid samples extraction method? Explain in brief about all method.                                      | <b>06</b> |
|            | (b) Describe instrumentation for Gas chromatography.  | <b>05</b> |
|            | (c) Describe flow injection analysis.   | <b>05</b> |
| <b>Q.6</b> | (a) Describe validation of HPLC system.   | <b>06</b> |
|            | (b) Enlist detectors used in HPLC. Explain solute property detector.  | <b>05</b> |
|            | (c) Write note on laboratory automation.  | <b>05</b> |
| <b>Q.7</b> | (a) Describe system suitability parameter and explain its significance in HPLC method development.  | <b>06</b> |
|            | (b) How we can validate the bio analytical HPLC method?   | <b>05</b> |
|            | (c) Discuss column and column packing material used in GC.  | <b>05</b> |

\*\*\*\*\*