

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.**

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