

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- 7 EXAMINATION – SUMMER -2019

Subject Code: 2270014

Date: 20-05-2019

Subject Name: Instrumental and Process Validation

Time: 02:30 PM TO 05:30 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) Describe different types of Process Validation with their advantages. | 06 |
| | (b) Discuss Validation Master Plan | 05 |
| | (c) Discuss column and column packing material used in GC | 05 |
| Q.2 | (a) Describe validation of HPLC system | 06 |
| | (b) Give objective and principle of equipment qualification. Discuss Design qualification and Installation qualification of equipment. | 05 |
| | (c) Discuss steps for Mobile phase selection and optimization in RP- HPLC. | 05 |
| Q.3 | (a) Explain extraction of Biological Fluid samples. | 06 |
| | (b) Enlist desirable qualities of critical components of HPLC system. How UPLC is better than HPLC. | 05 |
| | (c) Write a note on Laboratory Automation. | 05 |
| Q.4 | (a) Describe instrumentation of HPTLC. | 06 |
| | (b) Explain Resolution and Plate Number. What are minimum requirements of these parameters as per ICH guidelines? | 05 |
| | (c) Discuss detectors used in GC. | 05 |
| Q.5 | (a) Write a note on validation of manufacturing process for Sterile Products. | 06 |
| | (b) Explain LC-MS. | 05 |
| | (c) How can we validate the Bio-Analytical HPLC method? | 05 |
| Q. 6 | (a) What are objectives of Cleaning Validation? Explain Cleansing Validation methods used in Pharmaceutical Industry. | 06 |
| | (b) Discuss Performance qualification for the validation of Autoclave. | 05 |
| | (c) Explain Instrumentation of HPLC. | 05 |
| Q.7 | (a) Explain various steps involved in qualification of Dry Powder Mixer. | 06 |
| | (b) Discuss scope, types and advantages of Validation. | 05 |
| | (c) Explain Flow Injection Analysis. | 05 |
