

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- VII • EXAMINATION – WINTER -2020

Subject Code: 2270014**Date: 16/01/2021****Subject Name: Instrumental and Process Validation****Time: 10:30AM To 12:30PM****Total Marks: 54****Instructions:**

1. Attempt any **THREE** questions from Q-1 to Q-6.
2. Q.7 is compulsory to attempt.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks.

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|-------------|---|-----------|
| Q.1 | (a) Discuss methods of precipitation of protein from biological fluid | 06 |
| | (b) Describe Operational qualification and Performance qualification for Autoclave | 05 |
| | (c) What are the types of automated analytical systems | 05 |
| Q.2 | (a) Discuss steps for mobile phase optimization in HPLC | 06 |
| | (b) What is hyphenated technique? write note on LC-MS. | 05 |
| | (c) Explain different types of columns use in GC | 05 |
| Q.3 | (a) Discuss scope, types and advantages of validation | 06 |
| | (b) Give steps for validation of Fluidized Bed Drier. | 05 |
| | (c) Explain briefly validation master plan | 05 |
| Q.4 | (a) Discuss Column resolution, Selectivity factor and Capacity factor in Liquid chromatography. | 06 |
| | (b) Describe validation of HPLC system. | 05 |
| | (c) Explain injector and guard column in HPLC. | 05 |
| Q.5 | (a) Discuss Design qualification and Installation qualification of equipment. | 06 |
| | (b) Explain validation of Tablet manufacturing process. | 05 |
| | (c) What are objectives and stages of cleaning validation? | 05 |
| Q. 6 | (a) Enlist detectors used in GC. Discuss any two. | 06 |
| | (b) Discuss derivatization in GC | 05 |
| | (c) Discuss steps involved in qualification of Dry powder Mixer | 05 |
| Q.7 | (a) Write a note on HPTLC. | 06 |
| | OR | |
| | (a) Discuss troubleshooting in LC/MS | 06 |
| | OR | |
| | (a) Describe selection of detector in HPLC | 06 |
