



GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER- 7 EXAMINATION – WINTER -2019

Subject Code: 2270014

Date: 28-11-2019

Subject Name: Instrumental and process validation

Time: 10:30AM TO 01:30PM

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 the strategy of Industrial Process Validation of Solid Dosage Form. | 06 |
| | (b) | Discuss the steps involved in qualification of autoclave. | 05 |
| | (c) | Write in short about validation master plan. | 05 |
| Q.2 | (a) | Describe validation of HPLC system. | 06 |
| | (b) | What do you understand by Theoretical Plate concept and how HETP affects the separation of HPLC column? | 05 |
| | (c) | What is operational qualification and performance qualification of equipment. | 05 |
| Q.3 | (a) | What are the objectives and stages of cleaning validation. | 06 |
| | (b) | How will you optimize mobile phase in HPLC method development. | 05 |
| | (c) | Discuss the principles and application of flow injection analysis. | 05 |
| Q.4 | (a) | Draw schematic diagram of Gas chromatography. Give applications of GC. | 06 |
| | (b) | Define the following terms: i) Selectivity factor ii) Capacity factor iii) Plate height iv) Plate number v) Column resolution | 05 |
| | (c) | Discuss the various types of automated instruments. | 05 |
| Q.5 | (a) | Discuss the detectors used in gas chromatography. | 06 |
| | (b) | Discuss the scope and advantages of pharmaceutical process validation. | 05 |
| | (c) | What do you understand by flow injection analysis. | 05 |
| Q. 6 | (a) | How will you validate sterile products. Discuss in brief. | 06 |
| | (b) | Discuss the types of process validation. | 05 |
| | (c) | Write a note on HPLC instrumentation. | 05 |
| Q.7 | (a) | Discuss the steps involved in selection of detector in HPLC method development. | 06 |
| | (b) | How will you validate bioanalytical HPLC method. | 05 |
| | (c) | Discuss cleaning validation. | 05 |
