

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM – SEMESTER – VII • EXAMINATION – WINTER • 2015

Subject Code: 2270014

Date: 16-12-2015

Subject Name: Instrumental and Process Validation

Time: 10.30 am - 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.

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|-------------|---|-----------|
| Q.1 | (a) Define pharmaceutical validation. Discuss “Validation master plan”. | 10 |
| | (b) Discuss scope, types and advantages of validation. | 06 |
| Q.2 | (a) Outline objectives and principle of equipment validation. Discuss Design qualification and Installation qualification of equipment. | 10 |
| | (b) Describe validation of HPLC system. | 06 |
| Q.3 | (a) Discuss validation of dry powder mixing, wet granulation and drying of granules for tablet manufacturing. | 10 |
| | (b) Write note on laboratory automation. | 06 |
| Q.4 | (a) What are objectives and stages of cleaning validation? Explain cleansing validation methods used in pharmaceutical formulation industry. | 10 |
| | (b) Discuss performance qualifications for the validation of Autoclave? | 06 |
| Q.5 | (a) Enlist desirable qualities of critical components of HPLC system. How is UPLC better than HPLC? | 10 |
| | (b) Discuss steps for optimization of mobile phase with Three Organic Solvents for RP-HPLC. | 06 |
| Q. 6 | (a) How is Resolution and Plate Number calculated from a chromatogram? What is minimum requirement of these parameters as per ICH guidelines? How are these parameters optimized? | 10 |
| | (b) Classify detectors used in HPLC. Discuss selection of the detector in HPLC methods. | 06 |
| Q.7 | (a) Discuss methods of precipitation of protein from biological fluid and methods for sample clean up in bio-analytical HPLC method. | 10 |
| | (b) Write note on LC-MS. | 06 |
