

FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog) Examination,
January 2020**

Subject: Pharmaceutical Validation

Time: 3 Hrs

Max. Marks : 75

Note: Answer any five questions. All questions carry equal marks.

- 1 Explain the following terms. 5+5+5
 - (a) User requirement specification
 - (b) Factory acceptance test
 - (c) Site acceptance test
- 2 Write note on the following (7)
 - (a) Calibration of FTIR.
 - (b) Cleaning in place (8)
- 3 Define IPR. Explain the criteria of patentability of an invention and describe the steps involved in patent application. (1+7+7)
- 4 Explain the difference between qualification, calibration, validation and explain abt instrument qualification. (5+10)
- 5 Write note on the following.
 - (a) What are the different types of water used in pharmaceutical industry?
 - (b) Different steps involved in the calibration of HPLC instrument. (7+8)
- 6
 - (a) Discuss abt pharmaceutical water system validation.
 - (b) Explain the procedure to calibrate wavelength of UV instrument. (10+5)
- 7
 - (a) Describe the Method Validation parameters for new Analytical method.
 - (b) What is meant by revalidation and when to revalidate? (12+3)
- 8 Write note on the following (8+7)
 - (a) Types of process validation.
 - (b) Validation master plan.
