

**FACULTY OF PHARMACY****M. Pharmacy (Pharmaceutical Analysis) I – Semester (PCI) (Suppl.) Examination,****August 2019****Subject: Pharmaceutical Validation****Time: 3 Hrs****Max.Marks: 75****Note: Answer any five questions. All questions carry equal marks.**

- 1 Explain the following terms:
  - a) User requirement specification 5
  - b) Factory acceptance test 5
  - c) Site acceptance test. 5
- 2 Write note on the following:
  - a) Calibration of volumetric glassware 7
  - 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) Different types of waters used in pharmaceutical industry. 7
  - b) Different steps involved in the calibration of HPLC instrument. 8
- 6
  - a) Discuss abt pharmaceutical water system validation. 10
  - b) Explain the procedure to calibrate wavelength of UV instrument. 5
- 7
  - a) Describe the method validation parameters for new analytical method. 12
  - b) What is meant by revalidation and when to revalidate? 3
- 8 Write note on the following:
  - a) Types of process validation 8
  - b) Validation master plan. 7

\*\*\*\*