

Code No. 13161 / PCI

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

- 1 Explain the following:
  - a) Define and explain various Intellectual Property Rights. 5
  - b) Write about procedure of obtaining an International Patent. 10
- 2 Explain the procedure for following:
  - a) Calibration of FTIR 5
  - b) Sampling methods for cleaning validation. 10
- 3 List and explain the analytical method validation parameters. 15
- 4 Explain the various types of trademarks and do nots in trademarks with suitable examples. 10+5
- 5 Write note on the following:
  - a) Define and explain the types of process validation 8
  - b) Different steps involved in the calibration of analytical balance. 7
- 6
  - a) What are the different phases of water system validation? 10
  - b) Explain the procedure to calibrate wavelength of UV instrument. 5
- 7
  - a) What are the different parameters in HVAC to be examined? 12
  - b) What is meant by revalidation and when to revalidate? 3
- 8 Write note on the following:
  - a) Electronic records 5
  - b) Validation master plan. 10

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