

FACULTY OF PHARMACY**M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Supp.) Examination,
August 2018****Subject: Pharmaceutical Validation****Time: 3 Hrs****Max. Marks: 75****Note: Answer any five questions. All questions carry equal marks.**

- 1 (a) Define qualification and explain the different phases of qualification process of analytical equipments. 10
(b) Write short notes on re-validation process. 5
- 2 Write abt the following 3x5=15
(a) Validation master plan.
(b) Factory acceptance test and site acceptance test.
(c) Calibration of analytical balance.
- 3 (a) Describe validation procedure for HVAC system. 10
(b) Write abt cleaning -in-place (CIP). 5
- 4 Describe the method validation parameters for a new analytical method as per ICH guidelines. 15
- 5 (a) What is an intellectual property right? Explain abt different types of IPR. 8
(b) Discuss the rights and responsibilities of patentee. 7
- 6 (a) What is a Patent? Explain the procedure for filing an application for patent in India. 9
(b) What is patent infringement and its scope. 6
- 7 (a) Explain the procedure involved in qualification and calibration of HPLC 10
(b) Write short note on Digital significance of 21 CFR part II. 5
- 8 (a) Describe in detail abt cleaning validation process. 10
(b) Write abt preventive maintenance. 5
