Code No. 1152/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Main) Examination, February 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 validation. Write abt design qualification and performance qualification phases of analytical equipment.	10
	(b) Explain the calibration procedure of glassware used in analytical work.	5
2	(a) How do y qualify UV spectrophotometers ? Explain.	10
	(b) Write short note on re-validation process.	5
3	Write short notes on	
	(a) Cleaning validation	8
	(b) Pharmaceutical water system validation	7
4	Explain the ICH guidelines for validation of new analytical procedures.	15
5	(a) What is an intellectual property right? Explain abt different types of IPR.	8
	(b) Discuss abt violation of IPR and penalties.	7
6	(a) Write abt international patenting requirement procedure.	8
	(b) Write abt the role of Intellectual Property in Pharmaceutical Industry. Give few recent examples.	7
7	(a) Explain the procedure involved in qualification and calibration of FTIR.	10
	(b) Write abt factory acceptance test and site acceptance test.	5
8	(a) Explain the steps involved in preparation of validation Master Plan (VMP).	10
	(b) Write short note on Digital significance of 21 CFR part II.	5

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