

INDIRA UNIVERSITY, PUNE

SCHOOL OF PHARMACY- MPHARM (Pharmaceutical Quality Assurance)

Term End Examination (2025 Pattern) April- May – 2026- Semester – II

Course Name: Pharmaceutical Validation
Course Code: MQA202T

Max. Marks: 75
Time: 3:00 Hrs.

Instructions

- All Questions are Compulsory. Write two sections on separate answer sheets.
 - Neat diagram must be drawn wherever necessary.
 - Figures to the right indicate full marks.
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Section : I

Q.1 Solve any ONE from the following **15 Marks**

- a. What is Validation? Explain the Scope, Importance, frequency, and advantages of Validation.
- b. Discuss the qualification of HPLC and GC.

Q.2 Solve any FOUR from the following **20 Marks**

- a. Write a short note on – Qualification of Autoclave.
- b. Write short note on – FAT and SAT
- c. Discuss qualification of UV Visible spectrophotometer.
- d. Explain the importance of Validation master plan
- e. Explain in brief – Qualification of Dry powder Mixer
- f. Explain types of qualification with importance of each type.

Section : II

Q.3 Solve any ONE from the following **15 Marks**

- a. Elaborate concept of Intellectual property, IP protection in pharmaceutical industry
- b. What are the types of steam used in pharmaceutical industry? How is steam system validated?

Q.4 Solve any TWO from the following

15 Marks

- a. Discuss in brief - Rights of patentee.
- b. Discuss validation of HVAC system
- c. Comment on process validation of ointments/cream.
- d. Explain computerized system validation

Q.5 Solve any TWO from the following

10 Marks

- a. Write a note on - Qualification of Dissolution test apparatus as per USP.
- b. Write a short note on “Copyrights”.
- c. What are different stages of process validation as per USFDA guidelines?
- d. Explain the sampling in cleaning method validation.