

Roll No.

Total No. of Pages : 01

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M.Pharmacy (Pharmaceutical Analysis) (Sem.-1)

PHARMACEUTICAL VALIDATION

Subject Code : MPA-103T

M.Code : 74695

Date of Examination : 19-01-2023

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
 2. Each question carries FIFTEEN marks.
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1. a) What do you understand by the term validation? What are its advantages? Discuss the validation master plan.
b) Define patent. What are practical aspects of filing patent?
 2. a) Discuss the validation of pharmaceutical water system.
b) Write a detailed note on computerized system validation.
 3. a) What is the significance of transfer technology? Explain in detail.
b) Write a note on cleaning method development. Explain the validation method used in cleaning.
 4. Write short note on any three :
a) Qualification of volumetric flask
b) Streamlining of qualification process
c) PCT
d) HVAC system.
 5. a) Discuss qualification of measuring cylinder and volumetric flask.
b) Briefly explain the term re-qualification. Also discuss in detail about calibration preventive maintenance.
 6. a) What are the requirements for International Patenting?
b) Write a note of qualification of UV visible spectrophotometer.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.