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Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmaceutical Analysis) (2017 &amp; Onwards) (Sem.-1)

**PHARMACEUTICAL VALIDATION**

Subject Code : MPA-103T

M.Code : 74695

Time : 3 Hrs.

Max. Marks: 75

**INSTRUCTIONS TO CANDIDATES :**

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

- Q1. a) Define Qualification. How is qualification of manufacturing equipments done? (10)
- b) Discuss the qualification procedure for UV spectrophotometry. (5)
- Q2. a) Detail the validation test for HVAC system. (7.5)
- b) Explain the economic importance of intellectual property rights. (7.5)
- Q3. Discuss in detail different types of patent application. Describe the procedure for application of a PCT. (15)
- Q4. a) Write a detailed note on computerized system validation. (10)
- b) What do you understand by the terms performance qualification and re-qualification? (5)
- Q5. Write short notes on **Any Three** :
- a) Qualification of HPLC (5)
- b) Validation master plan (5)
- c) Intellectual Property Protection (5)
- d) Operational Qualification (5)
- Q6. a) Discuss the process of qualification of volumetric flask and pipette. (7)
- b) What do you mean by patent infringement? Discuss its scope. (8)

**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.**

