

**Roll No.**

**Total No. of Pages : 01**

**Total No. of Questions : 06**

**M.Pharmacy (Pharmaceutical Analysis) (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.

1. a) What do you understand by the term PCT? Discuss the international patenting requirement and costs. (10)  
b) Explain in detail the working of any two pumps used in HPLC. (5)
2. a) Explain the provisional and non provisional patent applications. (8)  
b) Discuss the process of qualification of analytical instruments. (7)
3. a) Explain the process of validation of analytical method used in cleaning. (10)  
b) Discuss the general principles of analytical method validation. (5)
4. a) Define Installation, operational and performance qualification? Explain the validation of utility systems. (10)  
b) Discuss the process for filing a patent application. (5)
5. a) Discuss various factors which affect the choice of IP protection. (5)  
b) Discuss qualification of glassware systems. (5)  
c) Explain the validation of HVAC system. (5)
6. Write short note on **any THREE** (5 × 3)  
a) Cleaning in place  
b) Qualification of UV visible spectrophotometer  
c) Rights and responsibilities of a patentee  
d) Streamlining of qualification and validation process

**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.**