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Total No. of Pages : 01

Total No. of Questions : 06

**M.Pharmacy (Pharmaceutical Quality Assurance) (2017 & Onwards)**  
**(Sem.-2)**

**PHARMACEUTICAL VALIDATION**

**Subject Code : MQA-202T**

**M.Code : 76351**

Time : 3 Hrs.

Max. Marks: 75

**INSTRUCTIONS TO CANDIDATES :**

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

1. A) What is meant by IQ, OQ and PQ? Outline the general procedures for them.  
B) What is meant by calibration? Briefly explain the process of calibrating a weighing balance.
2. A) Explain the procedure for validating dry powder mixers.  
B) Outline the essential steps involved in calibrating FTIR.
3. A) Mention the principle of operation of 'friability test apparatus'. Explain the process of validating its operation.  
B) Write a note on need and steps involved in validation of water systems in a pharmaceutical industry.
4. A) Explain repeatability and robustness with examples.  
B) Describe the validation of manufacturing process for coated tablet giving a fish-bone diagram.
5. A) Write a note on cleaning-in-place.  
B) Discuss the requirements for electronic records according to USFDA guidelines.
6. A) What are trademarks? Describe the importance of trademarks and penalties for its infringement.  
B) Describe the process of filing an International Patent.

**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.**

