

**Total No. of Pages : 01**

**Total No. of Questions : 06**

**M.Pharmacy(Industrial Pharmacy) (2017 Batch) (Sem.-2)**

## SCALE UP & TECHNOLOGY TRANSFER

**Subject Code : MIP-202T**

**Paper ID : [74932]**

**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 is meant by IQ, OQ and PQ? Justify your answer considering these for a Fluidized-bed dryer. (7.5)  
b) Distinguish between prospective, retrospective and concurrent validations. (7.5)
2. a) Describe the process for technology transfer of tablet process from R & D to production plant. (7.5)  
b) What is 're-qualification'? Mention the reasons for re-qualification and method used for this purpose. (7.5)
3. a) What is vendor qualification? Briefly discuss the parameters that should be taken into consideration for this purpose. (7.5)  
b) Comment on the importance of raw material validation and the parameters to be considered for this purpose. (7.5)
4. a) How are water process systems validated? (7.5)  
b) Comment on the importance and methods used for validating environment control systems in a pharmaceutical plant. (7.5)
5. a) Discuss the need and methods used for effluent treatment in a pharmaceutical plant. (7.5)  
b) Give an account of the chemical hazard monitoring and prevention systems. (7.5)
6. Write short notes on the following :  
a) Validation of liquid filling machine. (5)  
b) Requirements for a semi-solid formulation unit. (5)  
c) OQ for double cone blender. (5)