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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

M.Code : 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.

- Q1. a) Describe the scaling up process for tablets. Give its importance. (7.5)  
b) How is the qualification of an autoclave done? (7.5)
- Q2. Write notes on the following :  
a) IQ for tablet compression machine (5)  
b) Process validation parameter for sterilization (5)  
c) Aseptic room validation (5)
- Q3. a) How can we scale up from pilot scale to large scale? Give suitable examples. (10)  
b) Discuss the various safety measures to be taken in a pharmaceutical industry. (5)
- Q4. a) Discuss in details the general concept, procedures and protocols involved in analytical validation process. (10)  
b) Write a note on industrial effluent testing and treatment. (5)
- Q5. What do you understand by the term in process and finished product specifications? What are the various problems encountered during transfer of technology? (15)
- Q6. Write short note on **any three** :  
a) Performance qualification (5)  
b) Qualification for a membrane filter (5)  
c) Industrial effluent testing (5)  
d) Vendor qualification (5)

**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.**

