

Jadavpur University
Department of Pharmaceutical Technology
Kolkata-700032.

M.Pharm (IP)/ 1st year/2nd Sem/Time 3 hrs/ FM 75/ 2025

Course: Scale Up and Technology Transfer

Code: MIP 202T

Note: 1. Answer ALL the questions.

2. Question 1 is Compulsory.

1. Answer the following questions. 10x2M=20 Marks

- i. How many batches are taken for process validation?
- ii. Define process validation.
- iii. Define scale up with its importance.
- iv. Give the WHO definition of validation.
- v. Define VMF.
- vi. Explain design qualification in short.
- vii. Mention the types of industrial Hazards.
- viii. Who is responsible for performance qualification checking and why?
- ix. What is class A and class B fire?
- x. Write the full form of HCS in industrial hazards and give one example.

Short Answer Question

7 x 5 Marks = 35 Marks

(Answer 7 out of 9)

2. Discuss in detail about design qualification.
3. Write on installation qualification of rapid mixer granulator.
4. How prospective validation is done in general?
5. What are safety aspects considered in chemical hazards?
6. Which steps are to be taken during fire hazards?.
7. Write down about operational qualification for fluidized bed dryer .

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8. Explain the importance of validation and qualification
9. Name the different apparatus/equipment for controlling dust hazards
10. Name the different person who should do equipment qualification.

Long Answer Questions. **2 x 10M = 20 Marks**

(Answer 2 out of 3)

11. Enlist the critical steps in tablet granulation which are considered to be validated.
12. Write in details about the process scale up of Tablets.
13. Define cleaning validation. Give its importance. Write the process of cleaning validation.