

Jadavpur University
Department of Pharmaceutical Technology
Kolkata-700032.

M.Pharm (IP)/ 1st year/2nd Sem/Time 3 hrs/ FM 75/ 2024

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. Give the WHO definition of validation.
- ii. Define VMF.
- iii. How many batches are taken for process validation?
- iv. Define scale up with its importance.
- v. Define technology transfer.
- vi. Explain qualification.
- vii. Why cooling tower is needed to reduce thermal pollution.
- viii. How electrostatic separator works in air pollution?
- ix. Why and how Biological treatment is done?
- x. Classify different types of qualification.

Short Answer Question

7 x 5Marks = 35Marks

(Answer 7 out of 9)

2. Differentiate analytical method validation and process validation.
3. Differentiate validation & calibration.
4. Give the objectives and importance of technology transfer.
5. Write short note on basic requirements for pilot plant scale up technique.
6. Give the significance of pilot plant.
7. Write down installation qualification for rapid mixer granulator.
8. How operation qualification is done for tray dryer?

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9. Name the different person who should do equipment qualification.
10. How water pollution treatment is done. Describe about physical, chemical and biological treatment method necessary for it.

Long Answer Questions. 2 x 10M = 20 Marks

(Answer 2 out of 3)

11. Write in details about the process validation of tablets in pharmaceutical industry.
12. Write in details about the process scale up of Tablets.
13. Write in details about design qualification, installation qualification, operational qualification and performance qualification. 2.5x4=10