

PARUL UNIVERSITY
FACULTY OF PHARMACY
M.Pharm Winter 2022 - 23 Examination

Semester: 1**Subject Code: MPA103T****Subject Name: PHARMACEUTICAL VALIDATION****Date: 17/03/2023****Time: 10:00 am to 01:00 pm****Total Marks: 75****Instructions:**

1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

Q.1 Essay Type Questions. (any 2 out of 3) (15 Marks Each) (30)

1. Define Qualification and Validation. List out various qualification stages. Write in detail about qualification of UV-Visible spectrophotometer.
2. Define Utility in pharmaceutical Industries. Write about validation of HVAC system. List out Analytical method validation parameters as per ICH Q2(R1).
3. List out various Intellectual property rights. Write in detail about filing a patent application.

Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) (25)

1. Differentiate FAT and SAT.
2. Write about calibration of Burette and Pipette.
3. Explain the validation of compressed air and nitrogen.
4. Write a note on Electronic records and Digital signature
5. Write about Factors affecting choice of IP protection.
6. Write a short note on cleaning validation.

Q.3 Short Answers. (2 Marks Each) (20)

1. What is Validation Master Plan?
2. List out tests to be performed for validation of HPLC.
3. Define CIP and write its significance.
4. Describe about 21CFR part 11.
5. What is PCT application?
6. Explain about GAMP-5
7. Write about validation parameters for FTIR
8. What are Global ramifications and financial implications?
9. List out computerized system validation parameters
10. Explain significance of TOT.