

QP CODE: 113329

Reg. No:.....

**First Semester M.Pharm Degree Regular/Supplementary Examinations
November 2021**

M.Pharm (Pharmaceutical Analysis)

Paper III - Pharmaceutical Validation (MPA 103T)

(Common for 2017 and 2019 Scheme)

Time: 3 Hours

Total Marks: 75

- *Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space*
- *Answer all parts of a single question together • Leave sufficient space between answers*
- *Draw table/diagrams/flow charts wherever necessary*

Essays

(3x10=30)

1. Define the terms qualification, validation and calibration. Discuss about DQ, IQ, OQ and PQ. Brief about Validation of Master Plan (VMP).
2. Discuss in detail about validation of pharmaceutical water and water for injection IP.
3. Discuss the significance of role of IP in pharmaceutical industry, global ramification and financial implications

Short Notes

(9x5=45)

4. Calibration of FT-IR instrument
5. Specificity and selectivity
6. Calibration of UV-Vis spectrophotometer.
7. Factors affecting the choice of IP protection
8. Significance of tech transfer.
9. Qualification of electronic balance and standard flask.
10. Site Acceptance Test (SAT)
11. Right and responsibilities of the patentee
12. Change management.
