

QP CODE: 113329

Reg. No:.....

**First Semester M.Pharm Degree Regular/Supplementary Examinations
April 2023**

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. Explain computerized validation system, electronic records and significance
2. Discuss on qualification of various glass wares
3. Discuss on mechanism of protection of intellectual property

Short Notes

(9x5=45)

4. Qualification of manufacturing equipment's and analytical instruments
5. pH meter qualification
6. Pharmaceutical water system and pure steam
7. Patent filing
8. Significance of transfer of technology
9. Cleaning of equipments
10. Patent infringement
11. Calibration preventive maintenance
12. Factory acceptance test and site acceptance test.
