QP CODE: 113329 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations June 2024
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. Describe the principles involved in analytical method validation as per International Council for Harmonisation guidelines.

2. Discuss in detail about the qualification of FT-IR and HPTLC.

3. Define calibration and validation. Discuss the validation master plan (VMP), advantages of calibration and validation

Short Notes **(9x5=45)**

4. Cleaning in Place (CIP)

5. Revalidation.

6. Calibration of pipette and burette.

7. Water for injection I.P.

8. Validation of compressed air.

9. GAMP 5 (Good Automated Manufacturing Practice).

10. Principles of intellectual property.

11. Factory Acceptance Test (FAT).

12. Change control.

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