QP CODE: 113329 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations March 2020
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 about computerized system validation of electronic records and digital significance-21 CFR part 11.

2. Explain the general principle of intellectual property. Mechanism for protection of IP of patents and copy right.

3. Discuss the validation of utility system for pharmaceutical water system and pure steam

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

4. Validation master plan.

5. Factory acceptance test.

6. Give the qualification of HPLC.

7. The ICH guidelines for analytical method validation.

8. What are the rights and responsibilities of patentee.

9. Discuss the negative and positive aspects of ethics.

10. Patent application forms and guidelines.

11. Qualification of manufacturing equipment.

12. Cleaning validation — cleaning in place.

****