

QP CODE: 113329

Reg. No:.....

First Semester M.Pharm Degree Supplementary Examinations July 2019

M.Pharm (Pharmaceutical Analysis)

Paper III - Pharmaceutical Validation (MPA 103T)

Time: 3 Hours

Total Marks: 75

- Answer all Questions.
- Draw Diagrams wherever necessary.

Essays

(3x10=30)

1. Discuss the operational and performance qualifications for manufacturing equipments.
2. Elaborate the ICH guidelines for method validation of high performance liquid chromatography
3. Describe in detail about the qualification of HPLC & FTIR instruments

Short Notes

(9x5=45)

4. Advantages of validation process.
5. Factory acceptance test.
6. Qualification of pH meter.
7. Validation of HAVC system
8. GAMP-5 guidelines.
9. Validation of analytical method used in cleaning
10. Trade mark.
11. Filing of patent applications
12. Role of intellectual property in pharmaceutical industry.
