

QP CODE: 113329

Reg. No:.....

First Semester M.pharm Degree Examinations March 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. Elaborate the types of intellectual property rights and factors affecting choice of intellectual property protection.
2. Discuss factory acceptance test and site acceptance test
3. Describe in detail about the qualification of HPLC and GC instruments

Short Notes

(9x5=45)

4. Qualification of FTIR instrument
5. Validation of pharmaceutical water system
6. Qualification of standard flask and pipette.
7. Installation qualification.
8. Validation of cleaning method development
9. Validation of master plan.
10. Significance of electronic records -CFR part-11
11. Salient features of intellectual property protection
12. Penalties for violation in intellectual property.
