

QP CODE: 113329

Reg. No:.....

First Semester M.pharm Degree Examinations April 2018

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. Define qualification and validation. Streamlining of qualification and validation process
2. Explain the qualification of FTIR and pipette.
3. Describe about global ramification and financial implication in IP

Short Notes

(9x5=45)

4. Enlist the factors affecting choice of IP protection.
5. The validation of HVAC system.
6. Re-qualification.
7. Cleaning method development.
8. The signification of transfer technology in IP.
9. Give an account of patent infringement and scope.
10. Site acceptance test.
11. GAMP 5.
12. Describe the role of IP in pharmaceutical industry.
