

Code: 17S07102

M.Pharm I Semester Regular Examinations February 2018

PHARMACEUTICAL VALIDATION

(Pharmaceutical Analysis)

(For students admitted in 2017 only)

Time: 3 hours

Max. Marks: 60

Answer all the questions

- 1 Define validation. Write note on validation master plan.
OR
- 2 Explain in detail design qualification and installation qualification.
- 3 Write note on qualification of HPLC.
OR
- 4 Explain the qualification of dissolution apparatus.
- 5 Write the note on compressed air used in the validation of utility systems.
OR
- 6 Explain in detail cleaning validation.
- 7 Write about computerized system validation techniques.
OR
- 8 Explain validation of analytical method as per ICH guidelines and USP.
- 9 Explain in detail intellectual property rights (IPR).
OR
- 10 Describe in detail right and responsibilities of patentee.

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