

Total No. of Questions : 4]

SEAT No. :

P3982

[Total No. of Pages : 1

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M.Pharmacy (Semester - II)
PHARMACEUTICAL VALIDATION
(2013 Pattern) (Credit System)

Time : 3 Hours]

[Max. Marks : 50

Instructions to the candidates :

- 1) *All questions are compulsory.*
- 2) *Figures to the right indicate full marks.*
- 3) *Draw well labelled diagrams where necessary.*

Q1) Define validation. Describe in detail concept of IQ, OQ, PQ. **[10]**

Q2) Answer any three of the following : **[15]**

- a) Validation of autoclave
- b) Validation of dissolution test apparatus
- c) Validation of fluid bed dryer
- d) Describe validation master plan

Q3) Write note on (any three) : **[15]**

- a) Validation of dry powder mixer
- b) Enlist & explain the steps for stability indicating HPLC method
- c) State the protocol for validation of blister strip packing machine
- d) Validation of pure steam

Q4) Explain validation of HVAC system. **[10]**

OR

Describe in detail vendor certification.

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