

Total No. of Questions : 4]

SEAT No. :

P3984

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**M.Pharmacy (Semester - I & II) Common (Elective) (Theory)**

**QUALITY CONTROL & ASSURANCE OF  
PHARMACEUTICALS**

**(2013 Pattern) (Credit System)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidates :*

- 1) *Question number one is compulsory.*
- 2) *Draw well labeled diagrams wherever necessary.*
- 3) *Figures to the right indicates full marks.*

**Q1)** What is Master production and control record? Give its contents. **[10]**

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

- a) Describe sources of contamination & their control
- b) Components of QA
- c) Types of pharmaceutical plant audits
- d) Define SOP? Give its significance.

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

- a) Revalidation
- b) Quality culture
- c) Change control
- d) GMP requirements of equipments of sterile products

**Q4)** Explain the concept of material management. **[10]**

OR

Explain validation of pharmaceutical HVAC system.

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