Total No. of Questions : 4]

SEAT No. :

P3972

[Total No. of Pages : 1

[5246]-107

M. Pharmacy (Semester - I)

ADVANCED QUALITY ASSURANCE TECHNIQUES (CGMP AND DOCUMENTATION)

(2013 Pattern)

Time : 3 Hours] *[Max. Marks : 50*

Instructions to the candidate :

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***

Q1) Explain the principle of Quality Audit, add a note on preparations required for FDA Inspection of manufacturing site. **[10]**

Q2) Solve any Three **[15]**

a) Discuss the regulatory guidelines related to equipment identification and equipment log.

b) Elaborate various aspects of material management.

c) Explain the cGMP requirements with respect to labels and printed materials.

d) Explain the GMP guidelines related to recalled and returned products.

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

a) Batch production records

b) IPQC

c) HVAC system

d) Standard Operating Procedure

Q4) Discuss cGMP requirements regarding building, premises, sanitation and hygiene for pharmaceutical products. **[10]**

OR

Explain the hazard and risk analysis in pharmaceutical products.