Total No. of Questions : 6]

SEAT No. :

P3188

[Total No. of Pages : 3

[5245]- 807

Final Year B. Pharmacy (Semester - VIII)

QUALITY ASSURANCE TECHNIQUES

(2013 Pattern)

Time : 3 Hours] *[Max. Marks :70*

Instructions to the candidates:

1) ***All question are compulsory.***
2) ***Answers to the two sections should be written in separate answer books.***
3) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Discuss the concept of QA and QC. Write the difference between QA and QC. **[10]**

OR

Explain prospective, concurrent, retrospective and revalidation.

Q2) Attempt any five of the following : **[15]**

a) Write significance of QBD.

b) Explain DQ.

c) Discuss sources of variation.

d) Write the advantages of VMP.

e) Discuss the importance of statistical quality control.

f) Explain stages of validation.

g) Discuss guidelines for cleaning method validation.

P.T.O

Q3) Write short notes on any two of the following : **[10]**

a) Validation of tray dryers

b) Quality control of finished products.

c) Quality Audits

d) PQ

SECTION - II

Q4) What is change control? Explain and design documents for change control.**[10]**

OR

Elaborate on master production and control records.

Q5) Attempt any five of the following. **[15]**

a) Explain requirement of qualification and experience of personnel in cGMP.

b) Explain Design, size and location for equipment.

c) Explain accelerated testing in stability testing of new drug.

d) Discuss about Principal area of manufacturing plant.

e) Elaborate on Handling of rejected material.

f) Explain Expiration dating.

g) Explain Sewage disposal in manufacturing plant.

Q6) Write short notes on any two of the following : **[10]**

a) Measure for controlling contamination in clean room

b) GMP issues for personnel

c) Management of rejected and recovered material in pharmaceutical processing

d) Reference standards