Total No. of Questions : 6]

SEAT No. :

P2016

[Total No. of Pages : 2

[5145]- 807
Final Year B.Pharmacy
487: QUALITY ASSURANCE TECHNIQUES
(2013 Pattern) (Semester - VIII)

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

Instructions to the candidates:

1) ***All questions 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) What is quality control? Discuss the major components of quality control. **[10]**

OR

Discuss in detail validation master plan (VMP).

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

a) Explain Installation Qualification.

b) Write importance of QA.

c) Give the importance of QBD.

d) Write quality control of raw materials.

e) Explain validation of stream sterilization.

f) Discuss statistical quality control.

g) Explain Prospective validation.

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

a) Types and stages of validation.

b) Quality Audits.

c) URS.

d) Cleaning validation of equipment.

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SECTION - II

Q4) Discuss general requirements regarding equipment's in pharmaceutical manufacturing unit. **[10]**

OR

Explain Quality management system.

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

a) Write the contents and importance of equipment log.

b) Write the SOP for personal hygiene in pharmaceutical manufacturing plant.

c) Enlist the requirement of qualification and experience of personnel in cGMP.

d) Explain design, size and location for equipment.

e) Explain plumbing and drainage system in manufacturing plant.

f) State importance of staff training.

g) Explain storage conditions in stability testing of new drug.

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

a) Harmonization of GMP

b) Batch production and control records

c) Site master file

d) Functions of QA department in Pharmaceutical organization