[Total No. of Questions - 10] [Total No. of Printed Pages - 2]
(2124)

1758

M. Pharmacy 1st Semester Examination

Practical Analysis & Quality Assurance

MP-312

Time : 3 Hours **Max. Marks : 90**

The candidates shall limit their answers precisely within the answer-book (40 pages) issued to them and no supplementary/continuation sheet will be issued.

SECTION - A

Attempt any TWO questions, each question carry equal marks.

1. What is GMP? Describe the basic concepts of Good manufacturing Practice in detail.
2. Explain in details of standard operating procedure for compression, sterilization and constant distillation with suitable examples.
3. Describe the following terms with significance in the pharmaceutical industries - standard test procedure and protocols, retention, samples and sampling plans. (2×15=30)

SECTION - B

Attempt any FIVE questions, each question carry equal marks.

4. Describe personal validation and its importance in the Pharmaceutical industry.
5. Write an exhaustive note on routine controls on instruments.
6. Explain regulatory drug analysis with applications.

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7. What is validation? Give importance of validation in pharmaceutical industry.

8. Describe packaging and labeling controls in Industry.

9. Give an exhaustive note on security measures for electronic data processing. (5×8=40)

SECTION - C

10. Write short note on any five of the followings:

    (a) Reconciliation of labels

    (b) IPQC of compression

    (c) Regulatory drug analysis

    (d) Describe cleaning validation

    (e) Explain Batch formula record

    (f) Store selection of vendors

    (g) What is Line clearance in packaging? (5×4=20)