

[Total No. of Questions - 15] [Total No. of Print Pages - 2]
(2126)

16455(D)

M. Pharmacy 1st Semester Examination

Quality Assurance

MP-312

Time : 3 Hours

Max. Marks : 60

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

Attempt any one question.

1. Discuss about master formula and Batch formula record; give its importance and contents in detail. (18)
2. Write about good manufacturing practice and quality control as applied to the pharmaceutical industry. (18)

Attempt any three questions.

3. What do you understand by responsibility and laboratory practices, write about quality control laboratory. (7)
4. Discuss in detail about in process quality control of sterile dosage form. (7)
5. Write about standard operating procedure and its importance. (7)
6. Write a detailed note on quality control documentation. (7)

Write short notes on any seven of the following.

7. Regulatory drug analysis. (3)
8. Validation of water system. (3)
9. Audits of quality control facilities. (3)

10. Analytical and bio-analytical method validation. (3)
11. Sampling plans. (3)
12. Personnel validation. (3)
13. Raw materials. (3)
14. Manufacturing documents. (3)
15. Reconciliation of labels and other packaging materials. (3)