

[Total No. of Questions - 15] [Total No. of Printed Pages - 2]
(2125)

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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. Write in detail about in process quality control on various dosage forms of sterile and non-sterile. (18)
2. Discuss in detail about regulatory aspects of pharmaceutical and bulk drug manufacture. (18)

Attempt any three questions.

3. What is a batch formula record. Give its importance and contents in detail. (7)
4. What do you understand by standard operating procedure (SOP) and its significance. For how many types of operation, standard operating procedure can be developed. (7)
5. What do you understand by concepts of quality assurance and its significance? (7)
6. Write about good manufacturing practice and quality control as applied to the pharmaceutical industry. (7)

Attempt any seven questions.

7. Write short note on procedure for vendor selection. (3)

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8. Write short note on controls on raw material. (3)
9. Discuss on purchase specification. (3)
10. Write short note on packaging and labeling controls. (3)
11. What do you understand by line clearance? (3)
12. Discuss on quality control documentation. (3)
13. Write short note on non-clinical testing. (3)
14. Discuss on process validation. (3)
15. Write short note on aseptic validation. (3)