

[Total No. of Questions - 15] [Total No. Printed Pages - 2]
(2066)

16436(J)

M. Pharmacy 2nd Semester Examination

Quality Management

MP-321

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.

Note : Attempt seven questions of section A, three questions of section B and one question of section C.

SECTION - A

1. What are the three key functions of quality management?
2. What is master formula record?
3. What is document?
4. Write a note on batch manufacturing document.
5. Name various methods of sterilization.
6. Comment on sanitation of manufacturing premises.
7. Discuss sanitation in aseptic area.
8. What is quality manual?
9. Discuss the ISO certification. (5×7=35)

SECTION - B

10. Write a note on Scrap disposal procedure.
11. Explain the concept of quality culture and importance of staff training in maintaining it.

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12. Define key personnel and explain the responsibilities of key personnel in pharmaceutical industry.

13. Give the layout of manufacturing premises. (10×3=30)

SECTION - C

14. Discuss different factors affecting GMP.
15. What are the procedures required for evaluation of complaints and recall of distributed finished products? (25×1=25)