[Total No. of Questions - 15] [Total No. of Printed Pages - 2]
(2063)

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B. Pharmacy 2nd Semester Examination

Pharmaceutical Analysis and Quality Management

MP-321

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.

SECTION - A

Attempt any seven out of the following: Each question carry equal marks. **(3×7=21)**

1. What is master production and control record? What details are included in it?
2. Discuss good ware housing practices for pharmaceutical and biological products.
3. Define biological indicator. What are the general requirements for the control of contamination of pharmaceutical products?
4. What are the different measures to maintain sterile area?
5. Discuss about the maintenance of warehouse for raw material.
6. Give the layout of manufacturing premises for oral liquids.
7. How does material management facilitates the quality control of products.

8. Write a note on the batch release documents.

9. What should be the qualification of personnel working in quality control as per CGMP?

SECTION - B

Attempt any three of the following questions: Each question carry equal marks. **(7×3=21)**

1. Discuss about the good manufacturing practices for API (Active Pharmaceutical Ingredients) with reference to production and in-process quality controls.

2. What are the concerns for cleaning and sterilization of equipments used in pharmaceutical industries?

3. Give a detail account of waste and scrap disposal procedures and records related to them.

4. What are the criterion for the selection and purchase of equipment for production of pharmaceuticals?

SECTION - C

Attempt any one of the following question. Each question carry equal marks. **(18×1=18)**

1. What is the purpose of a pharmaceutical audit? What are the areas that needs corrective action according to pharmaceutical auditing plan?

2. What are the current good manufacturing practices meant for? Discuss the role of CGMP in quality control of pharmaceutical products.