

**[Total No. of Questions - 15] [Total No. of Printed Pages - 2]
(2064)**

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**M. Pharmacy 2nd Semester Examination
Pharmaceutical Analysis and 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.

SECTION - A

Attempt any seven out of the following questions. Each question carry equal marks.

1. What is Batch Production Record? What is included in a Batch Production Record?
2. Discuss material management for pharmaceuticals and biological products.
3. Define aseptic processing area. What are the general requirements for maintenance of sterile area?
4. What are the different responsibilities of personnel according to CGMP specifications?
5. Discuss sanitation and environmental control of premises for pharmaceutical production.
6. Write a note on pharmaceutical finished product release.
7. What are the CGMP guidelines for handling of returned goods?
8. Give a brief account of maintenance of warehouse of finished product.

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9. Give the layout of manufacturing premises for tablets.
(5×7=35)

SECTION - B

Attempt any three questions. Each question carry equal marks.

10. Discuss about the GMP for API (Active pharmaceutical Ingredients) with reference to building and facilities.
11. What are the concerns for storage conditions and stock control of pharmaceutical products?
12. Outline the procedure for complaints and recall of pharmaceutical product.
13. Give a detail account of good distribution practices of pharmaceutical products according to WHO. (10×3=30)

SECTION - C

Attempt any one of the following questions. Each question carry equal marks.

14. More than just a regulatory requirement, an APR (Annual product review) helps the manufacturer to understand processes and make further improvement." Justify the above statement by discussing the structure of APR.
15. Discuss in detail about good laboratory practices in the production of pharmaceutical products. (25×1=25)