**[Total No. of Questions - 15] [Total No. of Printed Pages - 2]**
**(2123)**

**1582**

**M. Pharmacy 1st Semester Examination**

**Pharmaceutical Analysis & Quality Assurance**

**MP-312**

**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 any *one* question from Section A, *three* questions from Section B and *seven* questions from Section C.

**SECTION - A (Attempt any *one*)**

1. Differentiate between quality control and quality assurance. What considerations has to be taken under good manufacturing practices to regulate the quality of pharmaceutical products?

2. Comprehensively discuss regulatory aspects of pharmaceuticals and bulk drug manufacturing. **(25×1=25)**

**SECTION - B (Attempt any *three*)**

3. What are different methods of selection and control of raw materials?

4. Discuss standard operating procedures for the operations such as compression and sterilization.

5. Write a detailed note on manufacturing documents, master formula and batch formula records.

6. Discuss various validation and security measures for electronic data processing. **(10×3=30)**

**SECTION - C (Attempt any *seven*)**

7. What is procedure of stores selection of vendors for the purchasing of raw materials?

8. Write a short note on regulatory drug analysis.

9. Give the details of process validation.

10. Write a brief note on sampling plans.

11. Explain the reconsilation of labels.

12. Discuss the standard operating procedure for cleaning.

13. Explain validation of water systems.

14. Describe routine control on instruments.

15. Discuss aseptic validation. **(5×7=35)**