[Total No. of Questions - 5] [Total No. of Printed Pages - 2]
(2066)

16399(J)

B. Pharmacy 8th Semester Examination

Quality Control and Quality Assurance (NS)

BP-483

Time : 3 Hours **Max. Marks : 70**

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 two questions from Section-A, any eight questions from Section-B and Section-C is compulsory.

SECTION - A

1. What do you understand by good manufacturing practice? Discuss the requirements of GLP and ISO 9000 series.

2. Discuss the retrospecific validation involved in the production of tablet and capsules. Explain the validation of analytical instrument.

3. Elaborate the in-proccss quality control of non-sterile dosage form. Give SOP for drying of these dosage forms. (2×10=20)

SECTION - B

4. Explain the following:

   (i) Batch formula record.

   (ii) Quality audits and review.

   (iii) Marketing application for Indian market.

   (iv) Federal prospective on bioavailability.

   (v) Packaging material of liquid dosage form.

   (vi) SOP for filling operation.

   (vii) Requirements of GMP.

   (viii) Purchase specification in raw material control.

   (ix) Documentation of solid dosage form.

   (x) Process design. (8×5=40)

SECTION - C

5. Briefly explain:

   (i) Concurrent validation.

   (ii) cGMP.

   (iii) Quality control.

   (iv) Labeling of liquid dosage form.

   (v) Bioequivalence. (5×2=10)