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DEC-23 0089

BP-606 T (Quality Assurance)

B.Pharm-6th (PCI)

Time : 3 Hours **Max. Marks : 75**

Note: Section-I is Compulsory, attempt all questions in this section. Attempt any Two questions from Section II and Seven questions from Section III.

SECTION-I (10x2=20)

Short Answer (Compulsory)

1. Answer the following.

   a. Define calibration.

   b. Name any two parameters for qualification of UV-Vis spectrophotometer.

   c. Enlist the significance of Batch formula record.

   d. Define quality audit.

   e. Enlist the objectives of ICH.

   f. Differentiate between primary and secondary packaging material,

   g. Define NABL accrediation.

   h. Write the importance of SOP in manufacturing.

   i. Define TQM.

   j. What is contamination and cross-contamination?

SECTION-II (2x10=20)

Long Answer (Any Two)

2. (i) Define validation and explain the importance of validation. (4)

   (ii) Explain different types of validation. Write a note on validation master plan. (6)

3. Discuss briefly cGMP guidelines for construction, maintenance and sanitation of Pharmaceutical unit. (10)

4. Write a detailed account on stability testing of dosage form as per the ICH guidelines. (10)

SECTION-III (7x5=35)

Short Note Answer (Any Seven)

5. How is the cross contamination prevented in dispensing and production area? (5)

6. Explain the steps involved in ISO 9000 registration. (5)

7. Write a note on quality control and quality assurance as per GMP. (5)

8. Explain various quality control tests for containers. (5)

9. Discuss handling of return goods. (5)

10 What is the reason for disqualification of testing facilities? (5)

11 Write briefly about master Formula Record. (5)

12. What are complaints and how they are evaluated? (5)

13. Describe the maintenance of sterile area facilities. (5)