[Total No. of Questions - 13] [Total No. of Printed Pages - 2]

DEC-23-0091

**BP-702 T (Industrial Pharmacy-II)**

**B.Pharm-7th (PCI)**

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

**Note:** The question paper contains three sections, Sections A, B and C. In Section A, student has to attempt all questions. From Section B student has to attempt any two questions and from Section C attempt any seven questions.

## SECTION- A

### Short Answer (Compulsory)

1. Answer the following:
   - i. Give a detailed account of regulatory requirements for drug approval.
   - ii. What do you mean by quality risk management?
   - iii. Write an exhaustive note on technology transfer agencies in India.
   - iv. Discuss pilot plant scale-up considerations for solid.
   - v. Write an exhaustive note on quality management systems.
   - vi. What are the different regulatory authorities?
   - vii. Discuss the role of the regulatory affairs department and the responsibility of regulatory affairs professionals.
   - viii. Discuss the concept of Quality, Total Quality Management, and Quality by Design (QbD).
   - ix. Write short notes on the Management of clinical studies.
   - x. Mention the significance of NABL. (10×2=20)



## SECTION-B

### Long Answer (Any Two)

2. Describe the procedure for pilot plant scale-up for semi-solid.
3. Elaborate steps for technology transfer from R&D to production.
4. Explain pharmacology, toxicology, and drug metabolism in non-clinical drug development. (2×10=20)

## SECTION-C

### Short Note Answer (Any Seven)

5. Define Pilot plant and give its objective.
6. What is Qualification? Explain DQ, IQ, and PQa
7. Define drug regulatory Affairs.
8. Write the advantage & disadvantages of TQMa
9. How do you implement QBD in the industry?
10. What are the elements of QBD?
11. Write down the different phases of clinical trials.
12. Write down the name of the Port/Airport Offices of CDSCO.
13. Give the stage of the drug approval Process. (7×5=35)