Total No. of Questions : 8] *[Total No. of Printed Pages : 2*

Roll No .....

BP-702T/PY-702-CBGS

B.Pharmacy VII Semester (PCI Scheme)/ (Non-PCI Scheme)

Examination, June 2020

Choice Based Grading System (CBGS)

Industrial Pharmacy - II

Time : Three Hours

Maximum Marks : 75

Note: i) Attempt any five questions.
ii) All questions carry equal marks.

1. What is pilot plant scale up? Discuss the significance and requirements for scale up of pharmaceutical product from R and D to plant.

2. What do you mean by the term "Technology Transfer"? Discuss in detail about WHO guidelines for technology transfer.

3. Define the term "Regulatory Affairs". Discuss about role of regulatory affairs department and responsibility of regulatory affairs professionals.

4. Discuss the concept of quality, total quality management and Quality by Design (QbD).

5. Give a detailed account on regulatory requirements and approval procedures for new drug.

6. Discuss general considerations of Investigational New Drug (IND) Application. Explain the role of biostatistics in pharmaceutical product development.

7. Discuss in detail about ISO 9000 and ISO 14000 series of quality systems standards.

8. Write short notes on any three of the following:
   a) Technology transfer agencies in India
   b) SUPAC guidelines
   c) Six Sigma concept
   d) Management of clinical studies

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