...macy VII Semester (PCI Scheme)/ (Non-PCI Scheme)

Examination, November 2019

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. Give a detail account on regulatory requirements for drug approval.

2. What do you mean by quality risk management? Write an exhaustive note on technology transfer agencies in India.

3. Discuss pilot plant scale up considerations for solids and semi-solids.

4. Write an exhaustive note on quality management systems.

5. What are the different regulatory authorities? Discuss the role of regulatory affairs department and responsibility of regulatory affairs professionals.

6. Discuss the concept of Quality, Total Quality Management and Quality by Design (QbD).

7. Discuss general considerations of Investigational New Drug (IND) Application and Clinical Research Protocols.

8. Write short notes on any two of the following :
   i) SUPAC guidelines
   ii) Six Sigma concept
   iii) Management of clinical studies.

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