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

Roll No .....

PY-702 (CBGS)

B.Pharmacy VII Semester (Non-PCI Scheme)

Examination, November 2018

Choice Based Grading System (CBGS)

Industrial Pharmacy-II

Time : Three Hours

 Maximum Marks : 75

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

ii) Subparts of the question should be attempted in continuation.

1. a) Discuss Pilot plant scale-up considerations for solid dosage form.
   b) What is full form of SUPAC guideline? Discuss its area application and significance.

2. Discuss salient features of WHO guidelines for technology transfer and explain general layout of technology transfer protocol.

3. a) Explain stages of transfer of product from R and D to commercial production.
   b) Explain problems associated with commercialization of a Pharmaceutical product.

4. a) What is Total Quality Management? Discuss.
   b) Write a short note on GLP

5. a) Explain in brief the concept of Quality by design.
   b) Discuss documentation procedure for certificate of Pharmaceutical product.

6. Describe in detail general consideration for Investigational new drug application. Write a short note on: Investigator's Brochure.

7. Which are the different Pharmaceutical regulatory bodies in India? Discuss their role in regulation of Pharmaceuticals.

8. Write short notes on (Any two):
   i) Technology transfer documentation
   ii) ISO 9000 series
   iii) Regulatory requirement for Bioequivalence studies.

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