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Roll No

BP-606 T (CBGS)

B.Pharmacy, VI Semester (PCI Scheme)

Examination, May 2019

Choice Based Grading System (CBGS)

Quality Assurance

Time : Three Hours

Maximum Marks : 75

Note: i) Attempt any five questions.

ii) All questions carry equal marks.

1. What is the concept of TQM, describe in details various elements required for management of quality in pharmaceutical industry.
2. Compare calibration, qualification and validation. How do you prepare validation master plan? Describe qualification of UV-visible spectrophotometer.
3. Explain the following:
 - a) Quality Audit
 - b) Calibration of pH meter
4. Discuss the concept of Quality by design. What are various elements and tools required for the same?
5. How do you control sterile areas? What are various measures required for control of contamination in various utilities?

6. What is Good Manufacturing Practice? Compare the concept of QC and QA as per GMP.
7. What are the general provisions of good laboratory practices? How do you conduct a nonclinical laboratory study?
8. Write short notes on any two of the following:
 - a) Master formula record
 - b) Analytical method validation
 - c) ISO9000 and ISO14000

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