PY-606 (CBGS)

B.Pharmacy, VI Semester (Non-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 TOM, 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