Roll No…….. **Total No. of Printed Pages: [01]**

Total No. of Questions: [13]

B. Pharmacy (Semester-6th)

QUALITY ASSURANCE

Subject Code: BP-606T

Paper ID: [17170134]

Time: 03 Hours **Maximum Marks: 75**

Instruction for candidates:

1. Section A is compulsory. It consists of 10 parts of two marks each.
2. Section B consist of 9 questions of 5 marks each. The student has to attempt any 7 questions out of it.
3. Section C consist of 3 questions of 10 marks each. The student has to attempt any 2 questions.

Section – A **(2 marks each)**

Q1. Attempt the following:

a. Define the concept of quality control?
b. Classify types of validation?
c. Define the terms- Quality Audit and Quality Review?
d. What do you mean by product recall?
e. Differentiate between batch formula record and master formula record?
f. Define the terms-quality assurance and cGMP?
g. Write a short note on hydrolytic resistance test for glass containers?
h. Enlist various methods for the control of contamination?
i. Define good warehousing practices?
j. What do you mean by materials management?

Section – B **(5 marks each)**

Q2. Define quality by design (QbD)? Discuss its elements and tools?
Q3. Describe in brief about the purchase specifications and maintenance of stores for raw materials?
Q4. Write a brief account on the elements and philosophies of total quality management?
Q5. Write various steps for registration of ISO 9000 & ISO14000?
Q6. Describe the principle of NABL accreditations?
Q7. Write a brief note on the general principles of analytical method validation?
Q8. Enumerate the general provisions of good laboratory practices?
Q9. Write a protocol for the conduct of a nonclinical laboratory study?
Q10. Write the qualification of UV-Visible spectrophotometer?

Section – C **(10 marks each)**

Q11. Describe a detailed account on the quality control tests for containers, rubber closures and secondary packing materials?
Q12. Give an elaborated account on ICH stability testing guidelines?
Q13. Discuss in detail about the design, construction and plant layout of pharmaceutical industry?