Code No: 6404AN

R17

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy II Semester Examinations, June/July - 2018

QUALITY CONTROL AND QUALITY ASSURANCE

(Pharmaceutical Analysis and Quality Assurance)

Time: 3hours Max.Marks:75

Note: This question paper contains two parts A and B.
Part A is compulsory which carries 25 marks. Answer all questions in Part A. Part B consists of 5 Units. Answer any one full question from each unit. Each question carries 10 marks and may have a, b, c as sub questions.

PART - A

5 × 5 Marks = 25

1.a) What are organic impurities? List their sources. [5]
b) Explain the levels of Quality Assurance programme in brief. [5]
c) List the responsibilities of QC personnel in pharmaceutical manufacturing plant. [5]
d) Classify the packing materials used in pharmaceutical industries. [5]
e) Write the steps in pharmaceutical manufacturing documentation. [5]

PART - B

5 ×10 Marks = 50

2. What is degradation product? Explain the thresholds for degradation products in new drug products. [10]

OR

3. Write and explain the decision tree for identification and qualification degradation products. [10]

4. Explain the six concepts of TQM in detail. [10]

OR

5. Explain the garments and sanitation in large volume parenterals. [10]

6. Explain the concept of clean in place and sterilize in place in detail. [10]

OR

7. Write the location, design, plant layout, and construction of a liquid oral pharmaceutical manufacturing facility. [10]

8. Write in detail about control on instruments, reagents in quality control laboratory along with control on animal house. [10]

OR

9. Explain in detail about the labeling operation and issuance in packaging as per US FDA. [10]

10. Write an SOP for coating and manual tablet punching machine. [10]

OR

11. Write the significance of in-process quality control tests. Explain in-process quality control tests for sterile dosage form. [10]

---ooOoo---