

B. Pharmacy Third Year, Second Semester Examination, 2025

SUBJECT: QUALITY ASSURANCE

Time: 3hours

Full Marks: 75

Answer any **five (05)** questions taking at least **one (01)** question from each group

Group - A

Q1. Elaborate good laboratory practices principles. 15

Q2. Explain the various techniques in inventory management. What are the various types of equipment maintenance? Give a schematic representation for purchase of raw materials 15

Group – B

Q3. What do you mean by Critical Material Attributes (CMA) and Critical Process Parameters (CPP)? Describe the CMAs and CPPs of any 2 pharmaceutical unit operations. (5+5+5)

Q4. (a) A pharmaceutical company produces tablet dosage form. In this regard, discuss the role of the quality control chemist. What would be the role of the quality assurance personnel in manufacturing a pharmaceutically elegant tablet dosage form? (3+6)

(b) Write short notes on ICH and NABL. (3+3)

Group –C

Q5. 1. What is complain? Classify complain? Write the steps to handle a complain? 2+3+10=15

Q6 i. Classify recall and explain them. ii. Write the stages of product recall. 7+8=15

Q7. i. Classify the types of waste material. ii. Write in details about the disposal of waste material. 7+8=15
