

**B. PHARM. 3<sup>rd</sup> YEAR 2<sup>nd</sup> SEMESTER EXAMINATION, 2024**

**SUBJECT: QUALITY ASSURANCE**

Time : 3hours

Full Marks : 75

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

**Group - A**

1. Enlist GLP principles and elaborate any two. What GLP must contain? 15
2. Elaborate maintenance of equipment. What do you understand by purchase specifications of equipment? Elaborate the steps in purchasing raw materials in an organization. 15
3. Explain quality control test for closures 15

**Group - B**

4. Write the steps to handle a complain? Classify recall and explain them. Write the stages of product recall. 10+2+3=15
5. Classify the types of waste material. Write in details about the disposal of waste material. 5+10=15
6. (i) Write about the major phases of validation.  
(ii) Write a short note on
  - a. VMP
  - b. SOP
  - c. Process validation. 6+(3x3)=15

[ Turn over

**Group – C**

7. Define quality assurance. How the concept of quality assurance can produce a pharmaceutically elegant product? Discuss about ICH guidelines. **2+7+6=15**
8. Discuss the importance of calibration of pharmaceutical instruments. Write in detail about calibrating a UV-visible spectrophotometer? Write notes on NABL. **3+9+3=15**