

**B. PHARM**  
**(SEM VI) THEORY EXAMINATION 2022-23**  
**QUALITY ASSURANCE**

*Time: 3 Hours**Total Marks: 75***Note:** Attempt all Sections. If require any missing data; then choose suitably.**SECTION A****1. Attempt all questions in brief. 10 x 2 = 20**

- (a) Name the participants of ICH.
- (b) Differentiate QA and QC.
- (c) Name the Ancillary areas.
- (d) What is HVAC?
- (e) What is Cobb's test?
- (f) What refer to the subpart K in GLP?
- (g) Define Packaging
- (h) Outline the role of recalling.
- (i) Give importance and scope of validation.
- (j) Discuss general principles of qualification.

**SECTION B****2. Attempt any two parts of the following: 2 x 10 = 20**

- (a) Explain ISO14000: overview, benefits, elements and steps of registration
- (b) Discuss Design, construction and plant layout along with maintenance of organization premises in detail.
- (c) Define calibration. Elaborate general principles of calibration, qualification and validation, types of validation along with validation master plan.

**SECTION C****3. Attempt any five parts of the following: 7 x 5 = 35**

- (a) Describe in detail ICH Guidelines: purpose, process of harmonization, overview of QSEM and Q-series Guidelines.
- (b) Write short note Definition, elements, philosophies of Total Quality Management (TQM).
- (c) Write short note on:
  - (i) Quality control tests for Plastic Containers
  - (ii) Quality control tests for Metal Containers
- (d) Discuss purchase specifications and maintenance of stores for raw materials.
- (e) Discuss about Protocol for conduct of Non-Clinical Laboratory study.
- (f) Explain in detail about Master Formula Record and SOP.
- (g) Elaborate method of Qualification of UV-Visible spectrophotometer and General principles of Analytical method Validation