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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 andGeneral principles of Analytical method Validation