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

Time: 3 Hours

1.

Total Marks: 75

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Note: Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

 $10 \ge 2 = 20$

(a) Name the participants of ICH.

Attempt all questions in brief.

- (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.
- Discuss general principles of qualification. (j)

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SECTION B

Attempt any two parts of the following: 2.

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

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SECTION (

3. Attempt any *five* parts of the following:

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

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$7 \ge 5 = 35$

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