

Roll No:

--	--	--	--	--	--	--	--	--	--

The Assam Royal Global University, Guwahati

Royal School of Pharmacy

B. Pharmacy VI Semester

Semester End Examination, June 2023

Course Title : Quality Assurance

Course Code : PHR232C606

Time: 3 Hours

Maximum Marks: 75

Note: Attempt all questions as per instructions given.

The figures in the right-hand margin indicate marks.

Section – A

1. Attempt **all** questions. (Maximum word limit 50) 2.5 x 8
- What is NABL accreditation?
 - What is QbD?
 - What are the personal responsibilities in a quality control unit?
 - What is purchase specification?
 - Write down the importance of GLP.
 - What is primary and secondary packing material?
 - Write down the difference between calibration and validation.
 - Define IQ and DQ.

Section – B

2. Attempt **any one** of the following: 13 x 1
- Define ICH guideline? Write in brief about QSEM.
 - Discuss in detail about the elements of TQM.
3. Attempt **any two** of the following: 7 x 2
- Write a short note on importance of raw material in an organization.
 - Describe the criteria for selection of equipment in a pharmaceutical organization.
 - Write a detail note on maintenance of sterile area in a premises.
4. Attempt **any two** of the following: 7 x 2
- Discuss the various quality control test for containers.
 - Write a short note on good laboratory practices.
 - What are the protocol for conducting of a non-clinical laboratory study?
5. Attempt **any two** of the following: 7 x 2
- What is calibration and validation? Write a short note on method validation.
 - Write the procedure for qualification of pH meter.
 - What do you mean by complaints? Write a detail note on evaluation of complaints.