Title: IQ/OQ/PQ Protocol for <System Name>		
Document No.:	<Document No.>	**Page:**1 of 8

<IQ/OQ/PQ/IOQ/OPQ/IOPQ> Protocol for <System Name>

PRE-APPROVAL PAGE

Prepared By:

Name	Designation	Department	Signature	Date

Reviewed By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date

TABLE OF CONTENTS

REVISION HISTORY

Revision No.	Effective Date	Reason for Revision
		Initial Document

[Appendix 2j-Template of IQ/ OQ/ PQ/ IOQ/ OPQ/ IOPQ Protocol]

1.0 INTRODUCTION:

2.0 OBJECTIVE:

3.0 SCOPE:

4.0 RESPONSIBILITIES:

5.0 REFERENCES:

6.0 QUALIFICATION TEST PLAN:

6.1. Qualification Procedure

- Any supporting documentation required during testing should be included as an attachment to the document with appropriate attachment number. All the attachment shall be signed.
- All entries must be recorded legibly in indelible blue ink. Wherever date entry is required including signatures, date shall be written in DD Month' YY (e.g. 01 Jan'22).
- Wherever required screen shots or photographs of Software may be taken and print of the photograph may be presented as evidence of compliance or Discrepancy from the acceptance criteria.
- All test instruments utilized in the execution of this protocol must include calibration certification.
- The "Reviewed by" signature line will be signed by an independent reviewer who has read and agrees with the execution and conclusions.
- All recorded data must be completed using blue ballpoint pen only and must be legible
- Any individual involved in the execution or review of this document must complete the signature page. The individual should also be trained on the protocol and all related SOPs. If the individual is not the employee of SQUARE he /she should also be trained on all related SOPs such as documentation, qualification and general GMPs (all training records must be filed with the training department)
- Any blank spaces must be crossed out with a single line
- When completing information on the various checkout sheets, write N/A if not applicable or N/AV if not available then sign and date next to it
- If a mistake (which is self- evident) is made, place a single line through the item, write in the correct information and initial and date the entry. Include an explanation of the change in the comment section as needed
- All documentation must comply with SQUARE for good documentation practices
- All printouts and other supporting data included must be cross-referenced to the specific test in this protocol, signed and dated, then attached to this protocol as an appendix

6.2. Qualification Participants Data/Signatures Record:

Name	Designation	Signature/ Initials	Date

7.0 LIST OF TESTS:

S.No.	Test Description

VALIDATION STRATEGY:

This section contains all the tests that will be executed for the computerized system. Each test is to have an objective, Mention to execute the test, and an expected result.

Each test shall contain following sections:

- Objective
- Tools required
- Procedure
- Acceptance Criteria

7.1. Test 01

7.2. Test 02

7.3. Test 03

……..
……..

7.4. ERES/ 21 CFR Part 11 Testing

8.0 DISCREPANCY AND CORRECTIVE ACTION REPORT FORM:

If any of the tests carried out during the Installation Qualification does not meet the acceptance criteria, then discrepancy will be raised in a separate attachment/ annexure using below format for this Installation Qualification Protocol. The copy of the Discrepancy Report must be completed and provide with unique number traceable to the protocol. (E.g. IOQ/DR-XX), where XX is number e.g. 01, 02…

Protocol Number	
Discrepancy Number	

DISCREPANCY

Description of Discrepancy:	
Category:	
Reported by:	Date:

NATURE OF DISCREPANCY

Critical ❒Major ❒Non Critical❒

CORRECTIVEACTION

Describe Corrective Action taken:	
Reported by:	Date:

DISPOSITION ACTION

Acceptable? Yes ☐ No ☐	
Discussion:	
Approved by:	Date:

COMPLETION

Completed by:	Date:

- Category A (Minor): Discrepancy is accepted with deficiency
- Category B (Major): Provisional or conditional acceptance, discrepancy to be corrected either by Supplier or user
- Category C (Critical): Discrepancy to be rectified before proceeding further

9.0 DISCREPANCIES HANDLING DURING QUALIFICATION:

S.No.	Discrepancy/ Deviation Description	Discrepancy/ Deviation No.

10.0 SUMMARY OF TEST RESULTS:

This section summarizes the results of the testing and references any discrepancies that have been documented during protocol test execution. The following text should be used in this section:

S.No.	Test Name	Pass/ Fail	Discrepancy Found? Yes/ No	Verified By/ Date	Reviewed By/ Date

11.0 SUMMARY AND CONCLUSION:

This section provides summary of Annexure attached with protocol as test evidences.

12.0 LIST OF ATTACHMENTS:

This section provides summary of attachment attached with protocol as test evidences.

S.No.	Description of Attachment	TRS/ Attachment No.

13.0 ABBREVIATIONS:

This section will describe various abbreviations used in the document.

POST-APPROVAL PAGE

Prepared By:

Name	Designation	Department	Signature	Date

Reviewed By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date