# PERFORMANCE QUALIFICATION

# FOR

# COMPUTER SYSTEM

# OF

# QC (KARL FISCHER)

| | |
|---|---|
| **System Name** | **QC (KARL FISCHER)** |
| **System ID** | |
| **Location** | **Instrument Lab** |
| **Effective Date** | |

**PERFORMANCE QUALIFICATION FOR COMPUTER SYSTEM OF KARL FISCHER**

**System Name:** QC (KARL FISCHER) **System ID:**

## TABLE OF CONTENT

**PERFORMANCE QUALIFICATION FOR COMPUTER SYSTEM OF KARL FISCHER**

**System Name:** QC (KARL FISCHER) **System ID:**

## 1. PRE-APPROVALS:

The signature listed below indicates the pre-approval of this performance qualification. This approval is joint responsibility of listed functional areas.

| DOCUMENT DEVELOPMENT | SIGN / DATE |
|---|---|
| **Name** : _____<br>**Designation** : _____ | |

| DOCUMENT REVIEW AND APPROVAL (……. ) |
|---|
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**Engineering** |
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**IT** |
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**Quality Control** |

| DOCUMENT AUTHORIZATION (……. ) |
|---|
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**Quality Assurance** |

## 2. SIGNATURE OF EXECUTOR:

All the executer involved in this document have to sign within prescribed format given below.

**M/s …….**

| Name | Designation | Signature | Initial | Date |
|---|---|---|---|---|
| | | | | |
| | | | | |

**M/s …….**

| Name | Designation | Signature | Initial | Date |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

## 3. REVISION HISTORY:

| Date | Supersedes | Reason for Revision |
|---|---|---|
| | | |
| | | |

## 4. OBJECTIVE:

The objective of the system requirement specification defines the requirements of hardware software, functions and documentation for the Computer System (QC_KF) installed, and performs at M/s. …….. This document will be cross-referenced with the relevant system specification to ensure that the system specifications have been met according to M/s. …….. requirements.

## 5. SCOPE:

This document is applicable to validation of Hardware and Software of computer system installed and performs at M/s. …….. Quality control department. This system requirement specification shall define the documentation, references and acceptance criteria to establish that the validation of Hardware and Software of Computer system after modification is installed, Operated and performs in accordance with the guidelines laid down by the manufacturer of the system.

## 6. SYSTEM DESCRIPTION:

Computer system of QC_KF defines the controlling of analytical instrument connected to the system. It controlled the process of instrument connected to it by the software installed in the CS. The operator interface is carried out by CS screen. The CS is used to feed required parameters and set points in the system during operation. The system is connected to data server for printing and data backup. The system is secured by IT through password only within the system.

## 7. ROLE AND RESPONSIBILITY:

The validation team comprising of representative from each of the following departments should be responsible for overall compliance with this validation plan.

| Department | Responsibilities |
|---|---|
| **Validation Agency (……)** | ➢ To collect the necessary data for performance qualification activities.<br>➢ To prepare and execute the performance qualification in coordination with engineering, validation and quality assurance team.<br>➢ Comply with regulatory / Guidelines / Standards / validation plan requirements throughout the validation life cycle.<br>➢ To submit performance qualification for approval. |
| **Engineering (M/s. ……. )** | ➢ To provide the necessary data for performance qualification activities.<br>➢ To review the performance qualification. |
| **IT (M/s. …… )** | ➢ To provide the necessary data for performance qualification activities.<br>➢ To review the performance qualification. |
| **Quality Control (M/s. …… )** | ➢ To provide the necessary data for performance qualification activities.<br>➢ To review the performance qualification. |
| **Quality Assurance (M/s. …… )** | ➢ To approve and authorized the performance qualification. |

## 8. REFERENCES:

The publication listed below form part of this reference documents. Each publication shall have latest revision in effect on the date of this document is approved for execution.

| | |
|---|---|
| **GAMP 5** | Good Automated Manufacturing Practices, Version 5, Guideline Document for Automated Systems from International Society of Pharmaceutical Engineering |
| **21 Code of Federal Regulations (CFR), Part 210** | Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding off Drugs; General |
| **21 Code of Federal Regulations (CFR), Part 211** | Current Good Manufacturing Practice for finished Pharmaceuticals |
| **21 Code of Federal Regulations (CFR), Part 11** | 21 Code of Federal Regulations (CFR), Part 11 Electronic Records, Electronic Signatures, Final Rule Electronic Submissions; Establishment of Public Docket, Notice |
| **ICH Q9** | International Conference of Harmonization (ICH) quality risk assessment Q9 |
| **EU GMP** | Laying down the principles and guidelines of GMP in respect of medicinal products for human use. |
| **WHO** | Appendix 5, validation of computerized systems. |

## 9. DOCUMENTATION PROCEDURE:

- Qualification activities will be performed as defined in the approved document.
- All documentation will be completed during the execution of the qualification.
- Recording of information will be made in permanent ink.
- Fill out complete information in the verification table provided.
- Do not keep any space blank. Mark blank space with a single line throughout the appropriate space with mentioning NA (Not Applicable) and put initial and date.
- Correct the mistakes by drawing a single line through the incorrect data, recording the correct information and then initial sign and date the change.

## 10. QUALIFICATION COMPLETION AND APPROVAL:

- Verify that all tests required by qualification are completed and attached.
- Verify that all amendments and discrepancies are documented, approved and attached.
- If all items in the qualification for the Computer System Based system (QC_KF) have been reviewed and found to be acceptable, sign the corresponding block in the qualification completion and approval form.

## 11. ACCEPTANCE CRITERIA:

- Installation completion as per manufacturer's recommendations & cGMP requirements.
- Installation of major components as per the design specifications.
- The supply of all necessary documentation from manufacturer.
- The system is operating as intended and is under state of control.
- Performance features meet system requirements and system specifications.

## 12. PERFORMANCE VERIFICATION TEST:

### 12.1 Verification of Control Loops Test

**Objective** : To Verify the performance of Process.

**Tools Required** : Not Applicable

**Procedure** :
1. Start the equipment in normally.
2. Login with user level id.
3. Set require method/sequences for the test.
4. Start process and observe the set process method.
5. If printing facility available, attached the printout of whole integrated control loop test.

**Acceptance Criteria** : Computer system should able to control the set process method within the specified limit.

**Verification Table:**

| Description | Specified | Actual result | Discrepancy? (Y/N) |
|---|---|---|---|
| **Check all pre-requirement condition for system start and set the required method.** | All condition should be healthly and method should be set in within range. | | |
| **Login with user level id.** | Login shall be Successfully. | | |
| **Set the method/sequences.** | Machine should start and control process of method/sequences. | | |
| **Start the method/sequences.** | Observe the set process. | | |
| **Take the print report of control loop test** | Printed and set method/sequences should be same and attached the | | |

## PERFORMANCE QUALIFICATION FOR COMPUTER SYSTEM OF KARL FISCHER

**System Name:** QC (KARL FISCHER) **System ID:**

| Description | Specified | Actual result | Discrepancy? (Y/N) |
|---|---|---|---|
| | printout in attachment. | | |

**Remarks:**

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No Reference Attachment No. [ ]

**Checked by : _____** **Date: _____**

**Verified by : _____** **Date: _____**

## 13. PERFORMANCE QUALIFICATION TEST STATUS:

The performance qualification test status is as per below mentioned table.

| Test Description | Status (Pass / Fail) | Discrepancy? (Y/N) |
|---|---|---|
| **Verification of Control Loops Test** | | |

## 14. DISCREPANCIES HANDLING DURING COMPUTER QUALIFICATION:

- In case of discrepancy observed during qualification, document in the defined column in each table and document the details of the observation in the discrepancy log sheet.
- Inform to engineering IT quality control and quality assurance about discrepancy.
- Investigate the discrepancy and ensure the possible impact.
- If discrepancy does not have potential to impact on operation as well as performance of the system, close the discrepancy with proper justification.
- The engineering IT QC and QA will decide whether discrepancy is acceptable or not.
- If discrepancy is acceptable, provide conclusion and recommendation if any into respective column.

## 15. DISCREPANCY AND CORRECTIVE ACTION FORM:

| | |
|---|---|
| Protocol Reference | |
| Discrepancy Number | |

**DISCREPANCY:**

| | |
|---|---|
| Describe the Discrepancy | |
| | |
| | |
| | |
| Reported by | Date |

**CORRECTIVE ACTION:**

| | |
|---|---|
| Describe corrective action taken (Attach additional sheets if necessary) | |
| | |
| | |
| | |
| Reported by | Date |

**DISPOSITION ACTION :**

| | | | |
|---|---|---|---|
| Acceptable? | Yes | No | |
| Discussion | | | |
| | | | |
| | | | |
| | | | |
| Approved by | | | Date |

**COMPLETION:**

| | |
|---|---|
| Completed by | Date |

## 16. ABBREVIATION:

| Abbreviations | Description |
|---|---|
| GMP | Good Manufacturing Practices |
| SRS | System Requirement and Specification |
| IQ | Installation Qualification |
| OQ | Operation Qualification |
| PQ | Performance Qualification |
| QA | Quality Assurance |
| SOP | Standard Operating Procedure |
| NA | Not Applicable |
| ICH | International Conference of Harmonization |
| VAC | Alternate Current Voltage |
| VDC | Direct Current Voltage |
| WHO | World Health Organization |

**PERFORMANCE QUALIFICATION FOR COMPUTER SYSTEM OF KARL FISCHER**

**System Name:** QC (KARL FISCHER) **System ID:**

## 17. ATTACHMENT SUMMARY:

| Attachment No. | Description |
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## 18. PERFORMANCE QUALIFICATION SUMMARY & CONCLUSION:

**Compiled by:** _____ **Date:**_____

## 19. POST APPROVALS:

The signature listed below indicates the post approval of this performance qualification. This approval is joint responsibility of listed functional areas.

| DOCUMENT DEVELOPMENT | SIGN / DATE |
|---|---|
| **Name** : _____<br>**Designation** : _____ | |

| DOCUMENT REVIEW AND APPROVAL (……) |
|---|
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**Engineering** |
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**IT** |
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**Quality control** |

| DOCUMENT AUTHORIZATION (…….) |
|---|
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**Quality Assurance** |