INSTALLATION QUALIFICATION

FOR

COMPUTER SYSTEM OF

QC (KARL FISCHER)

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

INSTALLATION QUALIFICATION FOR COMPUTER SYSTEM OF KARL FISCHER

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

TABLE OF CONTENTS

INSTALLATION QUALIFICATION FOR COMPUTER SYSTEM OF KARL FISCHER

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

1. PRE-APPROVALS:

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

DOCUMENT DEVELOPMENT	SIGN / DATE
Name : _____ **Designation** : _____	

DOCUMENT REVIEW AND APPROVAL (M/S …….)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Engineering**
Sign / Date : _____ **Name** : _____ **Designation** : _____ **IT**
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Quality Control**

DOCUMENT APPROVAL (M/S …….)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **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 installation qualification is to collect the sufficient data pertaining to Computer System of QC_KF installed after modification at M/s. …….. and define the qualification requirements and acceptance criteria for the Computer System QC_KF supporting automation of the system. Successful completion of these qualification requirements will provide assurance that the Computer System of QC_KF for the M/s. …… was installed successfully.

5. SCOPE:

This document is applicable to validation for Hardware and Software system of QC_KF installed after modification at M/s. …….. This installation qualification shall define the documentation, references and acceptance criteria for validation of Hardware and Software system of QC_KF is installed 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 installation qualification activities. ➢ To prepare and execute the installation qualification in coordination with engineering, validation and quality assurance team. ➢ Comply with regulatory / Guidelines / Standards / validation plan requirements throughout the validation life cycle. ➢ To submit installation qualification for approval.
Engineering (M/s. ……)	➢ To provide the necessary data for installation qualification activities. ➢ To review the installation qualification.
IT (M/s. ……)	➢ To provide the necessary data for installation qualification activities. ➢ To review the installation qualification.
Quality Control (M/s. ……)	➢ To provide the necessary data for installation qualification activities. ➢ To review the installation qualification.
Quality Assurance (M/s. ……)	➢ To approve and authorized the installation 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.
SRS	System Requirement Specification
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 initialing and dating 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 validation to Hardware and Software system of QC_KF 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.

12. INSTALLATION VERIFICATION TEST:

12.1 Identification of System Details

Objective : This test sheet is intended to verification of equipment details.

Tools Required : Not Applicable

Procedure : 1. Record Equipment Name
2. Record Identification No.
3. Record Equipment Location

Acceptance Criteria : Data recorded from the equipment shall match with the data specified in verification table.

Verification Table:

Equipment Details	Specified As	As observed	Discrepancy? (Y/N)
Equipment Name			
Identification No.			
Location	Instrument Lab		

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.2 Verification of Master Documents

Objective : To verify the availability of related master documents.

Tools Required : Not Applicable

Procedure :
1. Verify Documents Name.
2. Verify Documents Reference.
3. Verify Documents Availability.

Acceptance Criteria : Documents should be available.

Verification Table:

Documents Name	Documents Reference	Availability (Yes/No)	Verified (Yes/No)	Discrepancy? (Y/N)
SRS				
Operational Manual	Refer attachment No. 1			
BOM	Refer attachment No. 2			

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.3 Verification of Capacity Requirement:

Objective : To verify the processing capacity of Computer System

Tools required : Not Applicable

Procedure : Physical verification of Capacity Requirement as per SRS

1. No more than 50% of the installed hard disk capacity in PC components should be consumed by installed software.
2. Historical data storage capacity should allow for online retrieval of at forever of any historical data.

Acceptance criteria : 1. Capacity Requirement of the control system shall match with SRS.

Verification Table:

S.No.	Item Name	Expected	Actual (Yes/No)	Discrepancy? (Y/N)
1	Local Electronic Storage	50 % should be consumed by installed software		
2	Historical data storage	50 % should be consumed by historical data		

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.4 Verification of Hardware Components:

Objective : To verify the installed hardware components as per the SRS.

Tools Required : Not Applicable

Procedure :
1. Verify Hardware Name.
2. Verify Hardware Make/ Assemble By
3. Verify Hardware Model No./Specification

Acceptance Criteria : Installed hardware component should match with SRS.

Verification Table:

Name	Make/ Assemble By	Model No./Specification	Qty.	Installation (Yes/No)	Discrepancy? (Y/N)
Monitor	Acer	-	01		
CPU	Acer	-	01		
UPS	Emerson Network System	20 kVA	01		
RAM	Acer	4 GB	01		
Processor	Intel	I3-6098P 3.60 GHz	01		
Printer	Canon	3300	01		
Analytical instrument	UV Spectrophotometer	80056	01		

Verification Table: Communication Port:

S.No.	Port Type	Qty.	Installation (Yes/No)	Discrepancy? (Y/N)
1	USB	3		
2	Ethernet	1		

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.5 Verification of Software Components:

Objective : To verify the installed software components as per the SRS.

Tools Required : Not Applicable

Procedure :
1. Verify Software Name.
2. Verify Software Version
3. Verify operating system .
4. Verify software backup availability.

Acceptance Criteria : Installed software component should match with SRS.

Verification Table:

A. For Software Components:

S.No.	Software Name	Version	Installation (Yes/No)	Discrepancy? (Y/N)
1	Tiamo Light	2.5		
2	Acrobat reader	18.011.20040		
3	Windows	7 64 bit SP1		

B. Operating system details:

S.No.	Window	Product key/ Liecence key	Discrepancy? (Y/N)
1	Windows 7		

C. Software Backup Availability:

S.No.	Available (Yes/ No)	Discrepancy? (Y/N)

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.6 Verification of Physical and Logical Security Control:

Objective : Verify the physical and logical security of Computer System.

Tools Required : Not Applicable

Procedure :
1. Verify physical Security.
2. Verify logical security of Application Window and Software
3. Verify User for Application access

Acceptance Criteria : Physical security should be maintained. Logical
- Window Login password Should be available.
- Application Software should have multiple numbers of user's role with user name.

A. Verification Table for Physical Security:

System	Security	Availablility (Yes/No)	Discrepancy? (Y/ N)
Computer system	PCB should be secure in control Panel.		

B. Verification Table for Logical Security Window:

Specified user	Logical security available (Yes/No)	Discrepancy? (Y/ N)
Admin		
Standard		

C. Verification Table for Logical User Application Software:

Specified user	Logical User available (Yes/No)	Discrepancy? (Y/ N)
Analyst		
Reviewer		
Admin		

INSTALLATION QUALIFICATION FOR COMPUTER SYSTEM OF KARL FISCHER

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

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.7 Verification of Test Instruments Calibration and Traceability:

Objective : To verify the test instruments traceability.

Tools Required : Not Applicable

Procedure :
1. Verify Certificate No.
2. Verify Traceability.
3. Verify Calibration Done Date.
4. Verify Calibration Due Date.

Acceptance Criteria : Test instruments should be calibrated at the execution.

Verification Table:

Certificate No.	Traceability	Calibration Done On	Calibration Due On	Verified (Yes/No)	Discrepancy? (Y/N)
	Refer attachment No. 3				
	Refer attachment No. 4				

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.8 Verification of Power Utility:

Objective : To verify the installed power utility is as per specifications.

Tools Required : Digital Multimeter

Procedure :
1. Switch ON the Power Supply.
2. Put the Multimeter in AC/DC range.
3. Record the supply voltage.

Acceptance Criteria : Measured voltage shall match with the specified voltage.

Verification Table:

Supply Voltage Measurement:

Name	Specified Voltage	Measured Voltage	Discrepancy? (Y/N)
Computer System Power Supply	230 VAC		
Analytical instrument	(220-240) VAC		

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.9 Verification of Environment Condition:

Objective : To verify the environment conditions.

Tools Required : Digital Thermo Hygrometer

Procedure :
1. Switch ON the thermo hygrometer.
2. Record maximum temperature.
3. Record maximum relative humidity.

Acceptance Criteria : Test instruments should be calibrated at the execution.

Verification Table:

Name	Temperature	Relative Humidity	Measured Results		Discrepancy? (Y/N)
Computer System Environmental Condition	NMT 25 °C	NA			
Analytical instrument	NMT 25 °C	NA			

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.10 Verification Of Communication Link Between Server To Computer System:

Objective : To Verify the communication link with server to client

Tools Required : Not Applicable

Procedure :
1. Verify and record the communication link between PC to Server
2. Verify and record the communication link between PC to Printer.

Acceptance Criteria : Communication link ping with PC to server should be executed and report should be proper.

Verification Table:

S.No.	Source	Destination	Ping Executed (Yes/No)	Discrepancy? (Y/N)
1.	Computer system	File Server		
2.	Computer system	Printer		

Remarks:

_____

_____

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

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.11 Verification of General System Installation:

Objective : To verify the general system installation.

Tools Required : Not Applicable

Procedure : 1. Check all the test given in verification table.
2. Record the result in verification table.

Acceptance Criteria : All the test result should match with expected result.

Verification Table:

Description	Expected Result (Yes/No)	Discrepancy? (Y/N)
Major components should be protected from shock.		
No visible physical damage should be available.		
Sufficient space should be available for maintenance.		
System identification nameplate should be available.		
System should be installed with all necessary instruments.		
Earthling should be connected properly.		
Power and signal cable should be separate.		
Unterminated and broken wire should not be open.		

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

12.12 Verification of Standard Operating Procedure:

Objective : To verify the availability of related standard operating procedure.

Tools Required : Not Applicable

Procedure :
1. Verify SOP Name.
2. Verify SOP No.
3. Verify SOP Availability.

Acceptance Criteria : Documents should be available.

Verification Table:

SOP Name	SOP No.	Availability (Yes/No)	Discrepancy ? (Y/N)
Standard Operating Procedure of Backup / Restoration of Analytical Instrument Data			
Standard Operating Desktop Policy for Computer Operated Analytical Instrument			
Standard Operating Procedure on Password Policy for Software in Laboratory and GMP System			

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date : _____

Verified by : _____ Date : _____

13. INSTALLATION QUALIFICATION TEST STATUS:

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

Test Description	Status (Pass / Fail)	Discrepancy? (Y/N)
Identification of System Details		
Verification of Master Documents		
Verification of Capacity Requirement		
Verification of Hardware Components		
Verification of Software Components		
Verification of Physical and Logical Security Control		
Verification of Test Instruments Calibration and Traceability		
Verification of Power Utility		
Verification of Environmental Condition		
Verification Of Communication Link Between Server To Computer System		
Verification of General System Installation		
Verification of Standard Operating Procedures		

14. DISCREPANCIES HANDLING DURING COMPUTER SYSTEM 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 User, engineering 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 User, engineering 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
IQ	Installation Qualification
OQ	Operation Qualification
QA	Quality Assurance
SOP	Standard Operating Procedure
NA	Not Applicable
ICH	International Conference of Harmonization
mA	Mili Ampere
VAC	Alternate Current Voltage
VDC	Direct Current Voltage
RH	Relative Humidity
CS	Computer System
NMT	Not More Than

INSTALLATION QUALIFICATION FOR COMPUTER SYSTEM OF KARL FISCHER

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

17. ATTACHMENT SUMMARY:

Attachment No.	Description

18. INSTALLATION QUALIFICATION SUMMARY & CONCLUSION:

Compiled by: _____ **Date:**_____

19. POST APPROVALS:

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

DOCUMENT DEVELOPMENT	SIGN / DATE
Name : _____ **Designation** : _____	

DOCUMENT REVIEW AND APPROVAL (M/S …….)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Engineering**
Sign / Date : _____ **Name** : _____ **Designation** : _____ **IT**
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Quality Control**

DOCUMENT APPROVAL (M/S …….)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Quality Assurance**