OPERATIONAL QUALIFICATION

FOR

COMPUTER SYSTEM

OF

QC DOCUMENTATION

System Name	**QC DOCUMENTATION**
System ID	
Location	**Instrument Lab**
Effective Date	

OPERATIONAL QUALIFICATION FOR COMPUTER SYSTEM

System Name: QC Documentation **System ID:**

TABLE OF CONTENT

OPERATIONAL QUALIFICATION FOR COMPUTER SYSTEM

System Name: QC Documentation **System ID:**

1. PRE APPROVALS:

The signature listed below indicates the pre-approval of this operational 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 AUTHORIZATION (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 the system requirement specification defines the requirements of hardware software, functions and documentation for the Computer System (QC_DOC) installed 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 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 in accordance with the guidelines laid down by the manufacturer of the system.

6. SYSTEM DESCRIPTION:

Computer system of QC_DOC defines to the system is use to calculating analytical data and protect with protected sheet by MS EXCEL. This system is also use to Mailing for document per pass, ERP (Enterprise resource planning) for management information system integrates areas. Control panel and other external device disable for this system to protect data and piracy and Data store 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 operational qualification activities. ➢ To prepare and execute the operational 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 operational qualification for approval.
Engineering (M/s. ……..)	➢ To provide the necessary data for operational qualification activities. ➢ To review the operational qualification.
IT (M/s. ……..)	➢ To provide the necessary data for operational qualification activities. ➢ To review the operational qualification.
Quality Control (M/s. ……)	➢ To provide the necessary data for operational qualification activities. ➢ To review the operational qualification.
Quality Assurance (M/s. ……)	➢ To approve and authorized the operational 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_DOC) 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.
- Operational features meet system requirements and system specifications.

12. OPERATIONAL VERIFICATION TEST:

12.1 Verification of Windows Security

Objective : To verify the windows security as defined.

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 shall match with expected result.

Verification Table:

Description	Specified	Actual result (Yes/No)	Discrepancy? (Y/N)
Login to PC with blank password.	Access Denied &Error message displayed.		
Login to PC with incorrect password.	Access Denied & Error message displayed.		
Login to PC with correct password.	Access granted.		

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.2 Verification of System Start-up & Shutdown:

Objective : To verify the system healthiness through start up and shutdown procedure.

Tools Required : Not Applicable

Procedure :
1. Switch ON system power supply.
2. Startup time should be minimum and during this time PC cannot generate any error message.
3. System safe shutdown with application.

Acceptance Criteria :
1. System start and shutdown should as per procedure defined in test data table.
2. Application software without any error.

Verification Table for Startup and Shut down Process:

Description	Procedure	Expected Result	Actual Result (Yes/No)	Discrepancy? (Y/N)
To Start Up The System	Turn On the Power Supply of System	System should be turn on no error message displaye on screen.		
Login To System	Click On Application Software To Run The Software	Application software run automatically without any error.		
To Shut Down the System	Exit From The Software & Click On Shut Down	Shut down the PC.		

Remarks:

_____

_____

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

Checked by : _____ Date : _____

Verified by : _____ Date: _____

12.3 Verification of System Response Failure:

Objective : To verify the system response failure as defined.

Tools Required : Not Applicable

Procedure :
1. Operate the system in run mode.
2. If any hardware of Computer system goes to fail.
3. Record the result in verification table.

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

Verification Table:

Description	Specified	Observation (Yes/No)	Discrepancy? (Y/N)
CPU Failure	CPU should be off and monitor cannot be response.		
Monitor Failure	Monitor should be off and CPU Should be On.		
UPS Failure	UPS should be off and CPU and Monitor cannot response.		
Communication Cable Failure Between CPU And Monitor	Monitor should not be response.		
Communication Failure Between CPU And Monitor	Monitor should not be response.		
Communication Failure With Local Area Network	Printing should be stop.		
Power Failure	UPS supply connected with System to safe shutdown.		

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.4 Verification of Electronic Data Security:

Objective : To verify the electronic data security as defined.

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 shall match with expected result.

Verification Table:

Description	Specified	Observation (Yes/No)	Discrepancy? (Y/N)
Electronic record storage	All the electronic should be store in a correct manner and specified location.		
Electronic data storage path accessbility	Only authorised user shall be access the elecronic storage data.		

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.5 Verification of User Prevented From Alternating Date and Time:

Objective : To verify the verification of user prevented from alternating date and time as defined.

Tools Required : Not Applicable

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

Acceptance Criteria : User cannot change or alter the date and time of system.

Verification Table:

User	Description	Observation	Discrepancy? (Y/N)
Administrator	User access/ not access date & time		
Repoter	User access/ not access date & time		

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.6 Verification of Data Back Up:

Objective : To verify the data backup as defined.

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:

S.No.	Test	Expected Result	Actual Results (Yes/No)	Discrepancy? Y/N
1.	Go to the following folder. "D:\Backup	Data size, folder name should be noted.		
2.	Copy the same folder & paste in external storage device. Note the data size, files & folders.	Folder should be copied successfully & noted the data size, folder name.		
3.	Compare the data size, files & folders of the same folder before & after data backup activity.	Data size, folder name of data should be matched.		

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.7 Verification of Excel Sheet:

Objective : To verify the Excel Sheet as defined.

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:

S.No.	Test Parameter	Expected Results	Actual Results	Discrepancy? Y/N
1.	Each Worksheet shall be Product and Test Specific	Works sheet should be Product and Test Specific		
2.	Work sheet No.	Record Work sheet No.		
3.	Path of sheet	Record Path of sheet		
4.	Validated Excel Sheet to be stored on a separated folder	Excel Sheet to be available on a separate folder		
5.	Workbook Protection: The excel workbook should be operational by the authorized personal with right password. On supplying wrong password system should display warning message of incorrect password supplied	After Login The System. The System Allows Opening Of Workbook		

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S.No.	Test Parameter	Expected Results	Actual Results	Discrepancy? Y/N
6.	Changes or Modification in the protected cells, Attempt to change formula or test in the protected cells	System disallows change in protected cells		
7.	Additional or deletion of the any row/column in the worksheet impacting on the operation of the formula	System disallows additional / deletion of any row or column		
8.	Calculations	Difference between values obtained from excel sheet and calculator should not differ.	Result By calculator:_____ Result by excel sheet:_____	

Remarks:

_____

_____

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

Checked by : _____ Date : _____

Verified by : _____ Date : _____

13. OPERATIONAL QUALIFICATION TEST STATUS:

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

Test Description	Status (Pass / Fail)	Discrepancy? (Y/N)
Verification of Windows Security		
Verification of System Start-up & Shutdown		
Verification of System Response Failure.		
Verification of Electronic Data Security		
Verification of User Prevented From Alternating Date and Time		
Verification of Data Back Up		
Verification of Excel Sheet		

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
CS	Computer System
WHO	World Health Organization
SRS	System Requirement and Specification
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

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System Name: QC Documentation **System ID:**

17. ATTACHMENT SUMMARY:

Attachment No.	Description

18. OPERATIONAL QUALIFICATION SUMMARY & CONCLUSION:

Compiled by: _____ **Date:** _____

19. POST APPROVALS:

The signature listed below indicates the post approval of this operational 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 AUTHORIZATION (M/S…….)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Quality Assurance**