OPERATIONAL QUALIFICATION

FOR

COMPUTER SYSTEM

OF

STABILITY-PC

System Name	**STABILITY-PC**
System ID	
Location	**QUALITY ASSURANCE**
Effective Date	

OPERATIONAL QUALIFICATION FOR COMPUTER SYSTEM OF STABILITY PC

System Name: Stability-PC **System ID:**

TABLE OF CONTENT

OPERATIONAL QUALIFICATION FOR COMPUTER SYSTEM OF STABILITY PC

System Name: Stability-PC **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 Assurance**

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

OPERATIONAL QUALIFICATION FOR COMPUTER SYSTEM OF STABILITY PC

System Name: Stability-PC **System ID:**

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 (STABILITY-PC) 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 Assurance 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 STABILITY-PC defines the controlling of Stability chamber connected to the system. The CS software of stability chamber is a communication software for data management. 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 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 Assurance (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 (STABILITY-PC) 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 Field Instruments Calibration:

Objective : To verify the field instruments calibration.

Tools Required : Not Applicable

Procedure :
1. Verify Instruments Name.
2. Verify Instruments ID.
3. Verify Instruments Calibration Date.
4. Verify Instruments Calibration Due Date.

Acceptance Criteria : Fields instruments should be calibrated.

Verification Table:

Instruments Name	Instruments ID	Calibration Done On	Calibration Due On	Verified (Yes/No)	Discrepancy? (Y/N)

OPERATIONAL QUALIFICATION FOR COMPUTER SYSTEM OF STABILITY PC

System Name: Stability-PC **System ID:**

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.2 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: _____

12.3 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		

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System Name: Stability-PC **System ID:**

Remarks:

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_____

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

Checked by : _____ Date : _____

Verified by : _____ Date: _____

12.4 Verification of Password Security:

Objective	:	To verify the password 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	Verified (Yes/No)	Discrepancy? (Y/N)
Wrong User Name at Admin Level	System shall be Generate the wrong password or user name popup		
Correct User Name Entry at Admin Level	Admin login the system successfully.		

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.5 Verification of Application software Screens:

Objective : To verify the Software screens 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:

Screen No.	Specified Screen	Actual Screen as per Specified? (Yes/No)	Verified (Yes/No)	Discrepancy? (Y/N)
1.	Login screen	Yes ( ) / No ( )		
2.	Current status screen	Yes ( ) / No ( )		
3.	Status details screen	Yes ( ) / No ( )		
4.	Data log table screen	Yes ( ) / No ( )		
5.	Data log graph screen	Yes ( ) / No ( )		
6.	Chamber graph screen	Yes ( ) / No ( )		
7.	Audit trail screen	Yes ( ) / No ( )		
8.	Event alarm screen	Yes ( ) / No ( )		
9.	MKT report screen	Yes ( ) / No ( )		
10.	Chamber report screen	Yes ( ) / No ( )		
11.	Chamber configuration/settings screen	Yes ( ) / No ( )		
12.	Chamber configuration/report settings screen	Yes ( ) / No ( )		

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System Name: Stability-PC **System ID:**

Screen No.	Specified Screen	Actual Screen as per Specified? (Yes/No)	Verified (Yes/No)	Discrepancy? (Y/N)
13.	Backup and restore screen	Yes ( ) / No ( )		
14.	Reports screen	Yes ( ) / No ( )		
15.	Help screen	Yes ( ) / No ( )		

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.6 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.		

OPERATIONAL QUALIFICATION FOR COMPUTER SYSTEM OF STABILITY PC

System Name: Stability-PC **System ID:**

Remarks:

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Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.7 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.		
Access of any other file beside the primary system software	Only qualified and authorized user shall be access other file beside the primary system software.		
Electronic Record Maintain	Electronic record should maintain in a redundent hard disk / IT server / DVD with specified location.		
Print the entire content of electronic records	User should be print the entire content of electroic records.		
Electronic Data Edition and Deletion	No editions and deletion possible in the Electronic Data.		

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System Name: Stability-PC **System ID:**

Remarks:

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Meet the acceptance Criteria [ ] Yes [ ] No

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.8 Verification of Audit Trail:

Objective : To verify the audit trail 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)
Attempt to login account from authorised user	Login Successful. The same is logged in the audit trail automatically.		
Attempt to login account from unauthorised user	Login Fail. The same is logged in the audit trail automatically.		
New Account Creation and Deletion	Audit trail should record the creation of new account and deletion.		
Password Change	Change in the password shall be logged into the audit trail.		
Audit Trail Content	Audit trail should have facility to logged the data with time, user identity, reason of change and type of change.		

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.9 Verification of Report Generation:

Objective : To verify the report generation and format as defined.

Tools Required : Not Applicable

Procedure : Verify that the standard report and analytical report will generate.

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

Verification Table:

Description	Expected Result	Actual Result (Yes/No)	Discrepancy? (Y/N)
Report Edition/Deletion	Report shall not be edit/ delete by user		
Date and Time stamp on Report during generation/Print	Date and Time stamp on Report during generation/Print.		
Redable Formate	Report shall be in human readable format		

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.10 Verification of Alarms and Interlocks:

Objective : To verify the alarms and interlocks 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:

Alarm Description	Alarm Condition	Actual Result (Yes/No)	Discrepancy? (Y/N)

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.11 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: _____

12.12 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)
Analsyt	User access/ not access date & time		
Reviwer	User access/ not access date & time		
Admin	User access/ not access date & time		

Remarks:

_____

_____

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

Checked by : _____ Date: _____

Verified by : _____ Date: _____

12.13 Verification of system software as per 21 CFR part 11 Clauses:

Objective : Verify the software as per 21 CFR Part 11 clauses

Tools Required : Not Applicable

Procedure : Check and record of 21 CFR Part 11 clauses for software.

- Open the Software in normally.
- Login with higher level id and password.
- Verify all the points as per the test table clause wise & record

Acceptance Criteria : System should complies 21 CFR part 11.

Verification Table:

S.No. (As per clause)	Question	Testing procedure and requirement	Actual Result	Discrepancy? (Y/N)
11.10(a)	Is it possible to discern invalid or altered records?	Try to change the possibilities of the record alteration in Process Data file. System should not allow altering record. Try to enter Invalid character or Value in the system.		
11.10(b)	Is the system capable of producing accurate and complete copies of electronic records on paper?	Take batch printout and Verify Print out of Data Recorded. Data display and Print should be match.		
11.10(c)	Are the records readily retrievable	Verify data backup location and data retrieving		

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S.No. (As per clause)	Question	Testing procedure and requirement	Actual Result	Discrepancy? (Y/N)
	throughout their retention period?	facilities. Check data retention period. It should be documented in DATA Backup SOP.		
11.10(d)	Is the system access is authorized to individuals?	Try to access the system by entering invalid user ID and Password for All Level for operating System and Application software. Check access rights of each level. System should not allow unauthorized person.		
11.10(e)	Is there a secure, computer generated, time stamped audit trail that records the date and time of operator entries and actions that create, modify or delete electronic records?	Try to change or modify the set parameter and check for audit trail generated by the system. Audit Trail should be available for any modification		
11.10(f)	Is an electronic record's audit trail retrievable throughout the record's retention period?	Verify that audit trail is available till data retention period.		

OPERATIONAL QUALIFICATION FOR COMPUTER SYSTEM OF STABILITY PC

System Name: Stability-PC **System ID:**

S.No. (As per clause)	Question	Testing procedure and requirement	Actual Result	Discrepancy? (Y/N)
11.10(g)	If the sequence of system steps or events is important, is this enforced by the system (e.g. As would be the case in a process control system)?	Check sequence of operation of Application software as per operation procedure. System should be operates as per sequence written in SOP.		
11.10(h)	Does the system ensure that only authorized individuals can use the system, electronically sign records, access the operation, or computer system input or output device, alter a record or perform other operations?	Try to access the system by entering invalid user ID and Password for Application software. Check access rights of each level. Minimum 2 level is required in Application software System should not allow unauthorized person.		

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System Name: Stability-PC **System ID:**

S.No. (As per clause)	Question	Testing procedure and requirement	Actual Result	Discrepancy? (Y/N)
11.10(i)	If it is a requirement of the system that input data or instructions can only come from certain input devices (e.g. Terminals) does the system check the validity of the source of any data or instructions received?	Verify system input data come from calibrated sensors and Transmitters.		
11.10 (j)	Is there documented training, including on the job training for system users, developers, it support staff? Is there a written policy that makes individuals fully accountable and responsible for actions initiated under their electronic signature?	Verify the training record. Responsibility documents for the all system user and related responsible person.		
11.10(k)	System operation and maintenance documentation	Verify and review System Operation and Maintenance Document		

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System Name: Stability-PC **System ID:**

S.No. (As per clause)	Question	Testing procedure and requirement	Actual Result	Discrepancy? (Y/N)
	controlled?			
11.10(l)	Is there a formal change control procedure for system documentation that maintains a time sequenced audit trail for those changes made by the pharmaceutical organization?	Verify the sop of change control, data backup, access control and maintenance.		

Remarks:

_____

_____

Meet the acceptance Criteria [ ] Yes [ ] 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 Field Instruments Calibration		
Verification of Windows Security		
Verification of System Start-up & Shutdown		
Verification of Password Security		
Verification of Application software Screens.		
Verification of System Response Failure.		
Verification of Electronic Data Security		
Verification of Audit Trail		
Verification of Report Generation		
Verification of Alarms and Interlocks		
Verification of Data Back Up		
Verification of User Prevented From Alternating Date and Time		
Verification of system software as per 21 CFR part 11 Clauses		

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 Assurance 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
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: Stability-PC **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 Assurance**

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