OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STABILITY CHAMBER

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OPERATIONAL QUALIFICATION FOR STABILITY CHAMBER

1.0 Pre-Approval Sheet:

Prepared By (Name & Designation)	Signature	Date
Quality control		
Quality Assurance		

Checked By (Name & Designation)	Signature	Date
Quality control		
Maintenance		
Quality Assurance		

Approve By (Name & Designation)	Signature	Date
Quality Assurance		

OPERATIONAL QUALIFICATION FOR STABILITY CHAMBER

2.0 **Objective**: The objective of developing and executing this Protocol cum report is to collect sufficient data pertaining to Walk - In Stability Chamber and define the qualification requirements and acceptance criteria for Walk - In Stability Chamber. Several prerequisites must be met before the OQ is performed: completion of the IQ; verification that deficiencies have been resolved and that the protocol cum report has been updated and approved. Successful completion of these qualification requirements will provide assurance that the Walk - In Stability Chamber is operates/functions as required in the processing environment and meets operational requirements.

3.0 **Scope:** The qualification study shall be performed to the control system supporting the Walk-in Stability Chamber. The direction of the sequence of operation shall be controlled by a control system. The calibration of temperature, Stability sensors and PLC shall be verified during qualifications. Training shall be given to users on operation, trouble shooting and preventive maintenance of equipment. Any exceptional conditions encountered during the OQ will be identified, investigated, and documented (including justification, correction, and any necessary re-qualification studies).

4.0 **Responsibility:**

4.1 **Quality control:**

QC personnel shall be responsible for:

4.1.1 Review Operation Qualification Protocol cum Report.

4.1.2 To execute Operation Qualification Protocol cum Report.

4.1.3 To support the engineering personnel during execution of operation activity.

4.2 **Engineering:**

Engineering personnel shall be responsible for:

4.2.1 To review Operation Qualification Protocol cum report.

4.2.2 To check and monitor technical parameter.

4.2.3 To provide technical guidance and instructions to the personnel involved in Operation Qualification.

4.2.4 To provide required utility for operation of equipment.

4.2.5 To Prepare draft standard operating procedure.

4.3 **Quality Assurance:** Quality Assurance personnel shall be responsible for:

4.3.1 To review and approve Operation Qualification Protocol cum report.

4.3.2 To provide technical guidance during Operation Qualification.

4.3.3 To verify that the equipment operation is as user recommendation.

4.3.4 To prepare and review Operation Qualification Protocol cum report.

4.3.5 To execute Operation Qualification Protocol cum report.

4.3.6 To support the engineering personnel during execution of operation activity.

4.3.7 To Prepare draft Standard Operating Procedure.

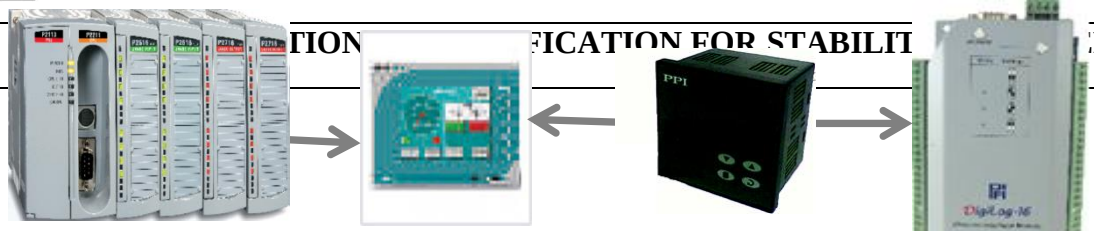
4.3.8 To verify that all related SOP's are available in draft form and are systematically prepared according to operation sequence. QA Head shall approve Operation Qualification Protocol cum report for execution.

5.0 Equipment Description:

The system is composed of the following components:

PLC monitors and controls parameters as per set values. Alarm is generated for out of range conditions and any system faults. Data are recorded at regular interval as per recording interval. Those data are then transferred to PC.

PLC HMI Data logger Scanner



Inputs/Outputs

Computer / PC

Walk – In Stabilitv Chamber

5.1 System Architecture:

5.2 Test Qualification Instruments

To execute this protocol cum report, the following will be needed by the executor:
Standard devices' (used for reference readings) calibration certificates shall be provided.

- Temperature, Stability Indicator – Minimum range 20~60ºC, 40~95%RH
- PC - Fully compatible computer with Remi DAMS Software installed.

The above test instruments should have valid calibration on the date of protocol cum report execution and validity certificate to that effect should be available

6.0 EXECUTION

6.1 General

The satisfactory operation of Walk - In Stability Chamber shall be verified by executing the qualification studies described in this protocol cum report. The successfully executed protocol cum report will indicate that the Walk - In Stability Chamber operates satisfactorily.

6.2 Identification of Executor

All executors involved in this protocol cum report execution are to sign within the prescribed format given below:

Name	Designation	Signature	Initial	Date

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6.3 TEST PROCEDURE (S):

The operation of the Remi Equipment system shall be verified using the test data sheets provided in this protocol cum report. The test data sheets will be used to document the operation of the Equipment and to verify that the functions of all the components there in confirm to the Operation specifications.

6.4 Testing of System Healthiness:

Verify the status of equipment PLC's LED's/Panel indicators & status messages on the local MMI/Display that ensures system healthiness.
Test data sheet attached in Operational Qualification **Test.**

6.5 Testing of PLC Processor:

Verify the normal operation of the PLC controller operation, by verifying the LED status indications on the PLC processor after turning on the PLC. These LED's indicate normal operation and error conditions of the PLC. Document the result of the verification in the test table.
Test data sheet attached in Operation Qualification **Test.**

6.6 Testing of PLC Input/Output:

Verify the normal operation of PLC I/Os by observing the LED's on the module or data table of PLC processor after turning ON the PLC power.
Digital inputs are tested by simulating the input signals coming from field devices. Digital outputs are checked by either simulating the output condition or by forcefully making the output signal on from the PLC.
Test data sheet attached in Operation Qualification **Test.**

6.7 Testing of Display Function Keys, Command Buttons and Displays:

Verify Display Function Keys, Displays on all local MMI/Operator Interface Screens as identified in System Manual/Operator Guides.
Test data sheet attached in Operational Qualification **Test.**

6.8 Testing of Power Failure Conditions

Loss of power testing will be conducted to ensure that when power to the control system fails, system will revert to a fail-safe state. Testing will also be designed to verify that when power is restored, the Control System return to a specified state and is able to be restarted & system retains the set parameters values.
Test data sheet attached in Operational Qualification **Test.**

6.9 Review of Relevant Sops for the Control System and Training of Equipment

Review the availability & details/contents of the system relevant SOP's and procedures. Record training given to users by trainer regarding equipment's operations and preventive maintenance.
Test data sheet attached in Operational Qualification **Test**.

6.10 Operational Qualification Discrepancy

Document any discrepancies or variations noted during the execution of the Operational Qualification. Include the resolution of these items and/or any item outstanding that will require further effort to resolve.

6.11 Qualification Completion and Approval

1. Verify that all tests required by this protocol cum report are completed, reconciled and attached to this protocol cum report.
2. Verify that all amendments and Discrepancies are documented, approved and attached to this protocol cum report.
3. If all items in the Qualification Protocol cum report for the control system for Stability Chambers have been reviewed and found to be acceptable, sign the corresponding block in the Qualification Completion and Approval form.

7.0 Pre Requisite of Operation Qualification: The following documents shall be available before staring the operation qualification:

S.No.	Document Name	Available/Not Available	Checked by (Sign/Date)	Verified by (Sign/Date)
1.	Installation Qualification Protocol cum Report			
2.	Draft SOP's			
3.	Installation, Operation and Maintenance Manuals			

8.0 OPERATIONAL QUALIFICATION TESTS:

S.No.	Test Name
1	Testing of System Healthiness
2	Testing of PLC's Processor
3	Testing of PLC's Input / Output
4	Testing of Display Function Keys, Command Buttons And Displays
5	Testing of Power Failure Conditions
6	Review of Relevant SOPs For the Control System and Training of Equipment
7	Operational Qualification Test Status
8	Operational Qualification Discrepancy
9	Summary And Conclusion

8.1 Testing Of System Healthiness:

8.1.1 Objective: To verify the normal operation of the equipment by turning ON the supply.

8.1.2 Procedure: Turn Control System power to ON Position that is to power up the PLC and equipment. Document status of the indicators located on control system front panel and equipment response.

8.1.3 Acceptance Criteria: Front panel message and control system status shall match with the expected result.

Power-Up equipment and verify following messages on startup.

Device	Expected Status	Observation	Discrepancy? (Y/N)	Tested By/Date
Mitshubishi - Nexgenie-2000+	Run Mode			
Circulation Motor	Rotating			
HMI Display	Displays Temperature and Stability current values			

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Remarks:

_____

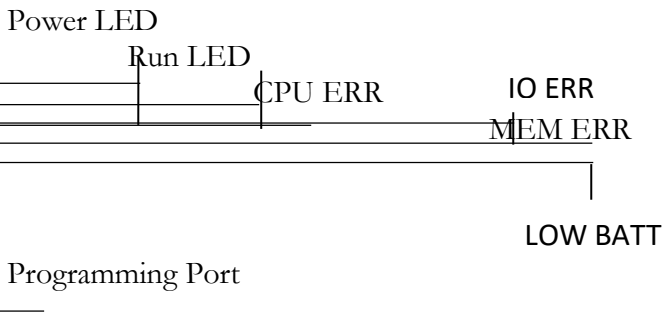
_____

Meet the acceptance Criteria [ ] Yes [ ] No

Verified by : _____ Date : _____

Reviewed by : _____ Date : _____

8.2 Testing Of PLC Processor



LED Indications

The CPU module has 6 LED indicators on the front side to help you to know the status and determine potential problems with the system. In normal runtime operation, only the POWER and RUN indicator is on.

8.2.1 **Objective:** To verify the normal operation of PLC Processor after turning on the PLC.

8.2.2 **Tools required:** Not Applicable

8.2.3 **Procedure:**

1. Turn panel power to On.
2. Turn PLC power to On Position.
3. Document status of the indicators located on PLC front panel.

8.2.4 **Acceptance Criteria:** Each Front panel LED indication should match with the expected result and mentioned in the Product Manual.

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The table below explains the significance of these LED's.

PROCESSOR UNIT- Nexgenie-2000+ (BASE UNIT)						
LED	**Color**	**Expected Result**	**Description**	**Observation**	**Discrepancy? (Y/N)**	**Tested By/Date**
POWER	Green	ON	Backplane 5V Supply is present			
RUN	Green	ON	CPU is in "RUN" mode i.e. in program execution mode			
CPU ERR	RED	OFF	CPU is Healthy			
IO ERR	RED	OFF	All modules inserted are as per configuration declared in the application program & are healthy			
MEM ERR	RED	OFF	Application program is healthy			
Low Battery	RED	OFF	Battery backup for CPU RAM is healthy			

Remarks:

Meet the acceptance Criteria **[ ] Yes** **[ ] No**

Verified by : _____ **Date** : _____

Reviewed by : _____ **Date** : _____

8.3 Testing Of PLC Input /Outputs:

8.3.1 Objective: To verify the normal operation of PLC Input/Outputs after turning on the PLC.

8.3.2 Tools required: PC, PLC Programming software, Multimeter, Calibrator.

8.3.3 Procedure: Turn panel power to On Position.

1 Turn PLC power to On Position.
2 Turn processor to RUN mode.
3 Simulate each Digital Input signal by doing one of the following and verify & record the status of that Input LED on PLC.

- Shorting / opening that signal to PLC input.
- Operating respective field instrument/sensor/transducer

4 Simulate each Digital Output signal by doing one of the following and verify & record the status of that output LED on PLC. Also measure the power status on the output terminal to check the proper functioning of hardware.

- Force on/off that output using the facility available in the PLC programming software. For that, connect PC to PLC through communication cable, run the PLC programming software, upload the program from PLC and go to online mode.
- Operate the output using the Man Machine Interface.
- Run the machine and check on/off of that output during run time.

5 In case of spare input / output check that no wiring is present on the PLC terminal. In case, if wiring is present on PLC terminal to Terminal Block (TB) for future expansion, is should not be connected to any filed device.

8.3.4 Acceptance criteria: After correctly power-up, each component should be operational. Status of individual Digital signals should reflect actual status of the system. Also status of Digital channel should reflect the simulated On/Off condition.

8.4 Inbuilt Digital Input in the PLC-Unit:

Inbuilt Digital Inputs					
Controller Address	**Description**	**Status**	**Observation**	**Discrepancy ? (Y/N)**	**Tested By / Date**
2.0	LOW_LEVEL	ON			
		OFF			
2.1	HIGH_LEVEL	ON			
		OFF			
2.2	DOOR_LOCK	ON			
		OFF			
2.3	POWER_FB	ON			
		OFF			
2.4	ALM_ACK_PB	ON			
		OFF			
2.5	DRY_HEATER_FB	ON			
		OFF			
2.6	HUM_HEATER_1_FB	ON			

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		OFF			
2.7	HUM_HEATER_2_FB	ON			
		OFF			
3.0	COM_1_FB	ON			
		OFF			
3.1	COM_2_FB	ON			
		OFF			

Inbuilt Digital Outputs

Controller Address	Description	Status	Observation	Discrepancy ? (Y/N)	Tested By/ Date
2.0	DRY_HEATER	ON			
		OFF			
2.1	STABILITY_HEATER	ON			
		OFF			
2.2	STABILITY_HEATER2	ON			
		OFF			
2.3	COMPRESSOR	ON			
		OFF			
2.4	COMPRESSOR2	ON			
		OFF			
2.5	SOLENOID_VALVE	ON			
		OFF			
2.6	DOOR_OPEN	ON			
		OFF			
2.7	HOOTER	ON			
		OFF			
3.0	REMOTE_HOOTER	ON			
		OFF			
3.1	HUMID_HEATER2_SAFETY	ON			
		OFF			
3.2	HUMID_HEATER_SAFETY	ON			
		OFF			
3.3	DRY_HETER_SAFETY	ON			
		OFF			

Remarks:

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Meet the acceptance Criteria [ ] Yes [ ] No

Verified by : _____ Date : _____

Reviewed by : _____ Date : _____

8.5 Testing Of HMI Display Function Keys (Fks), Command Buttons, And Displays

8.5.1 Objective: To verify each function of FKs, Command Buttons & Displays for Local HMI/Controller & Application Software.

8.5.2 Procedure:

1. On the Local HMI/Controller modules, verify each FKs, Displays & Set parameters with respective module Configuration details in Manuals.
2. Verify each Command buttons, Displays & Set parameters on Application software for its specified function as listed in the software manuals/guides.

8.5.3 Acceptance Criteria: Each FK, Command Button and Display shall perform as per its defined functions.

8.5.4 Controller Displays Function Key (Fk's) Testing

FK	Function	Specified As	Observation	Discrepancy? (Y/N)	Tested By/Date
Contact Information					
Company Information	Screen change	Show all details of company			
Set Parameters					
Set Temperature	Parameter	Shows Set Temperature			
Temperature Low alarm	Parameter	Shows Temperature Low alarm			
Temperature High alarm	Parameter	Shows Temperature High alarm			
Set Stability	Parameter	Shows Set Stability			
Stability Low alarm	Parameter	Shows Stability Low alarm			

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FK	Function	Specified As	Observation	Discrepancy? (Y/N)	Tested By/Date
Stability High alarm	Parameter	Shows Stability High alarm			
Login Interval	Parameter	Shows Login Interval			
Cooling System	Parameter	Shows Cooling System Status			
Datalogger The LCD Display has 2 rows, the Upper Row & the Lower Row; each having 16 Characters					
Channel 1	Value	Shows value of temperature for Sensor 1			
Channel 2	Value	Shows value of Humidity for Sensor 1			
Channel 3	Value	Shows value of temperature for Sensor 2			
Channel 4	Value	Shows value of Humidity for Sensor 2			
Channel 5	Value	Shows value of temperature for Sensor 3			
Channel 6	Value	Shows value of Humidity for Sensor 3			
Channel 7	Value	Shows value of temperature for Sensor 4			
Channel 8	Value	Shows value of Humidity for Sensor 4			
Channel 9	Value	Shows value of temperature for Sensor 5			
Channel 10	Value	Shows value of Humidity for Sensor 5			
Channel 11	Value	Shows value of temperature for Sensor 6			
Channel 12	Value	Shows value of Humidity for Sensor 6			
Channel 13	Value	Shows value of temperature for Sensor 7			
Channel 14	Value	Shows value of Humidity for Sensor 7			
Channel 15	Value	Shows value of temperature for Sensor 8			
Channel 16	Value	Shows value of Humidity for Sensor 8			
Indication / Panel Key					

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FK	Function	Specified As	Observation	Discrepancy? (Y/N)	Tested By/Date
ACK	Alarm	Switches off the Alarm Hooter			

Remarks:

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_____

Meet the acceptance Criteria [ ] Yes [ ] No

Verified by : _____ **Date :** _____

Reviewed by : _____ **Date :** _____

8.6 Testing Of PLC Power Failure Condition

8.6.1 Objective: To verify operation of PLC Control System after power failure occurs.

8.6.2 Procedure:

1. Record all of the set parameters in the main power fail test table of results.
2. While the system is operating, shut down the power to the main control panel.
3. Wait for 30 seconds then restore the power to the system.
4. Restart the system. Record whether the system starts normally, and note any adverse conditions.
5. Verify that the parameters recorded in the step 2 are unchanged after the power failure occurs.

8.6.3 Acceptance Criteria: After power restart, the system set parameters shall remain unchanged.

8.6.4 Test Results:

PLC Power Fail Verification				
Test	**Expected Observation**	**Actual Observation**	**Discrepancy? (Y/N)**	**Tested By / Date**
PLC Power Shut Down	Equipment must stop in safe and secure conditions.			

Remarks:

Meet the acceptance Criteria [ ] Yes [ ] No

Verified by : _____ **Date :** _____

Reviewed by : _____ **Date :** _____

8.7 Verification of Standard Operating Procedures and Training of Equipment

8.7.1 Objective: To review the availability of relevant SOP's/Procedures.

8.7.2 Procedure: Review existing Standard Operating procedure for the equipment.

8.7.3 Acceptance criteria: Formal Standard Operating Procedure for the system is in place and is current.

All system relevant SOP's & Procedures shall be in place and contain provisions for impact assessment, responsibility, implementation, qualification and training needs. In addition, updates to documentation shall be addressed as appropriate.

8.8 OPERATIONAL QUALIFICATION TEST STATUS:

Test Number	Test Name	Pass/Fail		Discrepancy Found	
		Pass	Fail	Yes	No
1	Testing Of System Healthiness				
2	Testing Of Programmable Logic Controller's Processor				
3	Testing Of PLC Input / Output				
4	Testing Of Display Function Keys, Command Buttons And Displays				
5	Testing Of Power Failure Conditions				

6	Review Of Relevant SOPs For the Control System				

9.0 Reference Draft SOP's:

S.No.	Particulars	SOP Name	SOP Number	Available/Not Available	Checked by (Sign/Date))
1.	Operation & Cleaning				
2.	Preventive Maintenance				

10.0 Training of Personnel: Training on equipment Operation, Cleaning and preventive maintenance shall be imparted to all concerned person after operation qualification.

11.0 Operation Qualification Test Parameter:

S. No.	Description	Acceptance Criteria	Observation	Checked by (Sign/Date)
1.	**Pre-Operational Checks**			
1.1	Installation Qualification completed before commencing the Operational Qualification	Installation Qualification should be completed before commencing the Operational Qualification		
1.2	All the tools are removed from the equipment before beginning the OQ	Ensure that all the tools are removed from the equipment before beginning the OQ		
1.3	Emergency Stop button is released	Ensure that emergency Stop button is released		
1.4	All external equipment is to be disconnected	All external equipment should be disconnected		
1.5	Mains power supply to the machine must be switched off	Ensure that mains power supply to the machine must be switched off		
1.6	Check the cleanliness Stability Chamber	Equipment and area should be cleaned properly		
1.7	Earthing	Proper earthing should be provided to equipment		
1.8	Motor safety guard	Should be closed properly		

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Verified by (EG) : Sign/Date	Verified by (QA): Sign/Date

11.1 Operation and Functional Test:

S. No.	Test	Method of testing	Acceptance criteria	Observation
1.	Main Power Supply	Connect the mail power supply to the operating panel of the machine	Check that there is no power supply to the machine when MCB is off and vice-versa. Check that mail motor of the Stability Chamber rotate in clockwise direction by provide the required input supply of suitable frequency of motor as per the utility mentioned in the utility list/cable schedule	
2.	Operating Panel Function Test			
2.1	Wiring Tug Test & Operating Panel Function Test	Lightly pull all the wires connected to the electrical switchgears one by one testing for any loose connections. Redo the connection, if any is found loose. Any discrepancies and deviation are to be noted, document in the deviation report. Check the operation of unit as per the start sequence detailed in the manual.	Smooth function of operating panel carried out and achieved as per required parameter	
3.	Equipment Control Functions and Interlocks Verification Test			

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S. No.	Test	Method of testing	Acceptance criteria	Observation
3.1	Equipment Control Functions and Interlocks Verification	Take a copy of the machine FDS and process description. Run the machine, by operating, verify and check whether all the controls and interlocks are in place by simulating the conditions. Any discrepancies and deviations are to be noted in this document in the deviation report	The controls and interlocks should function as per the machine FDS and process description	
4.	Equipment Operation Verification	Check the operation of unit as per the start sequence detailed in the manual. Record the readings in the below table	The equipment parameter without & with load should confirm to the rated capacities of the process equipment.	

Motor Performance Checks Without Load					
Operations	**Speed (rpm)**	**Time Interval**	**Temp.**	**Vibration**	**Motor Current**
Motor Performance					R: Y: B:
Motor Performance Checks With Load					
Operations	**Speed (rpm)**	**Time Interval**	**Temp.**	**Vibration**	**Motor Current**
Motor Performance					R: Y: B:

Verified by (EG) : Sign/Date	Verified by (QA): Sign/Date

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11.2 Draft SOP Verification:

S. No.	Particulars	SOP Name	SOP Number	Modification Required/Not Required
1.	Operation			
2.	Preventive Maintenance			

Checked by: Sign/Date	
Verified by: Sign/Date	

Comments: (Quality Control):

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……**Comments: (Engineering):**

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Engineering: Sign/Date	
Verified by (QA): Sign/Date	

12.0 Acceptance Criteria:

A. The equipment shall operate as per the manufacturer Operational manual.

B. All operation and function of equipment should meet in accordance to the desired requirement as mentioned in the specifications of the equipment.

13.0 Re Qualification Criteria: The equipment shall be subjected to Re-Qualification only under following reasons:-

A. Change in location of the equipment.

B. Shifting out of the equipment for major maintenance or modification & again locating at the same place after completion of work.

C. Equipment does not operate with in operational limit.

Engineering: Sign/Date	
Quality control: Sign/Date	
Quality Assurance: Sign/Date	

14.0 Deviation, if any:

S.No.	Deviation	Corrective Action	Checked by Sign/Date

OPERATIONAL QUALIFICATION FOR STABILITY CHAMBER

Verified by (EG): Sign/Date	Approved by (QA): Sign/Date

15.0 Change Control:

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Initiated by : Sign/Date	Verified by : Sign/Date	Approved by (QA) : Sign/Date

16.0 Abbreviation:

Abbreviation	Expended form
QC	Quality control
SOP	Standard Operating Procedure
V	Volt
amps	Ampere
Sr. No.	Serial Number
STB	Stability chamber
OQ	Operational qualification

17.0 Summary and Conclusion:

Summary:

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Conclusion:

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18.0 Annexure: NA

19.0 Certification: After successful completion of Operation Qualification equipment shall be certified by validation team and shall approve by Quality Assurance.

Certification

This is to certify that Operation Qualification activity of Stability Chamber Equipment ID No.: .....has successfully been completed as per the following documents:

Operation Qualification Protocol cum report No.:	.....

Remarks:……

……

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Approved by:

20.0 Post-Approval: Based on the data collection and compilation of the data, draw the conclusion of the complete study. A Protocol cum report shall be prepared for the complete activity. All the raw data generated during the study shall be documented for future reference.

Executed By (Name & Designation)	Signature	Date
Quality control		
Quality Assurance		

Checked By (Name & Designation)	Signature	Date
Quality contro		
Maintenance		
Quality Assurance		

Approve By (Name & Designation)	Signature	Date
Quality Assurance		