PERFORMANCE QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

NAME OF THE CUSTOMER	
ADDRESS	
PURCHASE ORDER No.	
DATE	
EQUIPMENT SERIAL No.	

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1.0 APPROVAL:

All executed test procedures in this qualification protocol have been reviewed and found to have been executed according to the approved procedures. The signatures below indicate acceptance of the results.

	Name	Designation	Sign / Date
Prepared By			
Reviewed By			
Approved By			

2.0 SIGNATURE IDENTIFICATION PAGE:

This page is a record of each individual who signs this qualification protocol. Each person shall be identified by written name, full signature, written initials and department represented Quality Assurance, Manufacturing and Engineering etc.

Name	Signature	Initials	Department

3.0 PURPOSE:

The purpose of preparing this protocol is to define qualification requirements and methodology for Walk in Stability Chamber Performance Qualification and ensure that by generating documented evidence shows that the performance of the equipment as per user's requirement specification in operating environment.

4.0 SCOPE:

The scope of this protocol is to provide clear path and procedure for executing the Performance Qualification of Walk in Stability Chamber.

5.0 REFERENCES:

The tests and execution procedures within the scope of this qualification protocol are consistent with the following references:

5.1 STANDARDS:

Current Good Manufacturing Practice
ICH Guideline

5.2 VALIDATION RELATED DOCUMENTS:

Quality Management System
Company Validation Policies and Plan

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6.0 RESPONSIBILITY:

Representative Area	Name	Designation
Engineering / Validation		
Quality Assurance		
Quality Control		

7.0 EXECUTION:

The satisfactory performance and integration of the Walk in Stability Chamber will be verified by executing the qualification studies described in this qualification protocol. The successfully executed protocol documents established that Walk in Stability Chamber operates satisfactory as per pre-defined specification and design in controlled environment.

S.No.	Name of Executor	Designation	Sign / Date
1			
2			
3			
4			

8.0 PERFORMANCE QUALIFICATION:

S.No.	Test
8.1	TEST VERIFICATION OF WALK IN STABILITY CHAMBER DETAILS
8.2	TEST VERIFICATION OF PERFORMANCE OF WALK IN STABILITY SYSTEM

8.1 TEST VERIFICATION OF WALK IN STABILITY CHAMBER DETAILS:

Objective: This test sheet of the PQ is intended to describe and identify the system going to be validated.

Tools required : Not Applicable

Procedure: Record following details from the equipment.

Model
Equipment Sr. No.
Capacity
Make
Record the equipment location from location tag plate.
Record the verification source. (I.e. Nameplates, Room location tag etc.)
Note any discrepancies and recommend follow-up actions if required.

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

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Equipment Details	Specified Data	Actual Data	Source of Verification	Verified By / Date
Model	GMP		MOC as per DQ	
Equipment Sr. No.	ET-64/12/19-20		Name plate	
Capacity / Size	3000 Ltrs		DQ	
Location			Room location tag	
Make	Effem		Name plate	
Environment Condition of Area	Below 30°C		Calibrator	
Temperature Range	20°C to 60°C		DC	
Humidity Range	40% RH to 98% RH		DC	

Remarks: _____

_____

Meet the Acceptance Criteria [ ] Yes [ ] No

Tested by : _____ Date : _____

Verified by : _____ Date : _____

8.2 TEST VERIFICATION OF PERFORMANCE OF WALK IN STABILITY SYSTEM:

Objective: To verify the performance of Walk in Stability Chamber temperature and humidity control system and establish that control system perform as specified.

Verify the accuracy of the temperature and humidity

Verify the uniformity of the temperature and humidity

Tool / Instrument: Calibrated 16- Data logging System with 8 Point Temperature and 8 Point RH Sensors.

Procedure:

1. Verify calibration status of data logger system traceable to National Standard.
2. Place the 8 – point temperature probes and 8 - RH sensors in different positions in the chamber as per defined and pre-approval drawing.
3. Wait till stabilization of process parameters and check loop controls function as specified.

4. Start data logger system and set print interval. Note down start time.
5. Observe system control and print process value of all channels of calibrator.
6. Verify accuracy for channel 1 of displayed value and print records.
7. Verify uniformity for all the channels of displayed value and print records.
8. Monitor the system performance and testing period of system should as per URS.
9. Review complete report of validation cycle it should be within specified limit as per specified in URS and take report with system ID no. Location, date and time.

Acceptance Criteria:

- Accuracy of the temperature and humidity should be within the specified limits of ± 0.2°C and± 2% RH respectively.
- Uniformity of the temperature and humidity should be within the specified limits of ± 2°C and ± 3% RH respectively.

8.2.1 DATA TABLE FOR PERFORMANCE OF WALK IN STABILITY SYSTEM WITH ACCURACY AND UNIFORMITY:

Test Condition : Temperature _____°C and Humidity _____%

Test Accuracy

Date	Time	Set Temp	Set RH	Actual Temp	Actual RH	Result Accepted	Verified By / Date
		°C	%	°C	%		

Test Uniformity of temperature

Date	Time	Set Temp	Set RH			Calibrator probe Temp						Result Accepted	Verified By/Date
		°C	%	°C	°C	°C	°C	°C	°C	°C	°C		
				T1	T2	T3	T4	T5	T6	T7	T8		

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Test Uniformity of Humidity

Date	Time	Set Temp	Set RH	Calibrator probe RH								Result Accepted	Verified By/Date
		°C	%	%	%	%	%	%	%	%	%		
				R1	R2	R3	R4	R5	R6	R7	R8		

Test Condition : Temperature _____°C and Humidity _____%

9.0 PERFORMANCE QUALIFICATION DISCREPANCY REPORT:

DISCREPANCY AND CORRECTIVE ACTION REPORT FORM:

DEVIATION:

Describe the deviation:

CORRECTIVE ACTION TAKEN:

Describe corrective action taken:	
Reported by	**Date**

CORRECTIVE ACTION APPROVAL:

Discussion:	
Approved by	**Date**

COMPLETION:

Completed by:	**Date**

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10.0 SUMMARY AND CONCLUSION:

PQ data sheets and discrepancy report shall be reviewed by validation team to prepare summary report. The summary of PQ shall be used to draw conclusion for approval of Performance Qualification

SUMMARY:

CONCLUSION:

COMMENTS:

Prepared by	**Reviewed by**	**Approved by**

11.0 QUALIFICATION COMPLETION AND APPROVAL:

Report No. **:** **Date Effective** **:**

Equipment Name **:** **Tag No.** **:**

Activity	Name	Area Representative	Signature / Date
Prepared By			
Reviewed By			
Approved By			