INSTALLATION QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

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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 Installation Qualification and ensure that by generating documented evidence shows that the installation of this equipment is as per pre-defined specification and design.

4.0 SCOPE:

The scope of this protocol is to provide a clear path and procedure for executing the Installation 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:

1. Current Good Manufacturing Practice
2. ICH Guideline

5.2 VALIDATION RELATED DOCUMENTS:

1. Quality Management System
2. Company Validation Policies and Plan

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6.0 TERMINOLOGY:

Validation: Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specification and quality attributes.

Installation Qualification: Establishing confidence that process equipment and ancillary systems are capable of consistently operating within established limits and tolerances

Validation Protocol: A written plan stating how validation will be conducted, including test parameters, product characteristics, production equipment and decision points on what constitutes acceptable test results

Calibration: Calibration is defined as a comparison between standard and measuring equipment with a standard of higher accuracy to detect, correct, adjust and document the accuracy of the equipment being compared or calibrated.

Accuracy: Accuracy of temperature and humidity is the variation in the process value with respect to the set value of the controller.

7.0 RESPONSIBILITY:

Representative Area	Name	Designation
Engineering / Validation		
Quality Assurance		
Quality Control		

8.0 EXECUTION:

The satisfactory installation 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 was installed and integrated satisfactory as per pre-defined specification and design in controlled environment.

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

9.0 INSTALLATION QUALIFICATION:

S.No.	Test
9.1	TEST VERIFICATION OF WALK IN STABILITY CHAMBER DETAILS
9.2	VERIFICATION OF REGULAR SYSTEM COMPONENTS INSTALLATION
9.3	VERIFICATION OF STAND - BY SYSTEM COMPONENTS INSTALLATION
9.4	VERIFICATION OF SYSTEM UTILITIES INSTALLATION
9.5	VERIFICATION OF SOFTWARE INSTALLATION COMPONENTS:
9.6	VERIFICATION OF TRAINING RECORDS:

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9.1 TEST VERIFICATION OF WALK IN STABILITY CHAMBER DETAILS:

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

Tools Required **:** Not Applicable

Procedure **:**

1. Record following details from the equipment.
   - Model
   - Equipment Sr. No.
   - Capacity
   - Make
2. Record the equipment location from location tag plate.
3. Record the verification source. (i.e. Name plates, Room location tag etc.)
4. 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.

9.1.1 DATA SHEET TABLE OF WALK IN STABILITY CHAMBER DETAILS:

Equipment Details	Specified Data	Actual Data	Source of Verification	Verified By / Date
Model	GMP		MOC as per DQ	
Equipment Sr. No.	.....		Name plate	
Capacity / Size	3000 Ltrs		DQ	
Location			Room location tag	
Make	……..		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** **:** _____

9.2 VERIFICATION OF REGULAR SYSTEM COMPONENTS INSTALLATION:

Objective: To verify that Walk In Stability Chamber is installed as per specified in the design documents and as built drawings.

Procedure: Verify physical installation of equipment with following documents and drawing.

- Verify installed system against as built drawing and system components list.
- Verify the component's model no, make and quantity as per component list and design documents.
- Record actual details of Mechanical, Electrical and Instrument components in test data sheets

Acceptance Criteria : All components should be installed in compliance with the approved drawing and documents

9.2.1 TEST DATA TABLE FOR MECHANICAL COMPONENTS:

Component	Available Yes / No
Trays	
Impeller	

9.2.2 TEST DATA TABLE FOR ELECTRICAL COMPONENTS:

Component	Available Yes / No
Motor Flange Mounting	
Float Switch	
Solid State Relay	
Contactor	
MCB	
MCB	
MCB	
Time Delay	
Power Supply	
Air Heater	
Boiler Heater	
Tube Light	
Three Pin Plug	
Relay	
Buzzer	
HMI	

9.2.3 TEST DATA TABLE FOR REFRIGERATION COMPONENTS:

Component	Available Yes / No
Condensing Unit	
Cooling Coil	
Refrigerant Gas	
MCB	
Drier	

9.2.4 TEST DATA TABLE FOR INSTRUMENTS AND SENSORS:

Component	Available Yes / No
HMI (Delta)	
PT 100 Sensor Mains & Safety	
RH Sensor Mains & Safety	
Safety Thermostat	

Remarks: _____

_____

Meet the Acceptance Criteria [ ] Yes [ ] No

Tested by : _____ Date : _____

Verified by : _____ Date : _____

9.3 VERIFICATION OF STAND BY SYSTEM COMPONENTS INSTALLATION:

Objective: To verify that Walk in Stability Chamber installed as per specified in the design documents and as built drawings.

Procedure: Verify physical installation of equipment with following documents and drawings.

1. Verify installed system against as built drawing and system components list.
2. Verify the component's model no, make and quantity as per bill of material list and design documents

9.3.1 TEST DATA SHEET FOR STAND BY REFRIGERATION SYSTEM COMPONENTS:

Component	Available Yes / No
Condensing Unit	
Cooling Coil	
Refrigerant Gas	
MCB	
Drier	

9.3.2 TEST DATA SHEET FOR STANDBY HUMIDITY SYSTEM COMPONENTS:

Component	Available Yes / No
Solid State Relay	
MCB	
Boiler Heater	

Remarks: _____

_____

Meet the Acceptance Criteria [ ] Yes [ ] No

Tested by : _____ Date : _____

Verified by : _____ Date : _____

9.4 VERIFICATION OF SYSTEM UTILITIES INSTALLATION:

- **Objective:** To verify that Walk in Stability Chamber utilities installed as per specified in the design documents and as built drawings.
- **Procedure:** Verify all type of utilities connected of equipment as per installation diagrams drawings.
- **Acceptance Criteria:** All type of utilities should be installed and connected as specified in the approved drawing and design documents.

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9.4.1 TEST DATA TABLE FOR UTILITIES DETAILS:

Utilities	Specified	Actual	Method
Power Supply For Equipment	Continuous stabilized power supply of 230 V AC, single phase, 50Hz, 16 Amps		
	Proper earthing		
	Stabilizer.		
	UPS (1 KVA for control system)		
Power Supply For Printer & Calibrator	230 V AC, single phase, 50 Hz, 6 Amps		
Environment condition	Cross ventilated and dust free environment. (Preferably air-condition room or exhaust fan. The room temperature should not exceed of 30°C)		
	Minimum one feet working space around the chamber and two feet behind the chamber.		
Water Supply	Continuous DM or Distilled water supply to the humidity system at 3 feet above the floor with ON / OFF valve and low-pressure line.		
Drain Line	Drain of ¾”at the floor level with little slope.		
Accessories	Lx-300+dot matrix printer for taking printouts having serial & parallel ports (Make Epson). (Compulsory required for taking the validation printouts from data logger during installation)		

Remarks: _____

_____

Meet the Acceptance Criteria [ ] Yes [ ] No

Tested by : _____ Date : _____

Verified by : _____ Date : _____

9.5 VERIFICATION OF SOFTWARE INSTALLATION COMPONENTS:

Objective: To verify that Walk in Stability Chamber Software Version installed as per specified in the design documents.

- **Procedure**: Verify physical installation of software with following procedure:.
  1. Verify installed system against as system components list.
  2. Verify the component's model no, make and quantity as per bill of material list and design documents
  3. Record actual details of Walk in Stability Software components in test data sheets.
- **Acceptance Criteria:** All components should be installed in compliance with the approved

9.5.1 TEST DATA SHEET FOR SOFTWARE SYSTEM COMPONENTS:

Component	Specification	Make	Quantity	Available Yes / No	Verified By (Sign/ Date)
Platform					
PC Hardware					
Com Port					
CD drive					
Hard Disk					
Mouse					
Monitor					
Cable					
CD					

9.5.2 INSTALLATION PROCESS OF SOFTWARE:

S.No.	INSTALLATION PROCESS	YES / NO
1.	Connect Networking wire 6-core cable from HMI to Hub.	
2.	Connect cable to the PC. OR Connect Hub networking cable to LAN Socket. or Connect IP Address to PC.	
3.	Insert License Key in software.	
4.	Keep the switch on of Hub which connect to PC	
5.	Check the power (PWR) indicator on the PC.	
6.	Insert the software CD and run the Setup program following the instruction in the manual. Reboot the system after installing the software.	

9.6 VERIFICATION OF TRAINING RECORDS:

Procedure : The required personnel shall review each applicable SOP for the Walk in Stability Chamber and formally sign off that they have received the training and they understand and are capable of executing the given procedure.

Method of Verification: Evaluation of personnel.

Acceptance Criteria: The trained persons should be capable of executing the given procedure independently.

9.6.1 DATA SHEET FOR TRAINING RECORDS:

Name of Person	Department	Sign / Date

9.6.2 TEST QUALIFICATION EQUIPMENT:

To execute this Installation Qualification protocol the following will be needed by the executor: Instruments and calibrator along with calibration certificates.

- Digital Multimeter
- Data Logger with Temperature and Humidity Inputs.

Remarks: _____

_____

Meet the Acceptance Criteria [ ] Yes [ ] No

Tested by : _____ Date : _____

Verified by : _____ Date : _____

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10.0 INSTALLATION QUALIFICATION TEST STATUS:

Test Number	Test Details	Pass / Fail		If Fail Describe
		Pass	Fail	
10.1	Test Verification of Walk in Stability Chamber Details			
10.2	Verification of Calibration And Test Certificates			
10.3	Verification of Regular System Component Installation			
10.4	Verification of Stand – By System Components Installation			
10.5	Verification of System Utility Requirements			

Remarks: _____

_____

Meet the Acceptance Criteria [ ] Yes [ ] No

Tested by : _____ Date : _____

Verified by : _____ Date : _____

11.0 INSTALLATION QUALIFICATION DISCREPANCY REPORT:

DISCREPANCY AND CORRECTIVE ACTION REPORT FORM:

DEVIATION:

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……
……

CORRECTIVE ACTION TAKEN:

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12.0 SUMMARY AND CONCLUSION:

Validation team to prepare summary report shall review IQ data sheets and discrepancy report. The summary of IQ shall be used to draw conclusion for approval of Installation Qualification package.

SUMMARY:

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CONCLUSION:

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COMMENTS:

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……

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13.0 QUALIFICATION COMPLETION AND APPROVAL:

Report No. : **Date Effective :**

Equipment Name : **Tag No. :**

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