OPERATIONA QUALIFICATION PROTOCOL
FOR
WALK IN TYPE STABILITY CHAMBER

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

PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT	

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

INDEX

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

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 Operational Qualification and ensure that by generating documented evidence shows that the operation equipment as per pre defined functional specification in operating environment.

4.0 SCOPE:

The scope of this protocol is to provide clear path and procedure for executing the Operational 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

6.0 RESPONSIBILITY:

Representative Area	Name	Designation
Engineering / Validation		
Quality Assurance		
Quality Control		

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

7.0 EXECUTION:

The satisfactory operational 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 OPERATIONAL QUALIFICATION:

S.No.	Test
8.1	TEST VERIFICATION OF WALK IN STABILITY CHAMBER DETAILS
8.2	VERIFICATION OF OPERATION OF WALK IN STABILITY SYSTEM
8.3	VERIFICATION OF OPERATION OF SAFETY DEVICES OF SYSTEM
8.4	VERIFICATION OF OPERATION OF THE STAND-BY SYSTEM
8.5	VERIFICATION OF TRAINING RECORDS
8.6	VERIFICATION OF SOP
8.7	VERIFICATION OF OPERATION FEATURE OF SOFTWARE

8.1 TEST VERIFICATION OF WALK IN STABILITY CHAMBER DETAILS:

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

Procedure: 1. Record following details from the equipment.
- Model
- Equipment S.No.
- Capacity
- Make

2. Record the equipment location from location tag plate.
3. Record the verification source. (I.e. Nameplates, Room location tag etc.)
4. Note any discrepancies and recommend follow-up actions if required.

Tools Required: Not Applicable

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

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.1.1 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			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 :** _____

8.2 VERIFICATION OF OPERATION OF WALK IN STABILITY SYSTEM:

Objective: To verify that operation of system components and devices of chamber is as per specified in the design documents specification.

Procedure: Verify physical operation of equipment with design documents and as built drawings.
1. Verify operation of system components against system design document and functional requirements.
2. Record actual details of Mechanical, Electrical and Instrument components in test data sheets.

8.2.1 VERIFICATION OF TEMPERATURE AND HUMIDITY PLC OPERATION:

Set the temperature and humidity on the respective PLC (within the operating range of equipment) as per the requirement and allow to stabilize the temperature and humidity conditions in the chamber.

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.2.1.1 DATA TABLE FOR VERIFICATION OF OPERATION OF CONTROLLERS:

Item	Display / Function	Specified Result		Actual Result	Result Accepted
Test Condition : Temperature ____°C and Humidity ____%					
Temperature Controller	Set Temperature at _____ °C	PV_____ °C ± 0.2°C			
	Relay / SSR O/P	SSR O/p should turn ON and OFF as per the controller operation.			
Humidity Controller	Set Humidity at ____% RH	____% ± 2% RH			
	Relay / SSR O/P	SSR O/p should turn ON and OFF as per the controller operation			

Remarks: _____

_____

Meet the Acceptance Criteria   [   ] Yes   [   ] No

Tested by   : _____   Date   : _____

Verified by: _____   Date   : _____

8.3 VERIFICATION OF OPERATION OF SAFETY DEVICES OF SYSTEM:

Objective: To verify that operation of safety devices of chamber is as per specified in the design documents and functional specification.

Procedure: Verify the operations of the safety devices of chamber with following tests against system design documents and functional requirement.

Test No.	Test Description
8.3.1	Verification of The Safety Cutoff Action Of The Safety Controller in HMI For Temperature Overshoot
8.3.2	Verification of The Safety Cutoff Action Of The Safety Controller in HMI For Temperature Undershoot
8.3.3	Verification of The Safety Cutoff Action Of The Safety Controller in HMI For Humidity Overshoot
8.3.4	Verification of The Safety Cutoff Action Of The Float Switch For Low Water Level
8.3.5	Verification of The Safety Cutoff Action Of The Safety Thermostat For Temperature Overshoot
8.3.6	Verification of The Safety Cutoff Action Of The Safety Thermostat For Temperature Overshoot in Evaporative Tray
8.3.7	Verification of The Working Of Time Delay in HMI

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.3.1 VERIFICATION OF THE SAFETY CUTOFF ACTION OF THE SAFETY CONTROLLER FOR TEMPERATURE OVERSHOOT:

Method:

Set the safety controller with the same set temperature as that set on the temperature controller. Then set the required alarm band between 2°C to 5°C and the stabilization time in the safety controller. The safety controller has the imaginary cutoff points as per the setting of the alarm band.

For overshoot test of temperature do the following exercise

After the completion of the stabilization time of the safety controller, set the set value of the temperature controller 6°C above the set value of the safety controller (in HMI).

8.3.1.1 TEST DATA SHEET FOR SAFETY CUTOFF ACTION OF THE SAFETY CONTROLLER IN HMI FOR TEMPERATURE OVERSHOOT:

Item	Display / Function	Specified Result	Actual Result	Result Accepted
Temperature Controller	Set value of Temperature controller at _____°C	PV of Temperature controller _____°C at the time of safety cutoff.		
Safety Controller	Set safety controller at _____°C	PV of Temperature on safety controller _____°C at the time of safety cutoff.		
	Alarm band set at _____°C	_____°C		

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.3.2 VERIFICATION OF THE SAFETY CUTOFF ACTION OF THE SAFETY CONTROLLER IN HMI FOR TEMPERATURE UNDERSHOOT:

Method:
Set the safety controller with the same set temperature as that set on the temperature controller. Then set the required alarm band between 2°C to 5°C and the initial time in the safety controller. The safety controller has the imaginary cutoff points as per the setting of the alarm band. For undershoot test of temperature do the following exercise

After the completion of the stabilization time of the safety controller, set the set value of the temperature controller 6°C below the set value of the safety controller.

Acceptance Criteria:
In case of undershoot of temperature above the alarm band the unit should give audio alarm while it cutoff the mains contactor.

8.3.2.1 TEST DATA SHEET FOR SAFETY CUTOFF ACTION OF THE SAFETY CONTROLLER IN HMI FOR TEMPERATURE UNDERSHOOT:

Item	Display / Function	Specified Result	Actual Result	Result Accepted
Temperature Controller	Set value of Temperature controller at _____°C	PV of Temperature controller ____°C at the time of safety cutoff.		
Safety Controller	Set safety controller at _____°C	PV of Temperature on safety controller ____°C at the time of safety cutoff.		
	Alarm band set at ____°C	_____°C		

8.3.3 VERIFICATION OF THE SAFETY CUTOFF ACTION OF THE SAFETY CONTROLLER IN HMI FOR HUMIDITY OVERSHOOT:
Method:

Set the safety controller with the same set humidity as that set on the humidity controller. Then set the required alarm band between 2% to 5% and the stabilization time in the safety controller. The safety controller has the imaginary cutoff points as per the setting of the alarm band.
For overshoot test of humidity do the following exercise
After the completion of the stabilization time of the safety controller, set the set value of the humidity controller 6% above the set value of the safety controller.

Acceptance Criteria:

In case of overshoot of humidity above the alarm band the unit should cutoff the evaporative heater and give audio alarm.

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.3.3.1 TEST DATA SHEET FOR SAFETY CUTOFF ACTION OF THE SAFETY CONTROLLER IN HMI FOR HUMIDITY OVERSHOOT:

Item	Display / Function	Specified Result	Actual Result	Result Accepted
Humidity Controller	Set value of Humidity controller at _____%	PV of Humidity Controller ____% at the time of safety cutoff.		
Safety Controller	Set Safety controller at _____%	PV of Humidity on safety Controller ____% at the time of safety cutoff.		
	Alarm band set at ____%	_____%		

8.3.4 VERIFICATION OF THE SAFETY CUTOFF ACTION OF THE FLOAT SWITCH FOR LOW WATER LEVEL:

Method:

In case of inadequate water supply the float switch provided in the reservoir tank will cutoff the mains contactor giving audio alarm. To check the low water safety cut off, the water in the reservoir tank should be removed.

Acceptance Criteria:

Float switch should cut off the mains contactor giving audio alarm in case of inadequate water supply.

8.3.4.1 TEST DATA SHEET FOR SAFETY CUTOFF OF THE FLOAT SWITCH FOR LOW WATER LEVEL:

Item	Display /Function	Specified Result	Actual Result	Result Accepted
Float switch	Water level cut off	The float switch should cut off at approx 50 mm.		

8.3.5 VERIFICATION OF THE SAFETY CUTOFF ACTION OF THE SAFETY THERMOSTAT FOR TEMPERATURE OVERSHOOT:

Method:

The safety thermostat has a fixed cutoff point at 45°C. The sensor of the thermostat is placed below the heaters in the chamber duct. To check the working of the safety thermostat the safety controller should be disconnected. Set 50°C on the temperature controller and switch off the compressor.

Acceptance Criteria:

The safety thermostat should cutoff the heaters supply in case the temperature exceeds its set value.

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.3.5.1 TEST DATA SHEET FOR SAFETY CUTOFF ACTION OF THE SAFETY THERMOSTAT FOR TEMPERATURE OVERSHOOT:

Item	Display /Function	Specified Result	Actual Result	Result Accepted
Temperature Controller	Set Temperature controller at ____°C	PV on Temperature controller at the time of safety thermostat cut off ____°C		
Safety Thermostat	Set the Safety thermostat at _____°C	The safety thermostat should cut off as the temperature exceeds upto +5°C of set point.		
	Relay O/P	Relay should operate at the time of safety thermostat cut off and cuts off the air heater supply.		

8.3.6 VERIFICATION OF THE SAFETY CUTOFF ACTION OF THE SAFETY THERMOSTAT FOR TEMPERATURE OVERSHOOT IN EVAPORATIVE TRAY:

Method:

The safety thermostat has a fixed cutoff point at 300°C. The sensor of the thermostat is placed near boiler heaters in the evaporative tray. To check the working of the safety thermostat, set the thermostat at 80°C, Set Humidity controller in HMI to 75%.

Acceptance Criteria:

The safety thermostat in the evaporative tray should cut off the Boiler heater supply in case the temperature exceeds its set value i.e. 80°C.

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.3.6.1 TEST DATA SHEET FOR SAFETY CUTOFF ACTION OF THE SAFETY THERMOSTAT FOR TEMPERATURE OVERSHOOT IN EVAPORATIVE TRAY:

Item	Display /Function	Specified Result	Actual Result	Result Accepted
Humidity Controller	Set Humidity controller at 75% RH	PV on Humidity controller at the time of safety thermostat cut off ____% RH		
Safety Thermostat	Set the Safety thermostat at 80°C	The safety thermostat should cut off water immersion heater supply as the temperature exceeds up to +5 °C above the set temperature of the safety thermostat.		

8.3.7 VERIFICATION OF WORKING OF TIME DELAY:

Method:
Time delay is provided for the safety of the condensing unit. Whenever the chamber is started, condensing unit will start after a delay of 2 min. i.e. the compressor and the motor will start after approximate 2 min.

Acceptance Criteria:
Condensing unit should start after a delay of 2 min.

8.3.7.1 TEST DATA SHEET FOR WORKING OF TIME DELAY:

Item	Display / Function	Specified Result	Actual Result	Result Accepted
Time Delay Unit	Time delay unit set at Approximately 2 minutes	The time delay unit ON at Approximately 2 minutes		
Condensing Unit	Time taken by the condensing unit to start	The condensing unit (Compressor, motor, fan) should start after 2 minutes		

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.3.8 TEST DATA SHEET FOR OPERATION OF SAFETY DEVICES:

Function	Actual Results
Cutoff Action Of The Safety Controller in HMI For Temperature Overshoot	
Cutoff Action of The Safety Controller in HMI For Temperature Undershoot	
Cutoff Action of The Safety Controller in HMI For Humidity Overshoot	
Cutoff Action of The Float Switch For Low Water Level	
Cutoff Action of The Safety Thermostat For Temperature Overshoot	
Cutoff Action of The Safety Thermostat For Temperature in Evaporative Tray	
Working of Time Delay	

Remarks: _____

_____

Meet the Acceptance Criteria   [   ] Yes   [   ] No

Tested by   : _____   **Date   :** _____

Verified by : _____   **Date   :** _____

8.4 VERIFICATION OF OPERATION OF THE STAND-BY SYSTEM:

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

8.4.1 VERIFICATION OF OPERATION OF THE STAND-BY HUMIDITY SYSTEM:

The chamber has been provided with a stand-by humidity system, which should be switched 'ON' in case the working system fails.

Method:

Put ON the mains and start the stand by humidity system by putting ON Humidity switch 1 provided. The stand-by humidity system should start working. (Please switch off the 1st humidity system when the 2nd is ON).

Acceptance Criteria:

The stand-by humidity system should start working when switched ON.

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.4.1.1 TEST DATA SHEET FOR WORKING OF STAND-BY HUMIDITY SYSTEM:

Method of Verification	Specified Results	Actual Results	Result Accepted
Humidity System			
Switch 'OFF' the working humidity system and then switch 'ON' the stand-by humidity system.	The stand-by humidity system should work, generating the steam.		

8.4.2 VERIFICATION OF OPERATION OF THE STAND-BY REFRIGERATION SYSTEM:

The entire refrigeration system is being provided as a stand by including a separate compressor, condenser, cooling coil and other refrigeration accessories. The system is along with gas charging and is ready for use if the other fails.

Method:

Put ON the mains and start the stand by cooling system by putting ON cooling switch 1 provided. The standby refrigeration system should start working. (Please switch off the 1st system when the 2nd is ON).

Acceptance Criteria:

The stand-by refrigeration system should start working after 2 minutes when switched ON.

8.4.2.1 TEST DATA SHEET FOR WORKING OF STAND-BY REFRIGERATION SYSTEM:

Method of Verification	Specified Results	Actual Results	Result Accepted
Cooling System			
Switch ON the mains and start the cooling system by putting ON cooling switch 1 provided for the standby cooling system. The stand-by refrigeration system should start working after 2 minutes. (Please switch off the 1st cooling system when the 2nd is ON).	The stand-by refrigeration system should start working after 2 minutes when switched ON and operation should be Normal as required		

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.4.2.2 TEST DATA TABLE FOR TESTING OF HMI INTERFACE UNIT OPERATION:

Function	Specified Results	Actual Results	Result Accepted
Printer	Print time interval is settable from 1 min to 60 min and the printing was as per the set print interval time. Print value of process Parameters should be match with actual value displayed on the HMI Controllers with Date and Time.		

Remarks: _____

_____

Meet the Acceptance Criteria   [   ] Yes   [   ] No

Tested by : _____   **Date   :** _____

Verified by : _____   **Date   :** _____

8.5 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.

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.5.1 DATA SHEET FOR TRAINING RECORDS:

Name of Person	Department	Sign / Date

Remarks: _____

_____

Meet the Acceptance Criteria   [   ] Yes   [   ] No

Tested by : _____   Date   : _____

Verified by : _____   Date   : _____

8.6 VERIFICATION OF THE STANDARD OPERATING PROCEDURE:

Objective: The objective of this test is to verify that the required operational SOP available with current version.

Procedure: Review existing Standard Operating Procedure and documentation for availability, completeness, is current, accuracy and compliance GMP.

Acceptance Criteria: The system related standard operating procedures and documentation should be available, complete, current and accurately reflected as the "Installed" system

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

8.6.1 DATA SHEET FOR STANDARD OPERATING PROCEDURE:

Title of SOP	Document No.	Availability	Verified By/Date
Standby System Changeover Procedure			
System Maintenance Procedure			
Standard Operating Procedure			
Software Installation Procedure			

Remarks: _____

_____

Meet the Acceptance Criteria   [   ] Yes   [   ] No

Tested by   : _____   **Date   :** _____

Verified by : _____   **Date   :** _____

8.7 VERIFICATION OF THE OPERATIONAL FEATURES OF SOFTWARE:

To verify that operation of Software of chamber is as per specified in the design documents and functional specification.

8.7.1 TO CHECK THE USER ACCESS PROTECTION FACILITY:

Test Method:

Open the software; log in form will be loaded. Select the online mode and enter the user name and password and the user type. The start up form will be loaded and access to only the authorized field will be available e.g. for the user type R & D and user name ABCDE and password is 12345678 and the access given is only for downloading data. Then when the user type is entered as R & D and user name entered is ABCDE and password entered is 12345678. Startup form will be opened and access to only downloading data will be available.

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

Acceptance Criteria:

When the correct user name, password and user type is entered start up form access should be available and only the fields authorized should be accessible.

Result:

It is observed that when the online mode, user name is ABCDE, password as 12345678 and user type as R & D was entered then only the startup form was loaded and in this login only data downloading was accessible.

Remarks: _____

_____

Meet the Acceptance Criteria   [   ] Yes   [   ] No

Tested by : _____   Date   : _____

Verified by : _____   Date   : _____

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

9.0 OPERATIONAL QUALIFICATION DISCREPANCY REPORT: 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

10.0 SUMMARY AND CONCLUSION:

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

SUMMARY:

OPERATIONAL QUALIFICATION PROTOCOL FOR WALK IN TYPE STABILITY CHAMBER

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			