



**PHARMA DEVILS**  
**QUALITY ASSURANCE DEPARTMENT**

**INSTALLATION QUALIFICATION FOR STABILITY CHAMBER**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT FOR  
STABILITY CHAMBER**



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### INSTALLATION QUALIFICATION FOR STABILITY CHAMBER

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#### 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		



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#### 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. Successful completion of these qualification requirements will provide assurance that the Walk - In Stability Chamber is installed as required in the processing environment and meets Installation requirements.

#### 3.0 Scope:

Scope of this Protocol cum report is limited to Installation Qualification of Stability Chamber, Equipment ID. No..... Installed in Stability area.

#### 4.0 Responsibility:

##### 4.1 Engineering

Engineering personnel shall be responsible for:

- 4.1.1 The execution of installation activity
- 4.1.2 The preparation and review of installation qualification protocol cum report.
- 4.1.3 Providing technical guidance and instructions to the personnel involved in installation.
- 4.1.4 To identify the standard operating procedure

##### 4.2 Quality control

Quality control personnel shall be responsible for:

- 4.2.1 Supporting the engineering personnel during execution of installation activity
- 4.2.2 The review of installation qualification protocol and report.
- 4.2.3 To identify the standard operating procedure

##### 4.3 Quality Assurance

Quality Assurance personnel shall be responsible for:

- 4.3.1 Approval of installation qualification protocol and report.
- 4.3.2 Verification of Installation Qualification activity.
- 4.3.3 Providing technical guidance during installation.
- 4.3.4 To verify that the equipment is installed as per approved drawing.



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**5.0 Equipment Description:** These chambers are designed especially for close control of storage temperature & Stability. These are used for storing of materials of pharmaceutical pathological & agricultural laboratories. For safe and reliable storage of laboratory products at temperatures from 10°C to 60 °C & Stability range of 25% to 90%, Optimum range of chamber is for small, medium and large laboratory. This instrument falls under category I of Medical Devices Directives (MDD) and complies with all the safety requirements as specified in the directive. In order to get maximum utility from the instrument purchased, we request you to use the instrument as per guidelines mentioned in the Operating Manual.

**6.0 Pre Requisite of Installation Qualification:** The following documents shall be available before starting the installation:

#### 6.1 Document Detail:

S.No.	Document Name	Available/Not Available	Checked by (Sign/Date)	Verified by (Sign/Date)
1.	Approved Design Qualification Report			
2.	Approved P & ID and layouts			
3.	Installation, Operation and Maintenance Manuals			

#### 6.2 Equipment Drawing:

A copy of the drawings, both technical and electrical shall be a part of the Installation Qualification Protocol. These drawings will be used for reference during actual installation and for any future trouble shooting purpose.

Parameters	Available/Not available	Checked by (Sign/Date)	Verified by (Sign/Date)
Electrical Circuit Diagrams			
Control panel Layout			

If there is any deviation from above documents then QA will be informed to Manufacturer through the purchase Department for corrective action.



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#### 6.3 Details of the Equipment Being Validated:

Equipment Name: Stability Chamber

Manufacturer Name: REMI

Location of the Equipment: Stability chamber

#### 7.0 Acceptance Criteria:

7.1 The equipment will be installed as per the supplier's recommendation, & as per the General arrangement drawing submitted with this installation qualification document.

7.2 The installation will be performed in the supervision of the validation team.

7.3 All checks of installation qualification will be found to be in accordance to the desired Requirement as mentioned in the specifications for the equipment.

#### 8.0 Re Qualification Criteria:

The equipment shall be subjected to installation re-qualification only under following reasons:-

- A. Change in location of the equipment.
- B. Change in the source of any of the utility being supplied to the equipment.
- C. Shifting out of the equipment for major maintenance or modification & again locating at the same place after completion of work.

#### 9.0 Installation Qualification Process:

##### 9.1 Site Acceptance Test:

S. No.	Description	Acceptance Criteria	Observation	Checked by Sign/Date
1.	Purchase Order copy	Should be Available		



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2.	Installation , Operation and maintenance Manual	Should be available		
3.	Qualification Document	Should be available		
4.	List of Spare Part	Should be available		
5.	Drawing and Layout	Should be available		
6.	Component packing	All the component should be packed properly to avoid any damage during transportation		
7.	Any physical damage to the equipment	No physical scratches or damage should be observed		

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

#### 10.0 SPECIAL FEATURES AND BENEFITS:

##### 10.1 PERFORMANCE:

- Designed as per ICH guidelines to meet, WHO AND USFDA requirement.
- Fulfills storage conditions of 25°C -60% RH, 40°C -75 % RH, 30°C -65% RH, 25°C -40% RH, 30°C -35% RH
- **Temperature Range:** 20°C To 60°C,Accuracy :  $\pm 0.2^{\circ}\text{C}$  ,Uniformity :  $\pm 1^{\circ}\text{C}$  (Stability Chambers)
- **Stability range:** 40% RH to 95% RH ,Accuracy :  $\pm 2\%$  RH, Uniformity:  $\pm 3\%$  RH (Stability Chambers)
- **Temperature Range:** 2°C to 8°C,Accuracy:  $\pm 0.2^{\circ}\text{C}$ ,Uniformity: $\pm 2^{\circ}\text{C}$ (Cold Rooms)
- In case of any trouble in running refrigeration system ,automatic change over to standby system for uninterrupted functioning (optional)
- In case of any trouble in running Stability system, Standby boiler heater in case of failure of first heater to ensure uninterrupted functioning (optional)

##### 10.2 LEADING TECHNOLOGY

- Auto change over to standby systems through PLC (Optional).



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- Auto switch over to standby sensor in case of controlling sensor failure
- PLC With touch screen HMI fully protected with password, instead of PID controller for precise control of temperature and Stability (optional).
- Data storage in PC server with LAN connectivity and password protection (Optional with software / under development stage).

#### 10.3 USER FRIENDLY

- Capacitance type Stability sensor enables direct display Of RH And temperature.(Stability Chambers)
- PC communication with RS-485 and software compiling to 21 CFR part 11 as per USFDA guidelines (Optional)
- Multipoint Temperature and Stability logger with printout facility (Optional)
- Five chambers connected to one software (Optional).
- Integration with BMS

#### 10.4 SAFETY

- Audio visual alarm for Temperature, Stability variations and utility failures
- Electrical circuit breaker.
- Safety includes shut off Stability and air heaters in case of temperature overshoots or undershoots beyond specified limits with alarms
- Low water level alarm and power cut off of boiler tank heater
- Time delay for compressor switch On
- Overload cut off relay for compressor.

#### 10.5 Overview of Walk - In Stability Chamber

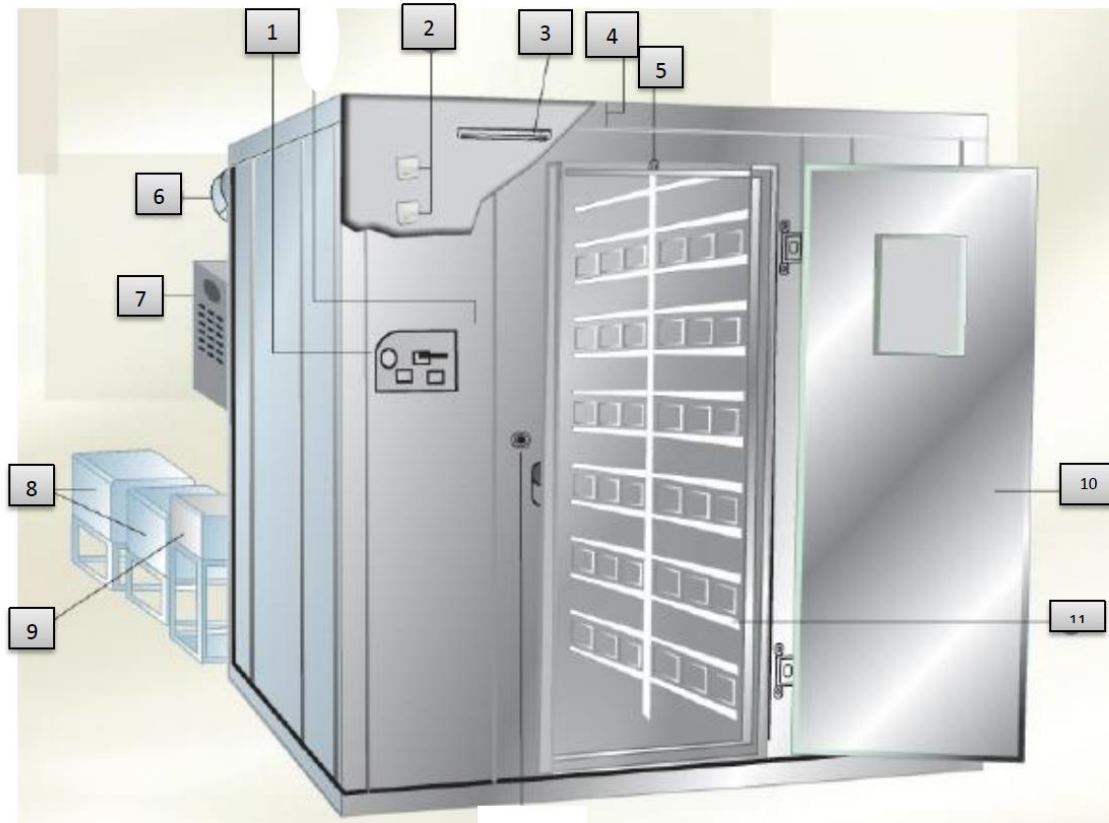




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#### 10.6 Identification of spares by Tag Number & its description:-

1. Intelligent PLC Control system helps maintain highly accurate set parameters
2. Dual Capacitance type Stability sensors failure of one sensor automatically transfers regulation to other sensor.
3. Chamber illumination by fluorescent tubes.
4. PUF insulation 80mm for maximum thermal protection.
5. Spring door latch for door closure
6. Blower motor for forced air circulation
7. Control panel with Data logger, PC connectivity and electrical components.
8. Standby refrigeration by compressor-1 and compressor-2 (Optional)
9. Standby Stability by heater -1 and heater-2 (Optional).
10. Highly ergonomic handle with unique multi lever key lock.



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11. SS

Racks and trays.

10.7 CONTROL PANEL  
(External):

In Chamber On extreme Right.

Location of Panel:  
Back Side of the Walk



Data Logger

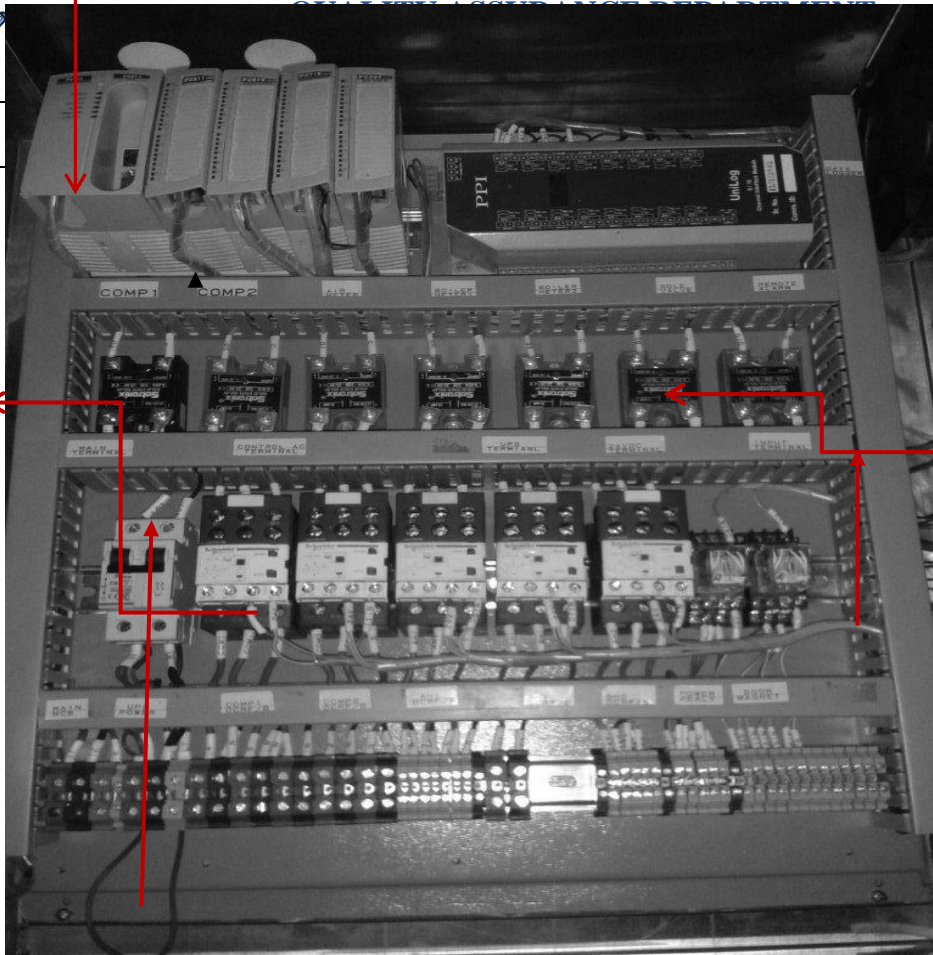
10.8 CONTROL PANEL (Internal)

PLC

SCANNER



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AMBER

OCR's  
RELAYS

CONNECTORS

UPS MCB



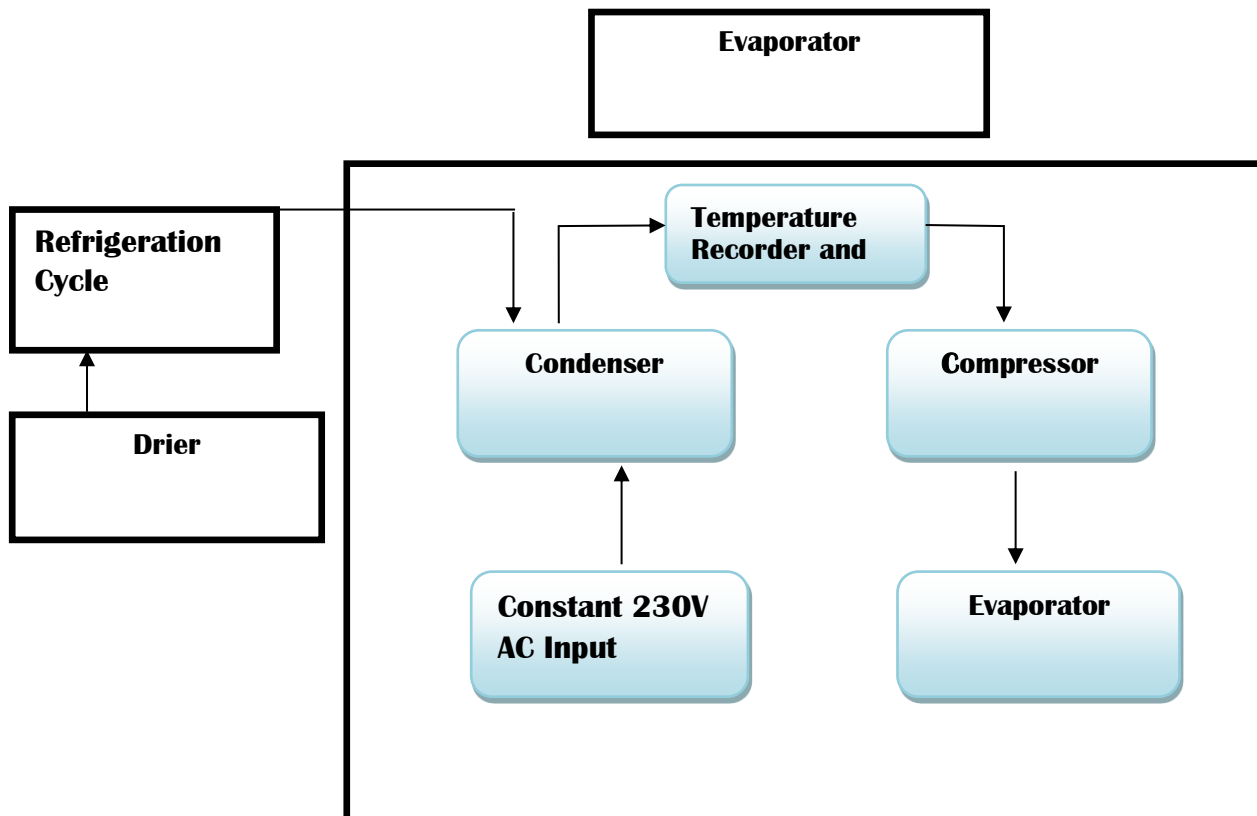
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#### 10.9 TECHNICAL DESCRIPTION

##### FUNCTIONAL FLOW DIAGRAM



#### 10.10 THE MAIN COMPONENTS OF THE REFRIGERATION SYSTEM ARE:

- **COMPRESSOR:**  
The compressor compresses low pressure low temperature refrigerant to high-pressure high temperature gas.
- **CONDENSER:**  
The condenser reduces the temperature of the high temperature, high- pressure gas in to the room temperature, high- pressure liquid.
- **DRIER:**  
This room temperature, high-pressure liquid passes through the drier where any traces of water vapor in the system are removed.
- **CAPILLARY:**  
From the drier, the liquid passes through the capillary where it suppresses to low-temperature low-pressure liquid.
- **EVAPORATOR:**



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This low pressure, low temperature liquid then passes through the evaporator. The evaporator is located within the cabinet whose temperature is to be maintained. The low temperature, low pressure liquid absorbs heat from the cabinet & changed into vapor system & is subsequently sucked into the compressor. The cycle then repeats.

#### 10.11 TECHNICAL SPECIFICATIONS:

##### TECHNICAL DATA FOR WALK – IN STABILITY CHAMBERS

Parameter	Specification
Internal Volume (Liters)	15000 Liters
Internal Dimensions W x D x H (mm)	2500 x 2500 x 2400
External Dimensions W x D x H (mm)	2660 x 2890 x 2560
Temperature range & Accuracy	20°C to 60°C, $\pm 1^\circ\text{C}$
Stability range (Rh) & Accuracy	40% to 95%, $\pm 3\%$
Temp. & Stability control	Microprocessor with capacitance type sensor
Display	6" Touch screen , Large size Display for ease of reading
Power failure alarm	Audio Visual alarm
Temp. / Stability variation alarm	Set Stability $\pm 5\%$ , Set temperature $\pm 2^\circ\text{C}$ , Audio visual alarm
Illumination	14 watts fluorescent Lamp
Internal Body Material	Stainless steel – 304 grade (GMP models)
External Body Material	Stainless steel – 304 grade (GMP models)
Insulation	80mm minimum for all panel & 40mm for door, CFC free polyurethane foam
Electrical	220 – 240 volts, 50Hz, Single Phase



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#### 11.0 INSTALLATION :

##### 11.1 UNPACKING & INSPECTION

At delivery, examine the exterior for physical damage. If there is no exterior damage, then carefully unpack & inspect the unit & all its accessories for any other kind of damage.

##### 11.2 INSTALLATION SITE

- ✓ Place the Walk In Chamber in AC or well-ventilated room.
- ✓ Flooring area should be zero level to avoid leveling of panels and zero leakages
- ✓ Ensure clear space of Two feet from backside and one feet from all remaining side for adequate ventilation. Poor ventilation will reduce the refrigeration capacity.
- ✓ Install the unit on a sturdy & leveled floor.
- ✓ The ambient temp. range at the location must be 15 to 32°C

##### 11.3 INSTALLATION PROCEDURE / CHECK POINTS

- ✓ Ensure proper Earthing of power point to the unit.
- ✓ Ensure the mains voltage is within the range as in the specification. If the voltage fluctuation is high, provide a servo voltage stabilizer.
- ✓ No power fluctuation should be there at site or use UPS supply for the PLC if it is necessary.
- ✓ Mark out by the area where Walk in CHAMBER is going to be installed.
- ✓ Install flooring panels first at location where Walk in CHAMBER is going to be installed.
- ✓ Install side & then ceiling panels.
- ✓ Install door at front panels as per drawing.
- ✓ Tight all panels by hexagonal key.
- ✓ Use sealant to fill gaps to avoid air leakages.
- ✓ Install the humidifier System
- ✓ Install outdoor refrigeration systems in service area. Length of copper piping from indoor to outdoor should not be more than 5 Meter Practically.
- ✓ Install internal lights & electrical control panel at particular place.
- ✓ Install electrical power & Control cabling from indoor to outdoor units with control panel.
- ✓ Charge up refrigeration systems as per standard procedure, leak test & nitrogen holding time should be proper before gas charging.
- ✓ Power up the Walk in CHAMBER and observe the operation.



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- ✓ Connect mains cord to 220/240 volts, 25 amp AC power points.
- ✓ Plug the unit & Switch ON MCB on right side of the unit.
- ✓ Check the HMI display glowing
- ✓ Add DM water in the boiler tank.
- ✓ The Walk In Chamber is now ready to use.

#### 11.4 Equipment Selection

Equipment name	Walk - In Stability Chamber
Process and product requirement	To control temperature and Stability in working chamber
Regulatory obligations	Equipment should maintain temperature with in $\pm 1^\circ \text{C}$ then set temperature and Stability in $\pm 3\% \text{RH}$ then set Stability.
Safety requirements	Temperature / Stability overshoot protection. Critical instrumentation such as Humidifier, Compressor safety protection devices.

#### 11.5 Vendor Details

Name	REMI ELEKTROTECHNIK LTD
Address	Survey 65/1, Valiv Village, Vasai (east), Thane – 401 208.
Contact person	Mr. V. Ramakrishnan
Phone no.	022-4058 9885
Fax no.	022-4058 9890
Email	.....

#### 11.6 Test Qualification Instruments

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

- Multimeter - 500 volts minimum, 10 amperes.
- Temperature, Stability Indicator – Minimum range 20~50°C, 40~85%RH

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

#### 11.7 EXECUTION:

The satisfactory installation of Walk - In Stability Chamber shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol will indicate that the Walk - In Stability Chamber is satisfactorily installed.

#### 11.8 Identification of Executor

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





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Name	Designation	Signature	Initial	Date

#### 11.9 Test Procedure (S)

The installation for Walk - In Stability Chamber shall be verified by reviewing the installed systems and physical parameters, using the test data sheets provided in this protocol. The test data sheets will be used to document the installation of the Walk - In Stability Chamber and to verify that the components of the Walk - In Stability Chamber confirm to design specifications.

#### 11.10 Verification of Test System Details

This test data sheet of the IQ is intended to provide identification of executable System verification.  
Test data sheet attached in Installation Qualification Test

#### 11.11 Verification of Master Documents

Compile list of specifications, documents, and manuals associated with system and record document number, title, Revision No and date of issue (if available).  
Test data sheet attached in Installation Qualification Test

#### 11.12 Verification of Scope of Equipment

Compile list of physical specifications associated with Walk - In Stability Chamber  
Test data sheet attached in Installation Qualification Test

#### 11.13 Verification of Control System Hardware Components

Physical system installation is verified with following documents and drawings. Verify the installed control system by visual inspection and record the relevant details of the individual control hardware components.  
Test data sheet attached in Installation Qualification Test

#### 11.14 Verification of Utility

Verify that the utility for the Walk - In Stability Chamber have been installed and is available as specified. Using the Multi meter, voltage at the unit power input end are measured and recorded. Measured readings are verified with system specification documents.  
Test data sheet attached in Installation Qualification Test

#### 11.15 Installation Qualification Discrepancy Report

Document any discrepancies or variations noted during the execution of the Installation Qualification. Include the resolution of these items and/or any item outstanding that will require further effort to resolve. When all the items are satisfactorily completed, document that the system is ready for the Operational Qualification.





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#### 11.16 Conclusion and Comments

All the IQ Data Sheets and discrepancy report shall be reviewed by validation team to prepare summary report. The summary of IQ shall be used to draw conclusion for approval of Installation Qualification Package.

#### 11.17 Qualification Completion and Approval

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

#### 11.18 INSTALLATION QUALIFICATION TESTS

S.No.	Test Name
1.	Verification of Test System Details
2.	Verification Of Master Documents
3.	Verification of Scope of Equipment
4.	Verification of Control System Hardware Components
5.	Verification Of Utility
6.	Installation Qualification Test Status
7.	Installation Qualification Discrepancy Report
8.	Summary And Conclusion



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#### 11.19 System Identification

Description	Specified As	As Observed	Verification Source	Discrepancy? (Y / N)	Tested By / Date
System Tag Number					
Location (Room #)					
Supplier					
Model No.					
Serial No.					

#### Remarks:

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Meet the acceptance Criteria      [      ] Yes                                      [      ] No

Verified by : \_\_\_\_\_ Date : \_\_\_\_\_

Reviewed by : \_\_\_\_\_ Date : \_\_\_\_\_

#### 11.20 Verification of Master Documents:

**Objective:** To ensure the system is adequately documented and this documentation is under appropriate document control.

**Procedure:** Verify availability of the listed documents with their reference no., revision no., date, etc details as specified in the test table.

**Acceptance criteria:** All the relevant documents listed in the test sheet must be available. Also the details specified in the test data sheet shall match with the documents.



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#### 11.21 DOCUMENTATION VERIFICATION

Sr. No.	Document Title	Document No.	Rev. No./ Date	Availability? (Y / N)	Checked By / Date
1.	System Operation Manual				
2.	General Assembly Drawing				
3.	System Wiring & Interconnection Diagram				

Remarks:

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Meet the acceptance Criteria [  ] Yes [  ] No

Verified by : \_\_\_\_\_ Date : \_\_\_\_\_

Reviewed by : \_\_\_\_\_ Date : \_\_\_\_\_

#### 11.22 Verification of Scope of Equipment:

**Objective:** To verify scope of equipment with system documents and drawings.

**Procedure:** Verify the scope of equipment by visual inspection and record the relevant details of the individual.

**Acceptance criteria:** Physical installation of the system shall be verified and details shall be recorded. Scope of the system shall match with details given in the Bill of Material or in the Manual of the system.



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#### 11.23 Scope of Equipment:

Description	Manufacturer Specification	Observation	Discrepancy? (Y / N / NA)	Tested By / Date
Make	REMI			
Model	WSC-150			
Serial No.	IHC - 3623			
Inner chamber size in mm	2500 × 2500 × 2400 (W × D × H)			
Number of Trays	30			
Tray Size in mm	765 x 800 x 50 (W x D x H)			
Temperature Range	20 ~ 60 °C			
Stability Range	40 ~ 90%RH			
Power Supply	230V, 50Hz,			

#### Material of construction

Outer chamber	SS-304			
Inner chamber	SS-304			
Trays	SS-304			
Insulation Material	PUF / 80 MM			

#### Remarks:

Verified by : \_\_\_\_\_ Date : \_\_\_\_\_

Reviewed by : \_\_\_\_\_ Date : \_\_\_\_\_

#### 11.24 Verification of Control System Hardware Components

**Objective:** To verify Physical system installation with system documents and drawings.

**Procedure:** Physical system installation is verified with following documents and drawings.

Verify the installed control system by visual inspection and record the relevant details of the individual control hardware components.

**Acceptance Criteria:** Physical installation of the system shall be verified and details shall be recorded. Model number and quantity of the Control System component shall match with details given in the Bill of Material of the system & physical system installation.



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#### 11.25 Hardware Components Verification (As Per Physical Installation):

Description	Manufacturer Specification	Observation	Discrepancy? (Y / N)	Tested By / Date
<b>Cooling System</b>				
Compressor Make	Emerson			
Compressor Model	KCM 519 CAL			
Condenser Motor Make	S.Z.C.D.F. Motor Co. Ltd			
Condenser Motor model	YDK 54-6/ 54 W			
Quantity	2			
<b>Heating System</b>				
Manufacturer / Supplier	Vijay Laxmi Electric Co			
Model No. / Cat. No. / Type	U Type Tubular heaters with fins			
Quantity	500 Watts x 4 Nos = 2000Watts.			
<b>Stability System</b>				
Manufacturer / Supplier	Sona Enterprises Electricals			
Model No. / Cat. No. / Type	Kettle Type			
Quantity	2000 Watts + Standby 2000 Watts			
<b>Air Circulation</b>				
Manufacturer / Supplier	REMI			
Type, Size	Flange Type, 0.21Hp			
Quantity	1			
<b>PLC</b>				
Manufacturer / Supplier	Mitshubishi Electrical			
Model No. / Cat. No. / Type	Nexgenie-2000+			
PSU	P2112			
CP U	P2211			
Serial Comm	P2511			



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Description	Manufacturer Specification	Observation	Discrepancy? (Y / N)	Tested By / Date
Digital Input Modules 16-pt. 24 VDC I/P	P2616			
Digital Output Modules 16-pt. 24 VDC I/P, 250mA	P2716			
24 V Dc 4 Channel Analog In	P2304			
Quantity	1 Each			
<b>HMI</b>				
Manufacturer / Supplier	Mitshubishi Electric			
Model No. / Cat. No. / Type	MS-70T-Ce			
Quantity	1			
<b>Temperature and Stability Sensors</b>				
Manufacturer / Supplier	Rotronic			
Model No. / Cat. No. / Type	HF120-WB1X			
Quantity	8			
<b>SMPS</b>				
Manufacturer / Supplier	Meanwell Electric			
Model No. / Cat. No. / Type	NES-150-24			
Quantity	1			
<b>Solid State Relays</b>				
Manufacturer / Supplier	SATRONIX			
Model No. / Cat. No. / Type	25 Amps			
Quantity	7			
<b>Electromagnetic Relay</b>				
Manufacturer / Supplier	Schneider Electric			



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Description	Manufacturer Specification	Observation	Discrepancy? (Y / N)	Tested By / Date
Model No. / Cat. No. / Type	LRD -14			
Quantity	5			
<b>Telemachanic Relay</b>				
Manufacturer / Supplier	Omron			
Model No. / Cat. No. / Type	MY2N / 24VDC & MY2N / 200-220 V AC			
Quantity	1 Each			
<b>Datalogger</b>				
Manufacturer / Supplier	PPI			
Model No. / Cat. No. / Type	Unilog / 8/16			
Quantity	1			

**Remarks:**

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Meet the acceptance Criteria [    ] Yes [    ] No

Verified by : \_\_\_\_\_ Date : \_\_\_\_\_

Reviewed by : \_\_\_\_\_ Date : \_\_\_\_\_



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#### 11.26 Verification of Utility

**Objective:** To verify that the utilities is installed and are available as specified.

**Procedure:**

1. Power on the system and put the Multimeter in AC voltage measurement range and measure the voltage at terminal end. Note down the voltage reading in the test data sheet.
2. Place the temperature near equipment. Note down temperature reading in the test data sheet.
3. Observe water tank size, quality and note down results.
4. Physically check water drainage location and note down observations.

**Acceptance Criteria:** Recorded measurements for voltage shall fall within the specified range.

Description	Specified	Observation	Discrepancy? (Y / N)	Tested By / Date
<b>Walk - In Stability Chamber</b>				
Voltage	200-230 V AC			
<b>UPS Supply for Monitoring System (Sensor and Display)</b>				
Voltage	200-230 V AC			
<b>Environment Conditions</b>				
Conditions	Temperature: 15 to 32 °C			
<b>Water Supply</b>				
Source	Continuous supply from an overhead tank			
Water tank capacity	Minimum 20 Liters			
Water Quality	DM Water/ Purified water/ Soft water free from impurities			
<b>Drainage</b>				
Location	At the back side bottom of the equipment			

#### 11.27 Test Instruments Used:

Test Instrument	Manufacturer	Tag number	Calibrated Date	Calibration Due Date	Tested By / Date

**Remarks:**

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Meet the acceptance Criteria [  ] Yes [  ] No

Verified by : \_\_\_\_\_ Date : \_\_\_\_\_

Reviewed by : \_\_\_\_\_ Date : \_\_\_\_\_



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### INSTALLATION QUALIFICATION FOR STABILITY CHAMBER

#### 11.28 INSTALLATION QUALIFICATION TEST STATUS:

Test Number	Test Name	Pass/Fail		Discrepancy Found	
		Pass	Fail	Yes	No
1	Verification of Test System Details				
2	Verification Of Master Documents				
3	Verification of Scope of Equipment				
4	Verification of Control System Hardware Components				
5	Verification Of Utility				

#### 11.29 Safety Features Identification:

S.No.	Safety Checks	Acceptance Criteria	Observation	Checked by/Date
1.	Electrical Insulation	Should be done		
2.	Earthing	Should be done		

Verified by (QC): Sign/Date

Verified by (QA) : Sign/Date

#### 11.30 Identification of Standard Operating Procedure:

S.No. No.	Particulars	Title	SOP No.
1.	Operation		
2.	Preventive Maintenance		

Verified by (QC): Sign/Date

Verified by (QA) : Sign/Date

#### 12.0 Deficiency and Corrective actions:



# PHARMA DEVILS

## QUALITY ASSURANCE DEPARTMENT

### INSTALLATION QUALIFICATION FOR STABILITY CHAMBER

S.No.	Deficiencies	Corrective action	Sign/Date

Verified by (QC): Sign/Date	Verified by (QA) : Sign/Date
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**13.0 Change Control:**

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.....

.....

**14.0 Reference & Attachment:**

Title	Available		Checked by	Date
	Yes	No		
<b>Documents:</b>				
Purchase Order				
Approved Design Qualification Report				
Installation, Operation & Maintenance Manual				
MOC Certificates				
<b>Drawing:</b>				



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### INSTALLATION QUALIFICATION FOR STABILITY CHAMBER

Electrical Circuit Diagram				
Electrical Termination Diagram				
P & I Diagram				
Control Panel Layout				



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### INSTALLATION QUALIFICATION FOR STABILITY CHAMBER

**15.0 Abbreviation:**

Abbreviation	Expanded Form
MOC	Material of Construction
ID.No.	Identification Number
QC	Quality control
QA	Quality Assurance
SOP	Standard Operating Procedure
STB	Stability chamber

**16.0 Summary and Conclusion:**

**Summary:**

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.....  
.....

**Conclusion:**

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.....

**17.0 Annexure: NA**



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### INSTALLATION QUALIFICATION FOR STABILITY CHAMBER

**18.0 Certification:** After successful completion of Installation Qualification equipment shall be certified by validation team and approved by In-charge QA.

#### *Certificate*

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

*Installation Qualification Protocol cum report No.:*

.....

**Remark:**.....

.....

.....

**Approved by:**



# PHARMA DEVILS

## QUALITY ASSURANCE DEPARTMENT

### INSTALLATION QUALIFICATION FOR STABILITY CHAMBER

19.0 Post- Approval:

Executed 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		