



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

FACTORY ACCEPTANCE TEST PROTOCOL CUM REPORT FOR STABILITY CHAMBER

Equipment Name: Stability Chamber

Document No.:

Rev. No.: 00

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Effective Date:

**FACTORY ACCEPTANCE TEST PROTOCOL CUM REPORT FOR
STABILITY CHAMBER**

EQUIPMENT: STABILITY CHAMBER

REVISION HISTORY

Rev.	Date	Authorized By:	Revision Summary
00	-----NA-----	-----NA-----	-----NA-----



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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
(Production)		
(Maintenance)		
(Quality Assurance)		

Approved By (Name & Designation)	Signature	Date
(Quality Assurance)		



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2.0 Objective: To define the protocol cum report for the FAT of the stability chamber.

3.0 Scope: This FAT Protocol cum report is applicable for Stability chamber to be installed.

4.0 Responsibility:

4.1 REMI Engineers shall be responsible for:

4.1.1 Fabrication of Equipment as per Design Specification.

4.1.2 To Provide the desired qualification document and component certificates.

4.1.3 To provide all related drawings and safety features.

4.1.4 To carry out Installation Qualification, Operation Qualification of equipment.

4.1.5 To coordinate in Factory Acceptance Test (FAT).

4.2 Site shall be responsible for:

4.2.1 Design the specification of equipment as per cGMP requirement.

4.2.2 To raise the purchase order after approval and authorization of Design Specification.

4.2.3 To carry FAT.

5.0 Equipment Description:

5.1 Intelligent PLC Control system helps maintain highly accurate set parameters

5.2 Dual Capacitance type Stability sensors failure of one sensor automatically transfers regulation to other sensor.

5.3 Chamber illumination by fluorescent tubes.

5.4 PUF insulation 80mm for maximum thermal protection.

5.5 Spring door latch for door closure

5.6 Blower motor for forced air circulation

5.7 Control panel with Data logger, PC connectivity and electrical components.

5.8 Standby refrigeration by compressor-1 and compressor-2 (Optional)

5.9 Standby Stability by heater -1 and heater-2 (Optional).

5.10 Highly ergonomic handle with unDQue multi lever key lock.

5.11 SS Racks and trays.

5.12 Equipment Details:

Stability Chamber Panels.

Stability Chamber Panels Accessories.

Flooring Panels.

Stability Chamber Door.

Stability Chamber Refrigeration Indoor & Outdoor Units.



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Stability Fiery System Details.

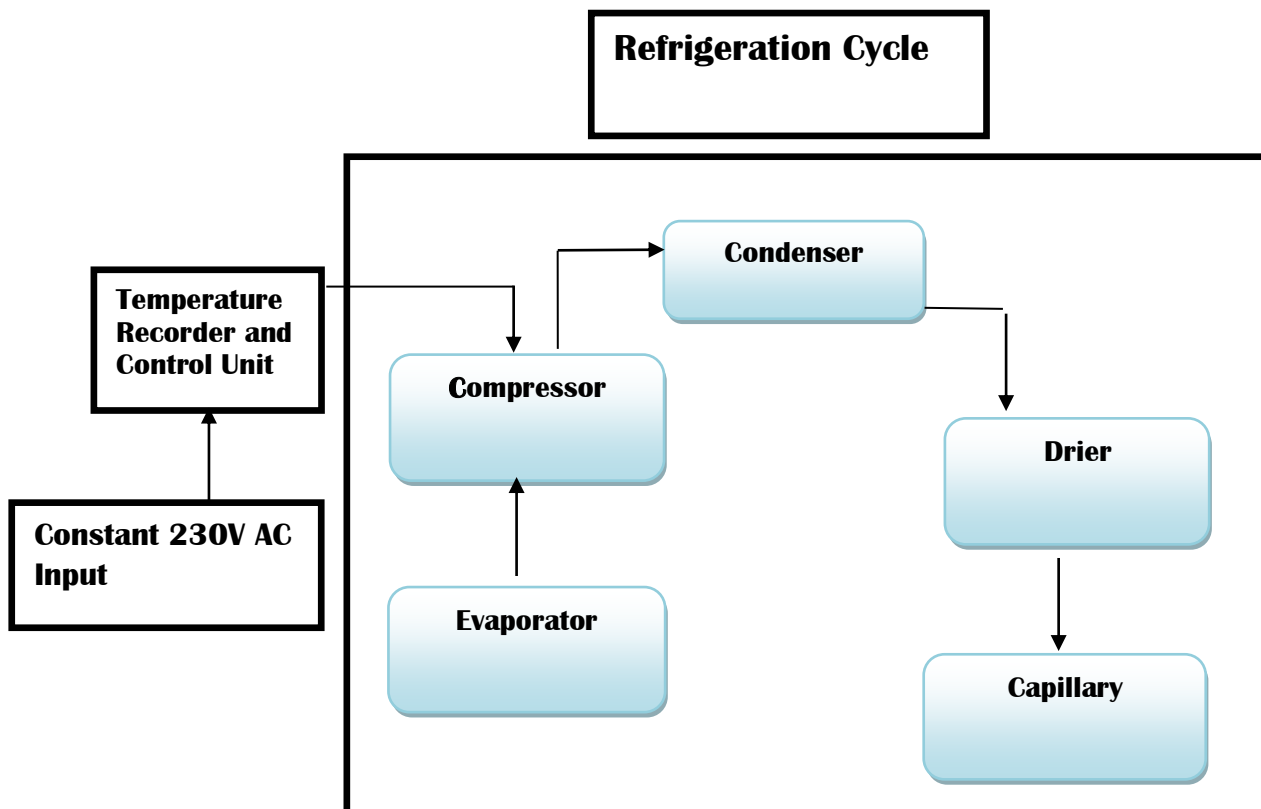
Refrigeration Installation Accessories.

Electrical Control Panel.

Control Cabling.

6.0 Function Mechanism:

6.1 FUNCTIONAL FLOW DIAGRAM





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6.2 THE MAIN COMPONENTS OF THE REFRIGERATION SYSTEM ARE:

6.2.1 COMPRESSOR:

The compressor compresses low pressure low temperature refrigerant to high-pressure high temperature gas.

6.2.2 CONDENSER:

The condenser reduces the temperature of the high temperature, high- pressure gas in to the room temperature, high- pressure IDQuid.

6.2.3 DRIER:

This room temperature, high-pressure IDQuid passes through the drier where any traces of water vapor in the system are removed.

6.2.4 CAPILLARY:

From the drier, the IDQuid passes through the capillary where it suppresses to low-temperature low-pressure IDQuid.

6.2.5 EVAPORATOR:

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



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6.3 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 2860 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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6.4 Test Procedure (S):

The design of the Walk - In Stability Chamber shall be verified by reviewing the installed systems and physical parameters, using the test data sheets provided in this protocol cum report. 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.

6.4.1 Verification of Test System Details:

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



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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 Design Qualification Test

6.4.2 Verification of Scope of Equipment

Compile list of physical specifications associated with Walk - In Stability Chamber

Test data sheet attached in Design Qualification Test

6.4.3 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 Design Qualification Test

6.4.4 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 Design Qualification Test

6.4.5 Design 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 Installation Qualification.

6.4.6 Conclusion and Comments

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

6.4.7 Qualification Completion and Approval

1. Verify that all tests required by these reports 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 Walk - In Stability Chamber have been reviewed and found to be acceptable, sign the corresponding block in the Qualification Completion and Approval form.



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6.5 Factory Acceptance Test:

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.	Design Qualification Test Status
7.	Design Qualification Discrepancy Report
8.	Summary And Conclusion

6.5.1 Test System Details:

Objective: This test sheet of the FAT is intended to describe which and what system is being validated.

Procedure: Confirm the following parameters from the system.

- Identification Tag no.
- Manufacturer/Supplier
- Model No.
- Serial No.

1. Record the equipment/system location with location tag plate.
2. Record the verification source. (i.e. Nameplates, Room location tag etc.)

Acceptance criteria: Data recorded from the name tag plates/room plates shall match with the data specified in test data table.



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6.5.2 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:

Meet the acceptance Criteria [] Yes [] No

Verified by : _____ Date : _____

Reviewed by : _____ Date : _____



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6.5.3 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.

6.6 DOCUMENTATION VERIFICATION

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

Remarks:

Meet the acceptance Criteria [] Yes [] No

Verified by : _____ Date : _____

Reviewed by : _____ Date : _____



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6.6.1 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.

6.6.2 Scope of Equipment

Description	Manufacturer Specification	Observation	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,		
Outer chamber	SS-304		
Inner chamber	SS-304		
Trays	SS-304		
Insulation Material	PUF / 80 MM		

Remarks:

Verified by : _____

Date : _____

Reviewed by : _____

Date : _____



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6.6.3 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.

6.6.4 Hardware Components Verification (As Per Physical Installation)

Description	Manufacturer Specification	Observation	Discrepancy? (Y / N)	Tested By / Date
Cooling System				
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			
Heating System				
Manufacturer / Supplier	Vijay Laxmi Electric Co			
Model No. / Cat. No. / Type	U Type Tubular heaters with fins			
Quantity	500 Watts x 4 Nos = 2000Watts.			



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Description	Manufacturer Specification	Observation	Discrepancy? (Y / N)	Tested By / Date
Stability System				
Manufacturer / Supplier	Sona Enterprises Electricals			
Model No. / Cat. No. / Type	Kettle Type			
Quantity	2000 Watts + Standby 2000 Watts			
Air Circulation				
Manufacturer / Supplier	REMI			
Type, Size	Flange Type, 0.16KW			
Quantity	1			
PLC				
Manufacturer / Supplier	Mitshubishi Electrical			
Model No. / Cat. No. / Type	Nexgenie-2000+			
PSU	P2112			
CP U	P2211			
Serial Comm	P2511			
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			



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Description	Manufacturer Specification	Observation	Discrepancy? (Y / N)	Tested By / Date
Quantity	1 Each			
HMI				
Manufacturer / Supplier	Mitshubishi Electric			
Model No. / Cat. No. / Type	MS-70T-Ce			
Quantity	1			
Temperature and Stability Sensors				
Manufacturer / Supplier	Rotronic			
Model No. / Cat. No. / Type	HF120-WB1X			
Quantity	8			
SMPS				
Manufacturer / Supplier	Meanwell Electric			
Model No. / Cat. No. / Type	NES-150-24			
Quantity	1			
Solid State Relays				
Manufacturer / Supplier	SATRONIX			
Model No. / Cat. No. / Type	25 Amps			
Quantity	7			
Electromagnetic Relay				
Manufacturer / Supplier	Schneider Electric			
Model No. / Cat. No. / Type	LRD-14			
Quantity	5			
Telemechanic Relay				



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

Remarks:

Meet the acceptance Criteria [] Yes [] No

Verified by : _____ Date : _____

Reviewed by : _____ Date : _____



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6.6.5 Verification of Utility

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

Procedure : 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.

1. Place the temperature near equipment. Note down temperature reading in the test data sheet.
2. Observe water tank size, quality and note down results.
3. 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
Walk - In Stability Chamber				
Voltage	200-230 V AC			
UPS Supply for Monitoring System (Sensor and Display)				
Voltage	200-230 V AC			
Environment Conditions				
Conditions	Temperature: 15 to 32 °C			
Water Supply				
Source	Continuous supply from an overhead tank			
Water tank capacity	Minimum 20 Liters			
Water Quality	DM Water / Purified water / Soft water free from impurities			
Drainage				
Location	At the back side bottom of the equipment			



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Remarks:

Meet the acceptance Criteria [] Yes [] No

Verified by: _____ Date: _____

Reviewed by: _____ Date: _____

6.7 FAT QUALIFICATION TEST STATUS:

Test Number	Test Name	Pass/Fail	
		Pass	Fail
1.	Verification of Test System Details		
2.	Verification Of Master Documents		
3.	Verification of Scope of Equipment		
4.	Verification of Control System Hardware Components		

6.8 TERMINOLOGIES& BASIC INFORMATION:

A. Alarm

A device or function that signals the existence of an abnormal condition by means of an audible or visible discrete change, or both, intended to attract attention.

B. Control System

A system in which deliberate guidance or manipulation is used to achieve a prescribed value of a variable.



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C. EEPROM

Is a PROM that is electrically erasable. The EEPROM can be programmed or erased while it is still in the circuit and used like a nonvolatile read / write memory.

D. LED

Light Emitting Diode. Status indicators available on the PLC modules to reflect the Input/output and processor status.

E. HMI

Human Machine Interface

F. PLC

Programmable Logic Control

G. DM Water

Demineralization

6.9 Specification Test:

S.No.	Specification	Observation	Checked by (Sign/Date)
1.	Equipment shall be fabricated in accordance with approved drawing		
2.	Arrangement/connection of required utility		
3.	Test certificate of MOC		
4.	Equipment shall be finished smoothly		
5.	General Arrangement Drawing shall be available		
6.	P&I Diagram shall be available		
7.	Purchase Order		
8.	System Specification		
9.	Installation, Operation and Maintenance Manuals		
10.	Spare part list		
11.	Drawings		



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6.10 Deficiencies and Corrective Action:

S.No.	Deficiencies	Corrective action	Responsibility	Sign/Date

7.0 Re qualification criteria: Re qualification shall be done if there is any variation of the equipment in design specification

8.0 List of Spare Part:

S.No.	Name of spare part	Quantity
1.	Cap retaining fingers	01 No.
2.	Top hold down	01 No.
3.	Suspension mount	01 No.
4.	Spring sets	01 No.
5.	Vibrator strips	01 No.
6.	Vibrator coil	01 No.
7.	Vibrator controller	01 No.
8.	Pick up plate	01 No.
9.	Sealing roller (crimping roller with bearing)	01 No.
10.	Chuck for different type of seals	01 No.
11.	SMPS	01 No.
12.	Sensor (No stopper no vial)	01 No.
13.	Sensor (No cap on chute)	01 No.

9.0 Change Control:

.....
.....

10.0 Abbreviation:

S.No.	Abbreviation	Expanded Form
1.	FAT	Factory acceptance test
2.	MOC	Material of construction
3.	GA	General Arrangement
4.	P& I	Piping & Instrumentation



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11.0 Equipment/ system Drawing & Documentation Requirement:

- GA Drawing
- Electrical circuit Diagram
- Control Panel Layout
- Pneumatic circuit Diagram
- P & I Diagram
- Installation operation & maintenance manuals
- MOC Certificates

12.0 Summary and Conclusion:

12.1 Summary:

.....
.....
.....

12.2 Conclusion:

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.....
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13.0 List of Reference Document/ Records:

- URS
- Equipment Drawing
- Layouts



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14.0 Annexure and Attachment: All the Drawing, lay out, MOC, certificates, shall be attached with FAT Protocol cum Report as Annexure and attachment.

15.0 Certification: The equipment shall be certified as per the following format –

Certificate

*This is to certified that FAT Qualification activity of **Stability Chamber** has successfully completed as per the following document.*

FAT Protocol cum Report No.	
------------------------------------	--

Remark:

.....
.....
.....

Approved By:
(Sign & Date)



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16.0 Post-Approval: Based on the data collection and combination of the data, draw the conclusion of complete study. A 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
(Production)		
(Maintenance)		
(Quality Assurance)		

Approved By (Name & Designation)	Signature	Date
(Quality Assurance)		