PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR STABILITY CHAMBER

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE 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

PERFORMANCE QUALIFICATION FOR STABILITY CHAMBER

Quality Control		
Maintenance		
Quality Assurance		

Approve By (Name & Designation)	Signature	Date
Quality Assurance		

PERFORMANCE QUALIFICATION FOR STABILITY CHAMBER

2.0 Objective:

To objective of this protocol is to check the performance of the Stability Chamber supplied by Remi.

Performance Qualification Protocol shall provide the methodology of qualification studies, formats for recording the observation, Criteria of Qualification and a guideline for documentation of the study.

3.0 Scope: This Protocol is applicable to check the performance 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 To review Performance Qualification protocol.

4.1.2 To provide required utility for performance of equipments.

4.2 Quality Control:

Quality control personnel shall be responsible for:

4.2.1 To review Performance Qualification protocol.

4.2.2 Carrying out the related tests outlined in the protocol.

4.3 Quality Assurance:

Quality Assurance personnel shall be responsible for:

4.3.1 To prepare and review of Performance qualification protocol.

4.3.2 Execution of the protocol after approval and carrying out the PQ tests outlined in the protocol.

4.3.3 To perform sampling as per sampling plan.

4.3.4 Verification and completion of the data for tests.

4.3.5 Preparation and review of PQ report

4.3.6 To review Performance Qualification protocol.

4.3.7 To execute Performance Qualification protocol.

4.3.8 Supervision of process & review of data.

PERFORMANCE QUALIFICATION FOR STABILITY CHAMBER

5.0 Equipment Description:

5.1 General Description:

The Stability Chamber consists of the following features.

- **The Stability Chamber is equipment** which can maintain the temperature and humidity as per the set point on the controller with in the specified limits.
- A conditioning duct is provided at the backside of the chamber, which consists of a cooling coil, air heaters, and air circulating blower and motor arrangement.
- The air is sucked in from the working chamber and thrown vertically downwards which passes through the cooling coil and air heater and later comes back in the working chamber.
- The same air is re-circulated again to give maximum uniformity of temperature inside the chamber.
- The chamber motor is placed at the backside of the chamber with blower inside the duct and motor projecting outside.
- The chamber is divided into three part, i.e
    1. Main working area.
    2. Refrigeration compartment (Top of the chamber).
    3. The control panel (Top of the chamber).
- The control panel is provided with Microprocessor based PLC controller with digital and connected to PT-100 sensor.
- A separate safety alarm system is fitted which will cut off the heater supply case the temperature and humidity over shoots the set temperature and humidity.
- The compressor is provided with an overload cut-off and a fuse.

5.2 Equipment Identification

The subjected instrument is identified as **stability chamber**

ID No.:.....

Name of the supplier: Remi

5.3 Standard operating procedure established during operation Qualification

Title: Operating Procedure of stability chamber. SOP No: ----------

PERFORMANCE QUALIFICATION FOR STABILITY CHAMBER

6.0 PERFORMANCE QUALIFICATION CHECKS:

Performance of the stability chamber shall be tested at extreme and optimum operation conditions, Which are identified as critical process variables.

6.1 Critical Process Variables

- Alarm verification
- Empty chamber heat distribution
- Loaded chamber heat distribution
- Door open recovery study
- Power failure recovery study

7.0 METHODOLOGY:

7.1 ALARM VERIFICATION

S.No.	Description of Method of Testing	Acceptance Criteria
1.	**High Temperature Safety Thermostat:** Set controller temperature of the chambers 2°C above the actual set temperature of safety thermostats. Now the heater will start and temperature will start rising. The safety thermostat will trip and cut off the supply to heater and alarm will start.	Alarm should start in the chambers
2.	**High Humidity Safety Thermostat:** Set controller Humidity of the chambers 5% RH above the actual set Humidity of safety thermostats. Now the humidifier will start and Humidity will start rising. The safety thermostat will trip and cut off the supply to humidifier and alarm will start.	Alarm should start in the chambers

S.No.	Description Of Method Of Testing	Acceptance Criteria
1	Low Temperature Safety Thermostat Set controller temperature of the chambers 2°C below the actual set temperature of safety thermostats. Now the refrigeration system will start and temperature will start decreasing. The safety thermostat will trip and alarm will start.	Alarm should start in the chambers
2	Low Humidity Safety Thermostat Set controller Humidity of the chambers 5% RH below the actual set Humidity of safety thermostats. Now humidity will start decreasing. The safety thermostat will trip and alarm will start.	Alarm should start in the chambers

7.2 EMPTY CHAMBER HEAT DISTRIBUTION:

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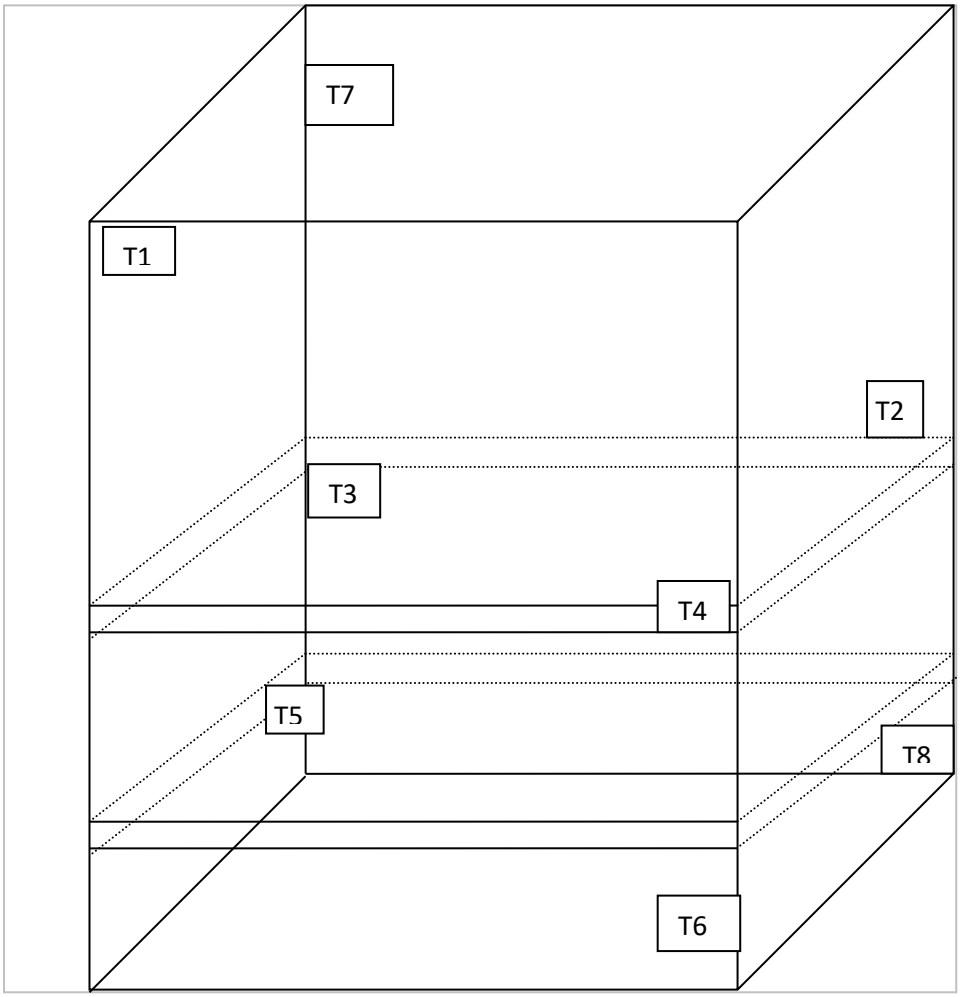
Purpose: To know the temperature and humidity at various position inside the empty chamber in running condition.

Scope: Temperature and humidity variation should not be more than ±2.0ºC and 3.0% RH respectively in sample storage area than the set temperature and humidity.

Temperature sensor position



Procedure:

a) Check that all the utilities before starting the activity.
b) Distribute temperature and humidity sensors in chamber as per temperature and humidity mapping diagram.
c) Now set the temperature and humidity of chamber (Temperature 40ºC and humidity 75%RH).
d) Set the recording /printing interval as 10 minutes in data loggers.
e) Close and lock the door of equipment: keep it locked till the test is over.

f) Allow the equipment to achieve required temperature and humidity.
g) Now start recording temperature and humidity.
h) Run the equipment for 24 hours.
i) Now take printing of performance of equipment. All the reading should be within the limit. If any reading going out of range due to failure of utility then make note of it.
j) Temperature variation should not be more than ±2.0ºC in sample storage area than the set temperature.
k) Humidity variation should not be more than ±3.0% RH in sample storage area than the set humidity.
l) Result: as per attached performance printout.

7.3 LOADED CHAMBER HEAT DISTRIBUTION

Purpose: The purpose of this test is to check the actual performance of the stability chamber under load condition.

Scope: Temperature and humidity variation should not be more than ±2.0ºC and 3.0% RH respectively than the set temperature and humidity in sample storage area.

Procedure:

a) Load the chamber with dummy loads keeping air circulation passage clear. Also the samples should be in the confined area of storage trays. Ensure that the chamber is loaded to approximately 70% of its capacity.
b) Check all the utilities before starting the activity.
c) Distribution temperature and humidity sensors in chamber as per temperature and humidity mapping diagram.
d) Set the recording/printing interval as 10 minutes in data loggers.
e) Close and lock the door of equipment: keep it locked till the test is over.
f) Allow the equipment to chieve required temperature and humidity.
g) Now take recording temperature and humidity.
h) Run the equipment for 24 hours.
i) Now take printing of performance of equipment. All the reading should be within the limit.if any reading goining out of range due to failure of utility then make note of it.
j) Temperature variation should not be more than ±2ºC in sample storage area than the set temperature.
k) Humidity variation should not be more than ±3% RH in sample storage area than the set humidity.
l) Result: as per attached performance printout.

7.4 DOOR OPEN RECOVERY (STUDY)

Purpose: this study is performed to know the recovery time of the equipment for the controlled parameter (Temperature) when the door is opened.

Procedure:

a) Check all the utility before starting the activity.
b) Distribute temperature sensors in chamber as per temperature mapping diagram
c) Now set the temprature and humidity of chamber (Temprature 40ºC and humidit 75.0%RH).
d) Set the recording/printing interval as 10 minute in data loggers.
e) Allow chamber to attain temprature and humidity.
f) Now open the door of chamber up to 90ºC angles and keep it open for the 10 minutes.
g) Now close the door and note recovery time for the controlled parameters: if they had moved out of range.
h) **Result:** As per attached printout

7.5 POWER FAILURE RECOVERY (STUDY)

Purpose: This study is performed to know the recovery time of the equipment for the controlled parameter (Temperature) when the power has failed.

Procedure:

a) Check all the utility before starting the activity.
b) Distribute temperature sensor in chamber as per temperature mapping diagram
c) Now set the temprature and humidity of chamber (Temperature 40°C and humidity 75.0%RH).
d) Set the recording /printing interval as 5 Minute in data loggers.
e) Allow chamber to attain temprature and humidity.
f) Now switch off the power of equipment keeping power to monitiring and recording system ON.
g) Turn ON the power after 15 minutes and note recovery time for the controlled parameter: if they had moved out of range.
h) **Result:** As per attched printout.

7.6 ACCEPTANCE CRITERIA

Stability chamber tested during performance qualification studies should comply to the following parameter.

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S.No.	Test Parameters	Acceptance Limit
1.	Alarm verification	Alarm should start
2.	Empty chamber test run	Temperature variation should not be more than ±2.0°C and humidity should not be more than 3.0%RH in sample storage area then the set temperature and humidity.
3.	Loaded chamber test Run	Temperature variation should not be more than ±2.0°C and humidity should not be more than 3.0%RH in sample storage area then the set temperature and humidity.
4.	Door open recovery study	Temperature and humidity should be recovered to set value after closing the door. Data to be compiled.
5.	Power Failure recovery study	Temperature and humidity should be recovered to set value after turning ON the power. Data to be compiled.

Any deviation from the acceptance criteria of the specific check point shall be reported and decision shall be taken for the rejection, replacement or rectification of the equipment/component.

7.7 PRESENTATION OF DATA:

7.7.1 Alarm verification

7.7.2 High Tempeature/Humidity Safety

Set Temperature	Observed temperature at which alarm started (higher side)	Acceptance Criteria
40°C		Alarm should start after rise in 'chamber temperature' than the 'set temperature of safety thermostat + 2°C'
Set Humidity	Observed Humidity at which alarm	Acceptance Criteria

	started (higher side)	
75%		Alarm should start after rise in 'chamber Humidity' than the 'set humidity + 5%'

7.7.3 Low Tempeature/Humidity Safety

Set Temperature	Observed temperature at which alarm started (lower side)	Acceptance Criteria
40°C		Alarm should start after decrease in 'chamber temperature' than the 'set temperature of safety thermostat - 2°C'

Set Humidity	Observed Humidity at which alarm started (lower side)	Acceptance Criteria
75%		Alarm should start after decrease in 'chamber Humidity' than the 'set humidity - 5%'

Remark: _____

	Name	Signature	Date
Verified By			

7.7.4 Verification of temperature and humidity distribution study data in empty chamber

7.7.4.1. For Temperature

Channel no.	Set Temperature	Observed Temperature			Acceptance Criteria
		Min.	Max.	Average	
1	40°C				Temperature variation should not be more than ±2.0°C in sample storage area then the set temperature from 24 hours data
2					
3					
4					
5					
6					
7					
8					

7.7.4.2. For Humidity

Channel no.	Set humidity	Observed humidity			Acceptance Criteria
		Min.	Max.	Average	
1	75% RH				humidity variation should not be more than ±3.0°RH in
2					
3					
4					

5					sample storage area then the set humidity from 24 hours data
6					
7					
8					

Remark: _____

	Name	Signature	Date
Verified By			

PERFORMANCE QUALIFICATION FOR STABILITY CHAMBER

7.7.5 Verification of temperature and humidity distribution study data in loaded chamber

7.7.5.1. **For Temperature**

Channel no.	Set Temperature	Observed Temperature			Acceptance Criteria
		Min.	Max.	Average	
1	40°C				Temperature variation should not be more than ±2.0°C in sample storage area then the set temperature from 24 hours data
2					
3					
4					
5					
6					
7					
8					

7.7.5.2. **For Humidity**

Channel no.	Set humidity	Observed humidity			Acceptance Criteria
		Min.	Max.	Average	
1	75% RH				humidity variation should not be more than ±3.0°RH in sample storage area then the set humidity from 24 hours data
2					
3					
4					
5					
6					
7					
8					

Remark: _____

	Name	Signature	Date
Verified By			

PERFORMANCE QUALIFICATION FOR STABILITY CHAMBER

7.7.6 Door open Recovery Study:

Set Temperature	Initial Temperature reading	Observed Temperature after opening of the door for 10 minutes	Recovery temperature reading	Recovery time taken to get set temperature again
40°C				

Set Humidity	Initial Humidity reading	Observed Humidity after opening of the door for 10 minutes	Recovery Humidity reading	Recovery time taken to get set Humidity again
75%RH				

Remark: _____

_____

	Name	Signature	Date
Verified By			

7.7.7 Power failure Recovrey Study:

Set Temperature	Initial Temperature reading	Observed Temperature after power failure for 15 minutes	Recovery temperature reading	Recovery time taken to get set temperature again
40°C				

Set Humidity	Initial Humidity reading	Observed Humidity after after power failure for 15 minutes	Recovery Humidity reading	Recovery time taken to get set Humidity again
75%RH				

Remark: _____

_____

	Name	Signature	Date
Verified By			

8.0 EVALUATION OF RESULTS:

Results shall be documented in the test data sheets provided as attachement to the protocol. Based on the observation recorded in the performance qualification tests, evaluation of the results shall be carried out.

All the result meeting the acceptance criteria shall establish that the stability chamber qualifies for all relevent parameter when operated as per SOP No.---------- and can be used for routine jobs.

9.0 CHANGE CONTROL AND RE-QUALIFICATION CRITERIA:

Performance Qualification of stability chamber to be Re-Qualified on:

- Replacement of existing instrument / compound with a new one, which can have a direct impact on the performance of the machine.

- Any major modification to the existing machine which can affect the performance of the equipment.
- If the machine is found to be malfunctioning during performance qualification.
- Shifting / Reinstallation / Re commissioning of the equipment from one location to another.
- If there is any change in components, requalification shall be carried out through proper change control system.

Checks	Observations Yes/No	Remarks(if any)
Whether the acceptance criteria of the protocol and specific checkpoint are met.		

10.0 SUMMARY AND CONCLUSION

The stability chamber **is** qualifying / **is not** qualifying the performance Qualification test as per the guideline described in this protocol. The stability chamber **can be used/ cannot be used** for routine use.

10.1 Summary:

10.2 Conclusion:

11.0 APPENDIX

11.1 Abbreviations

SOP : Standard Operating Procedure
PQ : Performance Qualification
QC : Quality Control.

11.2 Annexure

S.No.	Annexure Details	Annexure Number

12.0 Re Qualification Criteria:

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

12.1 Change in location of the equipment.

12.2 Equipment does not perform within the predetermined specification

13.0 Deviation:

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14.0 Change Control:

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15.0 Summary and Conclusion:

Summary:

……

……

……

Conclusion:

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……

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PERFORMANCE QUALIFICATION FOR STABILITY CHAMBER

16.0 Certification: After successful completion of Performance Qualification, equipment shall be certified by validation team and shall approve by Head Quality Assurance as per the following format.

Certificate

This is to certify that Performance Qualification activity of Stability Chamber, Equipment ID.: ..... has successfully completed as per the following documents.

Performance Qualification Protocol cum Report No.:	.....

Remarks:

……

……

……

Approved by:

17.0 **Post-Approval:** Based on the data collection and compilation of the data, draw the conclusion of the complete study. A protocol cum 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
Quality control		
Maintenance		
Quality Assurance		

Approve By (Name & Designation)	Signature	Date
Quality Assurance		