



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR STABILITY CHAMBERS

USER REQUIREMENT SPECIFICATION

FOR

STABILITY CHAMBERS



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TABLE OF CONTENTS

S.No.	DETAILS	PAGE No.
1.	APPROVAL	03
2.	OBJECTIVE	04
3.	SCOPE	04
4.	RESPONSIBILITY	04
5.	PURPOSE	04
6.	INSTRUMENT/ EQUIPMENT SPECIFICATION	04-05
7.	HISTORY OF CHANGE	06
8.	ABBREVIATIONS	06



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1.0 APPROVAL:

This is a specific document prepared for Quality Assurance..... Hence, this document before being effective shall be authorized by the Head QA /Designee.

Prepared By:

Department	Name	Designation	Signature	Date
Quality Assurance				

Reviewed By:

Department	Name	Designation	Signature	Date
Engineering				
Quality Control				

Approved By:

Department	Name	Designation	Signature	Date
Quality Assurance				

Authorized By:

Department	Name	Designation	Signature	Date
Quality Assurance				

Vendor Approval:

Company	Name	Designation	Signature	Date



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2.0 OBJECTIVE:

The objective of this document to Identify the stability chamber to cater existing requirement for the charging the finished products.

3.0 SCOPE:

The scope of this document is limited to the Stability Chamber which will be installed in the Quality Control department.

4. RESPONSIBILITY:

QA Department: To provide the URS for the instrument

5. PURPOSE:

The purpose of this exercise is to clearly identify the detailed requirements of the equipment from an engineering, scientific, safety and user prospective. This would enable the user group to selection of the right vendor and have the equipment constructed and built to the exact requirements based on our technical specification.

6. INSTRUMENT SPECIFICATION:

Stability chambers for two different storage conditions, however remaining specification is quite similar in the both cases. Details tabulated below.

Requisites	Specification
Material of construction	<ul style="list-style-type: none">Stability chamber shall have Inner chamber & outer chamber made of stainless steel 304.Stability chamber must have Stainless steel double door system its locking facility and inner full size see through transparent door for viewing samples inside the chamber without disturbing insideChamber shall have intact circulation of temperature and Relative consistently
Capacity	<ul style="list-style-type: none">3000 liters
Area	<ul style="list-style-type: none">W 1500 X D 1860 X H 1960 mm (for each chamber)
Working Range	<ul style="list-style-type: none">30 °C $\pm 2^{\circ}\text{C}$ / RH 75\pm5 for one chamber40 °C $\pm 2^{\circ}\text{C}$ / RH 75\pm5 for second chamber
Temperature and Relative Humidity	<ul style="list-style-type: none">Cut off with above stated tolerance range
Utilities	<ul style="list-style-type: none">Water tank with boiler heater to attain desired Relative humidity and TemperatureWater circulation in the intact way no seepage.Air circulation blower with capacity range (Aprox 1400RPM).Heater and cooling coils run smoothly with consistent supply.Compatible and run on power supply of 230V /AC.
Safety Features and Alarm	<ul style="list-style-type: none">MCB shall in place.Provision of Light in the walk in chamber.Indicator buzzer.Emergency switch.Temperature excursion



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Requisites	Specification
	<ul style="list-style-type: none"> • Power failure. • Water level. • Power failure alarm. • Other utilities breakdown alarm.
Software	<ul style="list-style-type: none"> • 21 CFR Part 11 Compliance. • Access control (user level wise) shall be in place. • Data archival/data export provision shall be in place. • Printout provision is required. • Software shall have provision of SMS alert /equipment Parameter setting/Real time display/Real time Summary/Equipment status.
Back UP	<ul style="list-style-type: none"> • UPS provision • Double motor • Double compressor
Documents/Qualifications	<ul style="list-style-type: none"> • Operational Manual • Warranty letter • Complete qualification documents (DQ/IQ/OQ/PQ) • All traceable certificate

Remarks:

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7.0 HISTORY OF CHANGE:

Revision No.	Effective Date	Reason for change	Supersede No.	CC No.
00		New Equipment	Nil	

8.0 ABBREVIATIONS:

Abbreviation	Extended Form
URS	User Requirement Specifications
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operation Qualification
PQ	Performance Qualification
UPS	Uninterruptible Power Supply