



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Walk in Stability Chamber

Protocol No.:.....

Functional Area: Quality Control

Page No.: 1 of 7

Name of Equipment: Walk in Stability Chamber

Document Reference Number:

Effective Date :.....



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Walk in Stability Chamber

Protocol No.:.....

Functional Area: Quality Control

Page No.: 2 of 7

1.0 Approval:

Signing of this approval page of URS indicates agreement in this document. Should Modifications to the user Requirements Specification approach become necessary, an addendum will be prepared and approved.

Prepared by	Signature	Date
Checked By	Signature	Date
Reviewed By	Signature	Date
Approved By	Signature	Date



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Walk in Stability Chamber	Protocol No.:
Functional Area: Quality Control	Page No.: 3 of 7

2.0 Table of Content:

Table of Contents		Page No.
1.0	Approval	2
2.0	Table of Content	3
3.0	Introduction	4
4.0	Overview Definition	4
5.0	Operational Requirements.	5
5.1	Operation	5
5.2	Power failure / Recovery	5
5.3	Emergency stop	5
5.4	Alarms and Warnings	6
6.0	Salient Features.	6
6.1	Compatibility and support	7
6.2	Material of construction	7
6.3	Instruments & controls	
7.0	Maintenance	7
8.0	Delivery.	7
9.0	Documentation	7



USER REQUIREMENT SPECIFICATION

Name of Item: Walk in Stability Chamber	Protocol No.:
Functional Area: Quality Control	Page No.: 4 of 7

3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for a walk in stability chamber.

The URS shall be recognized as the integral part of the procurement agreement with the selected equipment vendor. The equipment supplier or vendor shall abide by the information and condition set forth by this document as well as purchasing and delivery terms and conditions of the Client.

The walk in chamber shall be interfaced with the 8 point temperature and 8 point humidity scanner complete with sensors and printer interface and data storage facility.

The chamber requires certain environmental conditions.

1. Temperature
2. Relative Humidity

This chamber will be used to find out of self life of products.

4.0 OVERVIEW DEFINITION:

4.1 The Walk in Stability Chamber shall have the following features:

- 4.1.1. The machine shall have updated operating screen panel for operating PLC.
- 4.1.2. The PLC shall be designed for auto change over of standard by humidity system and refrigeration system.
- 4.1.3. The chamber shall be designed to provide the temperature between 20°C to 60°C and humidity 40% RH to 98% RH.
- 4.1.4. The chamber shall be provided with the SS 316 racks and trays with mirror polished.
- 4.1.5. The chamber shall be provided with direct %RH electronic capacitor type humidity sensors which will avoid wick and water.
- 4.1.6. The chamber should be capable to shut off the boiler heater and air heater in case of over shoot and undershoot of temperature giving audio video alarm.
- 4.1.7. All chamber should be provided with scanner 8 point temperature and 8 point humidity scanner complete with sensor and printer interface and data storage facility.

4.2 The Walk in Chamber shall be used for:

Stability studies of finish product under the specified temperature and humidity.

4.3 Technical Specifications:



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Walk in Stability Chamber	Protocol No.:
Functional Area: Quality Control	Page No.: 5 of 7

- 4.3.1 **Chamber Capacity** : 36000 liters
- 4.3.2 **Dimension inner** : 3.2 x 4.5 x 2.5 meters
- 4.3.3 **Dimension outer** : 3.36 x 4.66 x 2.66 meters
- 4.3.4 **Temperature range** : 20 °C to 60°C
- 4.3.5 **Temperature Accuracy** : $\pm 0.2^{\circ}\text{C}$
- 4.3.6 **Temperature uniformity** : $\pm 0.2^{\circ}\text{C}$
- 4.3.7 **Humidity Range** : 40% RH to 98% RH
- 4.3.8 **Humidity Accuracy** : $\pm 2\%$ RH
- 4.3.9 **Humidity Uniformity** : $\pm 3\%$ RH

4.4 The machine is to be used at the following environmental conditions:

- 4.4.1 Temperature : Ambient
- 4.4.2 Relative Humidity : Ambient

4.5 Base Utilities Available:

- Electrical : Three Phase, 230V $\pm 10\%$ 50 HZ
- Compressors : Compressors
- Temperature Controller: Stand by Refrigerator System
- Humidity Controller : Stand by Humidity Controller
- Lock : Numeric Door Lock
- Data : Data Logger Interface

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The Walk in chamber shall operate with a minimum of operator involvement. Operation shall be safe both from an operator and environmental standpoint.

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system shall shut off automatically. The system will start automatically after getting the electricity and start functioning according to previous setting.



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Walk in Stability Chamber	Protocol No.:
Functional Area: Quality Control	Page No.: 6 of 7

5.3 SAFETY FEATURE:

The system shall be stop safely in emergency.

5.4 ALARMS AND WARNINGS:

The system shall have an Emergency alarming facility. Incase any parameter goes up or down from set parameter. The chamber should produce wipe sound until further command received or all set parameter comes within the set parameter.

The walk in stability chamber should have provision to produce wipe sound if door is opened for long while.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

The Supplier shall utilize Programmable Logic Controller that shall include a communication port.

UTILITIES:

The Supplier shall specify utility requirements. The User shall ensure that the utilities are available and that the utility supply lines and piping are terminated with fittings or connections.

6.2 MATERIAL OF CONSTRUCTION:

- Outer side** : Stainless Steel 304.
- Inner side** : Stainless Steel 304 Mirror Polish
- Racks & Trays** : Stainless steel 316 with mirror polish

6.3 Instruments & controls : PLC system

7.0 MAINTENANCE:

Do's and Don'ts to be provided

- 7.1 Preventive maintenance system and checks to be provided (Maintenance and operation manuals of vendor equipment)
- 7.2 A comprehensive lubrication list and recommended lubrication schedule
- 7.3 A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list)



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Walk in Stability Chamber	Protocol No.:
Functional Area: Quality Control	Page No.: 7 of 7

7.4 Supplier shall supply 2 Copies of Operation, Installation, and Maintenance manuals, DQ, Electrical drawing

8.0 DELIVERY:

The walk in stability chamber with all options, equipment, and the documentation listed below, shall be delivered to Site.

Delivered should be confirmation of the purchase order.

9.0 DOCUMENTATION:

9.1 The Supplier shall provide the documentation for preliminary review. The Supplier shall provide documentation reflecting “as-built” condition with final delivery.

9.2 All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect “As-Built” condition.

9.3 All documents shall be in English language and supplied with hard copies and supplied in the format identified for each document.

9.4 Design qualification.

9.5 Installation Qualification.

9.6 Operational Qualification.

9.7 Maintenance and service manuals.

9.8 Instrument listing.

9.9 Material of construction.