USER REQUIREMENT SPECIFICATION

Name of Item: Stability Chamber	**Protocol No**.:.....
Functional Area: Quality Control	**Page No.:** 1 of 3

1.0 **Purpose:** To describe the specific requirement of Stability Chambers.

2.0 **Scope:** This specification is applicable to the Stability Chambers to be installed at quality control laboratory.

3.0 **System Description:** Stability Chambers shall be used for conducting stability studies of finished products. As per ICH guidelines the stability monitoring shall be done at following conditions:

40 ± 2° C & 75 ± 5% RH for Accelerated study

30 ± 2° C & 60 ± 5% RH for Real Time study

Therefore, different chambers shall be set at the above mentioned conditions and samples shall be kept accordingly. Since stability of the drug product is the major concern for regulatory authorities therefore, the stability chamber should be equipped with sophisticated measuring devices for sensing all the minor variations in the chambers. Based on the requirements listed above the stability chamber shall consist of the following listed features. However, additional features shall also be considered.

3.1 Capacity1000 ltrs with minimum five perforated shelves to hold multiple sizes of bottles ranging from 30 ml to 200 ml and shall have the provision for expandable space for placing additional shelves, if required.

3.2 Material of construction: Outer SS316 and inner with SS316/SS304 (preferably SS316). The wall should be insulated with PUF / Glass Wool to minimize heat loss and maintenance of temperature uniformity. For inside view of the chamber, it should have clear view window and proper illumination of the chamber.

3.3 It should have independent boiler system for maintenance of humidity inside the chamber.

3.4 It should have rugged heating and cooling systems to avoid frequent breakdowns in the heating system. The heaters should be made of SS or Nichrome and the arrangement of the heaters should be such that all the corners and the middle of the chambers shall have the temperature within the specified range.

3.5 The cooling system should consist of a branded compressor and CFC free cooling gas filled inside the cooling system.

3.6 It should have the safety alarm systems whenever there is temperature and humidity display is on upper side and lower side of the set value. It should have the provision for cut -off device in case of temperature shoot up.

3.7 The temperature range should be between 20-60°C with variation of 1°C. The humidity range should be from 40-85% with variation of 3%. It should have provision for regulation of the temperature and humidity within the specified values.

3.8 It should have electronic or suitable sensors, fitted at suitable places for monitoring of temperature and humidity within the chamber.

3.9 It should have stand by cooling system and boiler system for temperature and humidity, so as to minimize breakdown time. This system should be equipped with automatic switching whenever the main system fails.

3.10 The temperature and humidity control should be through suitable electronic controlling device. The equipment should have facility for printer attachments for recording of all the values stored in PC.

3.11 The software for recording of the data should be 21CFR Compliant. The data for temperature, humidity and any deviation observed in the equipment should be recordable. Additional feature should also be taken into care..

3.12 The manufacturer/ supplier should provide complete documentation for validation of the equipment.

3.13 The manufacturer/ supplier should provide the following calibration certificates:

3.13.1 For material used for construction.

3.13.2 All the measuring devices including temperature, humidity, display units etc.

3.14 After sales service back up should be from approachable distance so as to minimize breakdown time, if any.

4.0 Documentation: Supplier/Manufacturer shall provide the following document.

- P & I diagram, circuit diagrams which ever applicable
- Calibration certificates for all gauges or measuring devices with trace-ability.
- Test and guarantee certificates.
- Qualification (DQ, IQ, OQ, PQ) documentation
- Individual part certificates, if any.
- Operator's manual

5.0 Other Considerations: The manufacture/ supplier shall have the commonly used spares in stock. If not, the manufacture/ supplier shall have the provision to arrange at the earliest. The manufacture/ supplier shall provide the validation/ calibration support for the next 3-5 years. The manufacture/ supplier shall provide the written document for the validation support at the time of placing the final order. The manufacture/supplier shall provide technical guidance to the Engineering section for general maintenance of the stability chambers.

Prepared By:
Date:

Approved By:
Date: