

# Stability Test Chamber



**TOPLAB INDIA'S** Our **stability test chambers** are easy to install, use and calibrate. Lamp replacement is safe, quick and easy to perform. The whole unit is mounted on casters helping in mobility of the equipment anywhere in laboratory. We also produce GMP compliant photo stability chambers that are supplied with IQ, OQ, PQ, & DQ documentation complete with reports, calibration and test certificate.

These Photo Stability chambers are specifically designed to perform near UV and visual light testing with fluorescent lamps per **ICH Q1B Guidelines, Option 2**. Designed matching with international standards **ICH, WHO Guideline, and USFDA Standards**. Our stability chambers are recommended for laboratories, universities and pharmaceutical research labs. These chambers provide uniform temperature control, low maintenance and allow quick response for forced degradation testing and confirmatory studies.

## Advantages:

- ❖ Conform to ICH, WHO Guideline, and USFDA Standards
- ❖ Automatic shut off after specified exposure level
- ❖ CFC free Poly Urethane Foam insulation
- ❖ High quality hermitically sealed compressor
- ❖ Mirror finished stainless Steel interior chamber
- ❖ Powder coated high grades stainless steel construction
- ❖ Mild Steel Doors with magnetic gasket & lock
- ❖ Uniform airflow distribution
- ❖ Safety controller with separate sensor
- ❖ Printer interface and data storage facility
- ❖ Printer interface for LUX & UV meter
- ❖ CE and ISO Certified
- ❖ 21 CFR Part II Data Compliance

## Stability Test Chamber

### Technical Features:

#### ❖ Capacity:

Standard models are available with capacity 100 Liters, 170 Liters, 255 Liters, 450 Liters, 800 Liters and 1000 Liters.

#### ❖ Temperature Humidity Range:

Temperature range from 10°C to 60°C with accuracy of  $\pm 0.1^\circ\text{C}$  -  $\pm 1^\circ\text{C}$ . The humidity range is 20% to 90% RH with accuracy of  $\pm 2\%RH \sim \pm 3\%RH$ .

#### ❖ Illumination:

Equipped with ICH-compliant illumination ideal for photo-stability testing and provides clear and meaningful test results, according to ICH guideline Q1B, Option 2).

A cool white florescent light for 1.2 million LUX hour's exposure

UV-A lights for 200 watt hours/square meter exposure

Both the lights have independent control to avoid over exposure

#### ❖ Control System:

Imported Microprocessor based PID controller with direct display of SET and Process value of temperature and humidity. The control panel consists of circuit breaker, dry / wet heater and compressor with indication lamps. Non-volatile memory to allow chamber to return to original set point when power is restored in the event of power failure.

#### ❖ Construction:

Come with double walled construction, with a choice of customers the external chamber can be made of Mild Steel, 304, 316 or 316L grades stainless steel with painted or powder coated finish. The internal chamber is made of 304 grades stainless steel with mirror finish. The gap between two chambers is filled with thick CFC free PUF insulation which minimizes heat loss and helps in low energy consumption. The whole unit is mounted on caster wheels for easy mobility.

#### ❖ Doors:

With inner glass door user can easily view samples inside without any botheration. Outer door is solid and made of M.S, 304 or 316 grades stainless steel. Door is fitted with magnetic gasket and locking system.

#### ❖ Heating and Cooling:

For highly efficient heating these equipment use **U shaped stainless steel jacketed heating element**. An automatic temperature limit keeps the system safe from over-heating due to workload. For cooling high capacity industrial cooling system is used which keeps set temperature and RH values unaffected. Superior cooling performance is achieved through **hermitically sealed compressor** which is CE marked and of reputed brand. Uniform air distribution system helps in maintaining steadiness in environment.

#### ❖ Humidity Generation:

Heater based humidity generator with float valve controlled water reservoir. Steam is conducted into the inner chamber by means of conduits from the Humidity Generator. An additional device, water failure protection is fitted for flawless performance. This device disconnects heater supply in case of water supply failure and starts automatically when the water supply resumes.

#### ❖ Pre-Installation Requirements:

Pharmaceutical Test Chambers or Photo stability Chambers require essential checks before installation.

Below 30°C room temperature

Adequate power supply with stabilizer, MCD and Earthing

Continuous DM or Distilled Water Supply

Air conditioned or cross ventilated environment

#### ❖ Validation:

Each stability chamber is validated before delivery to the customer. We offer complete validation with document evidence showing that the installed equipment meets the specifications of manufacturer, user and the applicable regulations. We also provide services to validate stability test chambers for our customers so they have complete documentation citing that their equipment will function properly **according to IQ, OQ and PQ protocols**. We also offer on-site validation services to **satisfy FDA guidelines** for qualification verification of equipment.

## Stability Test Chamber

### Technical Specifications:

Models	TL-100SC	TL-170SC	TL-255SC	TL-450SC	TL-800SC	TL-1000SC
Capacity (Liters)	100 Liters	170 Liters	255 Liters	450 Liters	800 Liters	1000 Liters
Capacity (Cubic Feet)	4 Cu. Ft.	6 Cu. Ft.	9 Cu. Ft.	16 Cu. Ft.	30 Cu. Ft.	35 Cu. Ft.
Temperature Range	10°C to 60°C					
Temperature Accuracy	±0.1°C - ±1°C					
Humidity Range	20 to 90 % RH					
Humidity Accuracy	±2%RH - ±3%RH					
Display	LCD / LED Display					
Resolution	0.1°C - 1%RH					
Temperature sensor	PT - 100					
Control	Microprocessor PID Controller					
RH sensor	Direct capacitance type					
Heating	'U' shaped Nichrome wire heater in SS sheathing					
Cooling	CFC free Copeland make compressor utilizing R 134A eco friendly refrigerant, with condenser, motor and relay					
Air circulation	Flange motor with impeller / blower					
Chamber illumination	Fluorescent light with door switch					
Illumination	1.2 Million LUX Hours					
Construction	Double Walled					
Construction Material	M.S. / 304 Grades Stainless Steel (Powder Coated)					
Shelves	Made of Stainless Steel wire					
Number of Shelves	2 to 8 (Extra Trays on Demand)					
Power Supply	230 / 240 Volts					
Standards	ICH, WHO Guideline, and USFDA					
Caster Wheels	Optional					
Safety features	High temperature safety cut off Electrical overload cut off relay for compressor Time delay for compressor switch ON Electrical circuit breaker					

### Optional Accessories:

PLC with (OSLOG) software	Magnetic door lock feature	GSM system
HMI (Human Machine Interface)	Digital light indicator (Lux meter w/ UV Indication)	Digital PID controller with printer interface
PC interface	Data logger	Calibration Certificate
Audio / Visual Alarm	Stainless Steel Water Tank	Extra Shelves or Trays

### Distributor:



### Product by:

## TOPLAB INDIA

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