

PHOTO STABILITY CHAMBER

AN ISO 9001: 2015 CERTIFIED CO. & CE MARK PRODUCT



Construction:

This unit is double walled chamber. Interior made of stainless steel and exterior is either mild steel Finished with powder coating or stainless steel. Glass wool/puf insulation between both the wall is Provided. Full-lenght inner glass door and outside metal door with magnetic gasket & lock. Forced air Circulation for uniform temperature. One stainless steel perforated tray is provided. The tray can be Placed at various heights to accommodate the change in sample height. The purpose of doing so is to Vary the exposure intensity to reduce the test duration. PU wheels for easy move ability.

Illumination:

Photo stability chambers provide lights as per option 2 mentioned in ICH guidelines A cool white florescent light for 1,2 million LUX hours exposure. UV-A lights for 200 watt hours / square meter exposure. Both the lights have independent control to avoid over exposure. Chamber is illuminated using 4nos of flourescent tube light to produce visible light (measure in lux). A one no. Near UV light of wavelength 365nm (measured in watt/sq. Meter) are fitted on topside of the chamber.

Controls:

The equipment is PLC controlled and has controlled exposure with temperature and humidity (optional). The light gets OFF automatically once the exposure is achieved. Refrigeration and PID control heating systems are provided to carry out testing at a precise Temperature. Humidity control system can also be provided. Temperature Controller with Ethernet Communication

Power Supply:

The unit works on 230 volts AC and 50Hz mains supply.

Cooling System:

19 - Daily, Weekly, Monthly.

Hermitically sealed compressor coupled with evaporation coil Temperature Range: +20°C To +60°C and condenser, safe guarded by time delay circuit. CFC free refrigerant.

Temp. Range:

Accuracy: + 0.2 C

Temperature Uniformity: + 1c

Humidity Range:

Stability Data Management Software 21 CFR Part 11 Compliance :

21 CFR part 11 Compliance. Online & Offline Data representation Temperature Range: 40% To 85% RH. in Tabular as well as Graphical Form. Separate display formats for Real time Data & Acquired Data for single or multiple chambers Mean Kinetic Value (MKT) as per USP 24 NP

Uniformity: ± 3% RH.

Accuracy: + 1% RH.

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Optional Accessories:

ICDAS Software: Centralized work station for viewing, trending performance of equipment. Software complies to US FDA21 CFR Part 11. Calibrated LUX and UV-A meters to measure visible light and UV light intensities Touch screen display. To satisfy regulatory requirements the equipment has Ethernet interface for communication with ICDAS software. It records temperature control, LUX exposure, UV exposure and optional Humidity control parameters.

Safety Features:

Supervisory Safety Monitoring System has been introduced for additional Safety measures. Individual additional micro - controlled is used for this supervisory system. If the temperature & humidity value crosses set Hi & Low limits for either or both parameters, safety control action will be taken over by this controller. If the parameters sets within the limit value, main control action will resume automatically. 2 Min. Compressor ON delay time for safety of compressor. Float switch to cutoff the main supply & audio visual alarms in case of low water level.

Validation:

With 8 Temp. & 8 RH point scanner with sensor printer interface & Data storage facility, 24 hrs with load & 24 hrs w/o load, 8 hrs power failure test, 15 mins door opening test for one condition only.

ICH Guidelines:

All stability chamber meet the ICH Q1A guidelines for stability testing including:

Long Term: 25°C/60% RH or 30°C/60% RH

Intermediate: 30°C/65% RH or 30°C/75% RH

Accelerated: 40°C/75% RH.

Documentation:

To comply with the documentation requirements, we provide ISO 900 IQ, OQ & PQ protocols to be executed before taking the chamber product. in to for regular use, and support the supply with the following documents with the detail operational and service manual.

Standard Operating Procedure (SOP)
Operational Manual for Controller
IQ,PQ,OQ protocols certificate.
Calibration certificate of all controlling modules with traceability.
Certificate of MOC.

Test Report of chamber prior to supply with mapping certificate. wiring diagram for ease of service maintenance.

Certification:

ISO 9001:2015 Certified Co. D&B registered & CE mark product.

Calibration & validation certificates traceable to NABL / ERTL accredited labs.

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Model No. PHSC-10	Cap cuft	acity Itrs.	Internal dimension W x D x H (cms)	External dimension W x D x H (cms)	TRAY (cms)
PHSC-A	4	80	45 X 45 X 40	87.5 X 70 X 64.5	45 X 45
PHSC-B	8	150	50 X 50 X 60	128.5 X 79 X 89.5	45 X 45

PHOTO STABILITY CHAMBER WITH HUMIDITY

Model No. PHSC-11	Cap cuft	acity Itrs.	Internal dimension W x D x H (cms)	External dimension W x D x H (cms)	TRAY (cms)
PHSC-A	4	80	45 X 45 X 40	87.5 X 70 X 64.5	45 X 45
PHSC-B	8	150	50 X 50 X 60	128.5 X 79 X 89.5	45 X 45

Due to continuos development & improvements in design, we reserve the right to change the specification without notice.