

PHOTO STABILITY CHAMBER

AN ISO 9001 : 2015 / 14001 : 2015 / WHO-GMP CERTIFIED CO. & CE MARK PRODUCT

Model No : SRL / PHSC-10



Construction:

MOC of the Chamber will be: Double walled Chamber with Inner of stainless steel 304 grade & outer of CRCA epoxy powder coated, PUF Insulation in between two walls.

- Double door, inner door of glass with frame & silicon gasket sealing, outer door metallic with PUF insulation.
- (ii) The unit will be made of double walled leak proof metal door with lock, with a provision of opening door from inside.
- (iii) Forced air circulation for uniform temperature.
- (iv) Lockable & Movable PU wheels for easy movement.

Insulation of Walls, ceiling and floor: 80mm thick puff panels with puff in-place density of minimum of 1kg per cubic foot. Exterior metal surface of insulation puff panels or its equivalent shall be of minimum 19 gauge embossed white stainless steel or its equivalent. Interior metal surface of insulation puff panels or its equivalent shall be of minimum 19 gauge stainless steel with baked white enamel finish or its equivalent. Exterior and interior metal surface shall not have metal-to- metal bonding.

Door : Flush type doors of metal surfaces (as per above specification of metal) with proper puff insulation of above mentioned standard or its equivalent. Doors shall have magnetic snap-in perimeter gasket or its equivalent, self-closing cam lift gravity hinges or its equivalent, a posi-seal door closure or its equivalent. Door shall have key lockable latch handle. Doorjambs shall be made fiberglass reinforced plastic or any other suitable material compatible with constructed door.

Trays : Removable SS bar type trays of suitable size are provided, are adjustable up to 0.5 inch increment/decrement and slide out for easy clean up.

Power Supply :

Single phase 230V AC, 50Hz.

Refrigeration system :

Emerson / Danfoss / Tecumseh: make compressors, 1 stage cooling system for TEMP. & Humidity Control. All accessories such as HPCO/LPCO, Oil Separators, Dryers, Relays, OLP etc. of Danfoss/Tecumseh Emerson Make. CFC free refrigerant to be used to comply with the New Environmental Regulation. Will have suitable tonnage compressor for maintain temperature with lights on. Will have hermetically sealed condensing unit compressor coupled with Evaporation coil and condenser, safe guarded by time delay circuit. Cabinet shall be supplied with air-cooled condensing unit with extended compressor life and close temperature control. Cooling system will be split type to place condenser unit in a ventilated area to avoid hot air in growth chamber. Cooled air shall be delivered in such a way to reduce or eliminate condensation within media dishes and to provide maximum uniformity In different research vessels. This may be through silent and durable fan motors or through any kind of advanced air diffusers. Air Cooled Condenser with solenoid & LP to pass hot gas to the chamber for uniformity & long life of compressor for continuous usage. Phenolic coating for cooling & condensing coils (All weather proof).

Application :

Used for large number of sample in hospitals, Research institution. Public health laboratories etc. These chamber can be used for environment testing of production sample & large size equipments where temp. & humidity are to be controlled. They are suitable for storage of electronic components, biological specimen & accelerated ageing test of large number of pharmaceutical samples. They can also used for botany, cytological, Deptsrturents, plan & animal breeding laboratories where controlled condition of temp. humidity & illumination are required.

Ecocentric System :

Chamber runs on the basis of Dewpoint control. Less deviations during short-term door opening & power failure. Less utility area Increased storage area. Low operating cost. Minimum power & water consumption. Reduced deviations. Less breakdowns due to standby refrigeration & humidification system. Due to PLC HMI & controlling through microprocessor based PID Temp. & RH operations the on time of both Temp. & RH system is reduced & efficiency of this system is increased with reduced energy consumption.

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Controller:

PID Action: Provides Precise Temperature, Maintain Uniform And Accurate Growth Environment, Timer, Alarm, Auto-Tuning And Auto Start Stop Function. Technical Design and Construction Silent Fan Motor to Maintain Uniform Temp. Over Temp. and Current Protection Capability Ensure User Safety, Adjustable Sliding Rack, Alert Unexpected Interruption Of Electrical Power Or Unauthorized Change. **Optional : [PLC with HMI TFT screen]**

PLC with HMI Control system with touch screen display & HMI for data Storage, data logger reading & audit trail, Door access & SMS records, Email alert. Data Logger 1 temp + 1 RH. Data Logger with LCD display window capable to store non volatile data memory up to 5000 readings with audit trail facility complies 21 CFR Part 11. Change over to stand by system automatically as per schedule or on detecting fault with current system Tempe. & Humidity overshoot and under shoot protection Mobile Alarm system, Door Access, system setting reset , Graph, SMS, Email alert, etc.

Test Condition :

All Photo 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.

Safety Features :

2 minute compressor "on" delay timer to safeguard the compressor. Compressors overload relay protector. Electronic low water level cut off device to cut off the supply to boiler heater in case of low water level. Safety Temp. Controller. MCB for mains.

- Unit will be provided with safety devices for temperature and humidity overshoot in case of malfunction.
- (ii) Built-in temp. Deviation, audio/visual alarms.
- Safety thermostat for over shooting of temp. Safety circuit to cut off the whole system.
- (iii) OLP (Overload Protector) & Time delay Circuit for safety of compressors.
- (iv) HRC fuses for compressors, Heaters & Mains.

Documentation :

To comply with the documentation requirements, we provide IQ, OQ & PQ protocols to be executed before taking the chamber 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.

Temp. & Humidity Range :

Temperature Range: +10°C To +60°C

Resolution : 0.1°C, Accuracy : <u>+</u> 0.2°C, Uniformity : <u>+</u> 2°C

Humidity Range: 40% To 95% RH.

Resolution : 0.1%, Accuracy : \pm 2%, Uniformity : \pm 3%.

Validation :

Validation of Chambers (Temperature Mapping) will be done at different zones in the chamber using pre calibrated multi channel Scanner (4 Channels for Temperature & 4 Channels for RH). Mapping of the chamber ensures the uniform temperature & Humidity inside the chamber as per the ICH norms and there by to determine the Hot zone and Cold zones.

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.

Air Circulation : [Laminar Type]

The chamber is provided with best air circulation to give better temperature uniformity this is achieved by using one set of motor & blower in baffle wall Compartment to push treated air in working chamber. This system gives better than 1 deg c. temperature uniformity in working chamber, evaporator, heaters & steam injection system is from back side, behind baffle wall, the air circulation blower is also fitted in this compartment only. This arrangement helps to mix steam and air together and pass well mixed air inside the working chamber. Due to above system the temperature and humidity (R.H.) in complete chamber almost remains equal.

Certification :

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

ISO 14001:2015 & WHO-GMP

ISO 45001:2018 & ISO/IEC 17025: 2017

NSIC & MSME registered / ROHS Compliance / UL Compliance

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