



STABILITY CHAMBER

[GMP MODEL]

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

Model No : SRL / SC-10A



Construction :

These chamber are Double wall PUF insulated modular panel. Construction material shall be double walled construction with backside triple. Insulation shall be thick PUF Insulation Exterior executed in Stainless Steel SS 304. Interior executed in Stainless Steel SS 304. The door shall be made of 80 mm thick PUF insulated panel clad with SS 304 inner & SS 304 inner on outer, flash type fitted with glass viewing window, imported Cam hinges, lock, and door closer. The door is sealed with the silicon gasket to prevent the leakage. Shall have Full view observation Acrylic door with gasket to observe sample inside the chamber. Lockable & Movable PU wheels for easy movement.

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.

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.

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.

Air Circulation :

The Stability 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. temp. 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.)

Refrigeration system : (Air Cooled)

Emerson / Danfoss / Tecumseh: make compressors, 1 stage cooling system for temp. & humidity system. 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).

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Controller :

Standard PID: 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 Temperature 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 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.

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.

- (i) 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.

Power Supply :

Single phase 230V AC, 50Hz.

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.

Temp. & Humidity Range :

+10°C to +60°C,
Accuracy : $\pm 0.2^{\circ}\text{C}$, Uniformity : $\pm 1^{\circ}\text{C}$, Resolution : 0.1°C

Relative humidity from 40% to 98%,
Accuracy : $\pm 1\%$ RH , Uniformity : $\pm 3\%$ RH., Resolution : 0.1% RH

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.

Heating / Humidification & Dehumidification :

Custom built U shaped Stainless Steel Nichrome tubular heaters are used as heating element. The Stainless Steel fins ensure better heat transfer.

Humidity is controlled by steam injection method. The boiler tank is used for steam generation, Electro-magnetic switch is used for sensing the Water Level. Thus eliminating the humidity interruption. De-humidification coils are installed below the cooling coils for lower humidity.

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.

Certification :

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

ISO 14001:2015 & WHO-GMP

NSIC & MSME registered

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