



STABILITY CHAMBER

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

Model No : SRL / SC-10A



Construction : {As Per GMP Guideline}

Pre-fabricated molecular panels with PUF insulation. Which can be easily assembled on site. Which are light weight & easy to handle. If can be assembled / disassembled for relocating. Interior is made of AISI S.S. 304 & Exterior is made of AISI S.S. 304 with PUF / Glasswool insulation, double walled door with PUF & Door heaters insulated tight fit doors & viewing windows with illumination.

Air Circulation :

Efficient forced air circulating system is provided to ensure uniform conditions inside the Chamber.

Temp. Range :

Temp. Range : 10°C to 60°C, Accuracy : $\pm 0.2^\circ\text{C}$
Humidity Range : 30% RH to 95% RH, Accuracy : $\pm 3\%$ RH

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.

Heating & Humidification :

S.S Air heaters are provided for heating above ambient temperature. A S.S water boiler with reservoir with float valve produces steam for humidifying the chamber. Ultra Sonic Humidification [Optional].

Refrigeration system :

A hermetical sealed compressor with CFC free refrigerant & optional stand by refrigeration system & humidity system for uninterrupted operation. The both system can be operated alternately for a certain period, thus increasing the life of the system & In case of break down the alternate stand by system can be operated for uninterrupted services.

Temp. Control : [PLC with HMI touch screen 3.8"]

Programmable Temp. & RH Controller 4-20 mA o/p for RPM Control Data Logger 8 Temp. +RH Data logger with LCD Display window capable to store non-volatile data memory up to 500 reading with audit trail facility complies USFDA 21 CFR part 11. Touch Panel Change over to stand by system automatically as per schedule or on detecting fault with current system. Temperatures & Humidity overshoot and under shoot protection. Mobile Alarm System. In built PC port for connectivity for PC base operation of data management. Protection of UPS system in built with the controller for safe and uninterrupted functioning.

STABILITY CHAMBER

Stability Data Management Software 21 CFR Part 11 Compliance : Safety Features :

21 CFR part 11 Compliance. Online & Offline Data representation 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 19 - Daily, Weekly, Monthly.

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 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.

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

TECHNICAL SPECIFICATIONS

Model SRL-SC-10A	Internal Dimension (W X D X H)(cms)	Capacity Ltrs
SC-A	45 x 45 x 50	100
SC-B	50 x 50 x 80	200
SC-C	55 x 55 x 100	300
SC-D	60 x 60 x 110	400
SC-E	60 x 60 x 140	500
SC-F	70 x 60 x 145	600
SC-G	70 x 70 x 145	700
SC-H	75 x 75 x 145	800
SC-I	80 x 75 x 150	900
SC-J	80 x 80 x 155	1000
SC-K	90 x 83 x 160	1200
SC-L	130 x 83 x 140	1500
SC-M	140 x 92 x 140	1800
SC-N	150 x 95 x 140	2000

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