

Stability Studies

Walk in Stability Chamber



UPTO 60% POWER SAVING

• Walk-in Stability Chambers

Thermolab Stability testing chambers are designed to meet, if not exceed, stringent quality standards recognized internationally. Offering all temperature & relative humidity conditions specified in ICH guidelines as below:

25°C / 60% RH
30°C / 65% RH
30°C / 75% RH
40°C / 75% RH
25°C / 40% RH
30°C / 35% RH
40°C / NMT 25% RH

Thermolab provides a worldwide service network of trained engineers who can take care of calibration, validation, repairs & maintenance contract of chambers.





Standard Features

- Prefabricated modular structure with PUF / Rockwool insulated panels & reinforced floor panel.
- Interior Stainless Steel & Exterior PPGI / Stainless Steel.
- Adequate illumination inside the chamber.
- Glass view panel with specially designed leak proof door.
- Racks & trays made of Stainless Steel with adjustable tray heights.
- CFC free refrigeration systems.

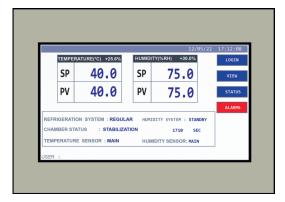
Man, Machine, Product & Environment Safety

- Safety system to cut off the power supply in case of overshoot & undershoot of Temperature & Humidity conditions giving audio visual alarms.
- Additional safety thermostat to cut off the power supply in case of temperature overshoots.
- Low water level alarm for humidity system.
- Emergency push button inside the chamber to de-energise magnetic lock with respect to door access system.
- Panic switch inside the chamber with audible alarm outside.
- Manual unlocking mechanism for door from inside the walk-in chamber.
- Environment friendly processes & refrigerant used.

Hydronic Cooling System

- A unique chilled water circulation system which reduces the electrical cost by 60% & water cost by 90%.
- This unique design enables maintenance of optimum cooling coil temperatures depending on the chamber conditions & resultant Dew Point.
- Factory assembled refrigeration system, avoiding onsite piping work.
- The life of compressor increases as the running time of compressor has enormously decreased.
- Compact plug & play design & can be placed behind the chamber or in the technical area.





Control Panel

- Newly designed control panel as per international electrical safety standards.
- PLC based control system with 7" colour HMI & front mounted compact design.
- Country specific electrical panel design to comply with local electrical standards.
- Works on 110 / 220 / 440 Volts & 50 / 60 Hz.

Air Processing Unit (APU)

- Designed to achieve optimum energy utilization with uniform airflow condition.
- The airflow is designed to have uniform conditions throughout the chamber.
- Custom designed supply & return air ducts with sleek APU design.



Technical Specifications

Temperature Control Accuracy / Uniformity: $\pm 0.2^{\circ}$ C / $\pm 1^{\circ}$ C Humidity Control Accuracy / Uniformity: $\pm 2^{\circ}$ RH / $\pm 3^{\circ}$ RH

Documentation

Complete with IQ, OQ, PQ document, Operation & Maintenance manual.



Additional features

- Windows based SCADA software for data management having support for 21 CFR Part 11 compliance.
- 100% redundant refrigeration & humidity systems with automatic changeover.
- 8 point temperature & 8 point relative humidity monitoring sensors for online mapping.
- Standby temperature & humidity sensors.
- Printer interface & data storage facility.
- Email & mobile alert systems.
- Ethernet communication protocol.
- Door Access Security system.
- Remote audio visual alarm.

Capacities Standalone Stability Chambers

90L, 200L, 400L, 500L, 800L, 1000L, 2000L & 3000 Litres.



Walk-in Stability Chambers

4000L, 8000L, 12500L, 18500L, 28000L, 36000L, 50000L up to 700,000 Litres.



Note: Other Walk-In sizes are available on request.

Low RH chambers can be specially designed as per user specifications

• Flameproof Chambers :

Rockwool Insulation, Spark Proof sensors, Flame Proof blower, Flame proof light fixtures, Smoke & Gas detector & other component required to make it a complete flame proof chamber.



Detailed technical specifications of Thermolab Flame proof chambers can be provided on request.

Pharma Coldrooms For Stability Testing

Thermolab offers a wide range of cold rooms (2°C-8°C) for stability testing of drug substances as per ICH guidelines.

Standby refrigeration system, PLC control with automatic changeover, Data logging & software connectivity intented for storage of raw material & finished good storage.

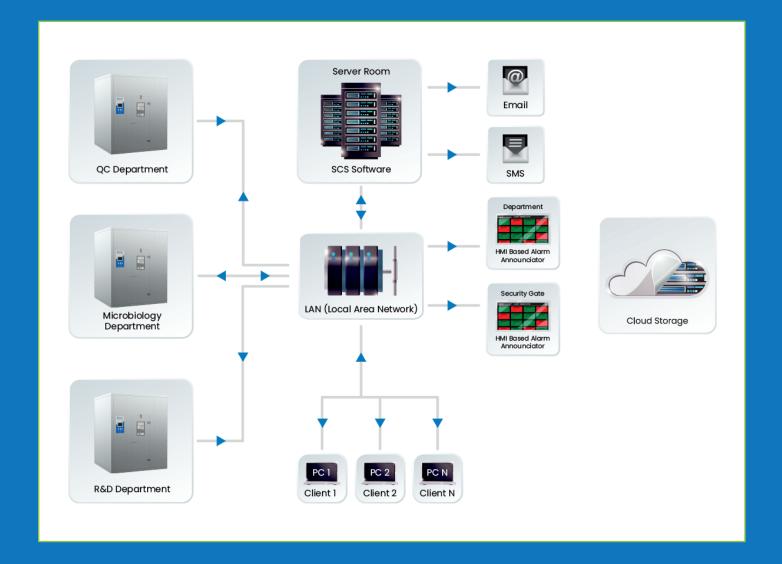
• 21 CFR Part 11 Compliant Software

21 CFR Part 11 requires that all appropriate electronic records are attributable, legible, contemporaneous, original, & accurate & maintained with integrity. Our software guarantees just that.

Salient features:

- Third party validated software
- Complies with GAMP 5 category 4
- Guaranteed Data Integrity
- Password protection
- Audit trails
- Secured electronic records
- Electronic signature
- MKT calculations
- Alarm report
- Event logging report
- Door access report
- Auto Back-up & restore facility
- Complete with IQ, OQ, PQ documents.





• Global Presence In More Than 75+ Countries



Awards

- Award for Leaders in Sustainable Stability Chambers
 For reducing electrical consumption by 60% & water consumption by 90%
- Best Innovation In Sustainability
- India Design Mark Award

Certifications & Approvals









Complete after sales service provided such as installation, calibration, validation, repairs, modification & annual maintenance contracts.



This NABL accredited laboratory is equipped to carry out on site calibration & validation of various parameters like temperature, relative humidity, pressure, vacuum, dimension etc.

Thermolab Scientific Equipments Pvt Ltd.

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Unit II





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