

# STABILITY STUDIES ?

Thermolab is a one stop solution for all your stability requirements



**BUY**

**RENT**

**SERVICE**

## Walk in Stability Chamber

## BUY- STABILITY STORAGE

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

- 25 °C / 60% RH
- 30 °C / 65% RH
- 30 °C / 70 % RH
- 30 °C / 75% RH
- 40 °C / 75% RH
- 25 °C / 40% RH
- 30 °C / 35% RH
- 40 °C / NMT 25% RH

Today, other than Pharma and Bio-pharma products, stability studies are required for Alternate medicines, Food & Beverages, Medical devices, Cosmetics and other items to check the environmental effects on the product.

## RENT- STABILITY STORAGE

Thermolab group also offers world class stability storage facility and Analytical testing laboratory. Thermolab Analyticals is a NABL accredited laboratory with FDA and ISO 9001:2015 certifications.

## SERVICE- STABILITY CHAMBERS

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

## STANDARD FEATURES



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

## MAN, MACHINE, PRODUCT AND ENVIRONMENTAL SAFETY

- Safety system to cut off the power supply in case of overshoot and undershoot of Temperature and 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.
- Panic switch inside the chamber with audible alarm outside.
- Manual unlocking mechanism for door from inside the walk-in chamber.
- Environment friendly processes and refrigerants used.

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



## AIR PROCESSING UNIT (APU)



- Designed to achieve optimum energy utilization with Integrated Cooling, Heating and Humidifying system.
- The airflow is designed to have uniform conditions throughout the chamber.
- Custom designed supply and return air ducts particularly for chambers having larger storage volumes.
- Sleek APU design resulted in increased storage volume.

## CONTROL PANEL

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





## 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 and 8 point relative humidity monitoring sensors for online mapping.
- Standby temperature and humidity sensors.
- Printer interface and data storage facility.
- Email and mobile alert systems.
- Ethernet communication protocol.
- Door Access Security system.
- Remote audio visual alarm.

## TECHNICAL SPECIFICATIONS

Temperature Control Accuracy / Uniformity :  $\pm 0.2^{\circ}\text{C}$  /  $\pm 1^{\circ}\text{C}$

Humidity Control Accuracy / Uniformity :  $\pm 2\% \text{ RH}$  /  $\pm 3\% \text{ RH}$

## CAPACITIES

### STANDALONE STABILITY CHAMBERS

90 L, 200 L, 325 L, 400 L, 600L, 800L, 1000L & 2000 Litres.

### WALK-IN STABILITY CHAMBERS

3000 L, 4500L, 8000L, 12,500L, 18,500L, 28,000L, 36,000L, 50,000L, 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

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

## COLDROOMS FOR STABILITY TESTING

Thermolab offers a wide range of cold rooms ( $2^{\circ}\text{C}$  -  $8^{\circ}\text{C}$ ) for stability testing of drug substances intended for storage in a refrigerator as per ICH guidelines.

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

## SALIENT FEATURES:

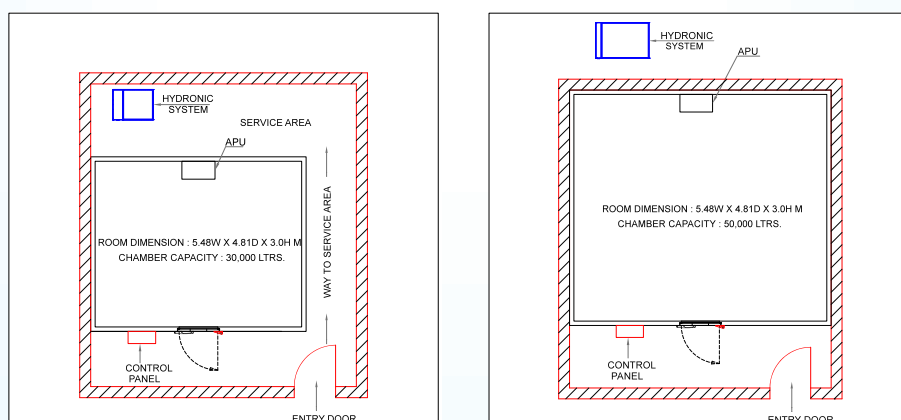
- Third party validated software
- Complies with GAMP 5 category 4
- Guaranteed Data Integrity
- Password protection
- Audit trails
- Secured electronic records
- Electronic signature
- MKT calculations
- Event logging report
- Door access report
- Auto Back-up and restore facility
- Complete with IQ,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



## DOCUMENTATION

Complete with IQ, OQ, PQ documents, Operation and Maintenance manuals

## WALK-IN STABILITY CHAMBER LAYOUT OPTIONS



## AWARDS

- Award for Leaders in Sustainable Stability Chambers  
For reducing electrical consumption by 60% and water consumption by 90%
- India Design Mark Award



## CERTIFICATIONS AND APPROVALS





## SALIENT FEATURES [CONTD...]

- Stand by refrigeration and humidity system.
- Complete safety and alarm system.
- GSM mobile alert system.
- Door access security system.
- Alternative PLC with touch screen display with ethernet.
- Web based online remote monitoring.
- Utility management system.
- Extensive DQ, IQ, OQ and PQ protocols.
- Works on 440V AC three phase 50Hz.

## TECHNICAL DATA

Standard Model (S) : Inside stainless steel matt finish & outside mild steel powder coated.

GMP Model (G) : Inside and outside stainless steel matt polish.

Temp. Range / Accu. : 20°C to 50°C /  $\pm 0.2^\circ\text{C}$  Temp. Uniformity :  $\pm 2.0^\circ\text{C}$

Humidity Range / Accu. : 40% to 90% RH /  $\pm 2.0\%$  RH Humidity Uniformity :  $\pm 3.0\%$  RH

Models	Capacity	Dimensions in mtrs.						No. of Trays
		Internal			External			
(S) OR (G)	Ltrs.	W	D	H	W	D	H	
TH 20 S/G	2000	1.76	0.95	2.00	2.22	1.11	2.16	10
TH 45 S/G	4500	2.45	0.95	2.00	2.91	1.11	2.16	14
TH 80 S/G	8000	2.00	2.00	2.00	2.16	2.95	2.16	24
TH 125 S/G	12500	2.50	2.50	2.00	2.70	3.45	2.16	28
TH 187 S/G	18750	2.50	3.00	2.50	2.70	3.95	2.70	36
TH 225 S/G	22500	3.00	3.00	2.50	3.16	3.95	2.70	40

### Note :

Other sizes are available on request.

- Above chambers are suitable for conditions such as 25°C / 60% RH, 40°C / 75% RH and 30°C / 65% RH.
- Low RH chambers are also available for conditions of 25°C / 40% RH, 40°C / 25% RH and 30°C / 35% RH.

**Biggest Walk-In Stability Chamber manufactured, installed and validated is of 2,67,500 ltrs volume with size of W X D X H = 11.89 X 7.5 X 3.0 mtrs.**

Note: Photographs are for reference purpose only. The dimensions / specifications may be changed without notice.



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