## STABILITY CHAMBERS | CUSTOM DESIGN & VALIDATION

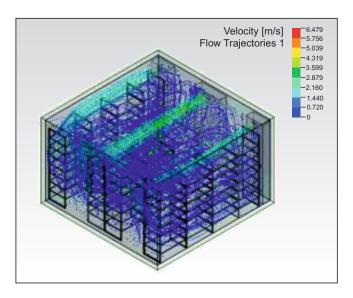
## **Specialized Design to meet Specific Needs**



### Fine Interior with specialised key features

- Complete Stability Solutions
- One-stop supplier for stability chambers
- Chambers built to last longer and to meet all requirements-now and in future
- Chambers from 200 liters to 2,50,000 liters as well as customised ones

## **Determination of Uniformity**



- Air Flow Stimulation Software
- Ensures uniformity of the conditions
- Determines an accurate air-path
- Determines the Hot & Cold Zones; Dry & Humid Zones
- Facilitates a proper sample loading pattern

## **Application**

Newtronic chambers are suitable to meet the regulatory requirements of the various international bodies such as (ICH, USFDA, MHRA, WHO, EU-GMP, TGA, JPMMA, ANVISA, ASEAN) or any of the other National Testing Standards.

#### The ICH Q1A(R2) & Q1B conditions for different application are as follows:

Application	Study	Conditions	Study Point	
General Conditions	Long Term*	25°C ± 2°C / 60% RH ± 5% RH 30°C ± 2°C / 65% RH ± 5% RH 30°C ± 2°C / 75% RH ± 5% RH	12 months	
	Accelerated	40°C ± 2°C / 75% RH ± 5% RH	06 months	
Drug Products packed in Semi-permeable	Long Term*	25°C ± 2°C / 40% RH ± 5% RH 30°C ± 2°C / 35% RH ± 5% RH	12 months	
container	Intermediate	$30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \text{ RH} \pm 5\% \text{ RH}$	06 months	
	Accelerated	40°C ± 2°C / NMT 25% RH	06 months	
Drug Products for	Long Term*	5°C ± 3°C	12 months	
storage in Refrigerator	Accelerated	25°C ± 2°C / 60% RH ± 5% RH	06 months	
Drug Products intended for storage in a Freezer	Long Term*	-20°C ± 5°C	12 months	
MVTR -		23°C / 75% RH		
Moisture Vapor	-	25°C / 80% RH		
Transmission Rate				
ICH		Exposure to Light intensity of 1.2 million		
Q1 B	Photostability	Lux Hours & UV Light intensity of		
		200 watt / sq. mtr.		

 $<sup>^{\</sup>star}$  If 30°C / 65% RH or 30°C / 35% RH is the long-term then there is no intermediate.

Temperature Range: 20°C to 60°C Humidity Range: 40% Rh to 95% Rh

## **Walk-In Stability Chambers**





- Double walled with 60mm PUF insulated modular panels with easy on-site assembly
- SS 304 Interior & Exterior either SS 304 or Pre Coated GI
- Stainless Steel Trays
- Observation window 300 x 300 mm
- PVC strip curtain for reducing temperature leakages
- Illuminated working area
- Flooring of Linoleum carpet
- Heater line along the door to avoid condensation
- U-shaped SS tubular heaters
- Forced air circulation for uniform temperature
- Humidity is primarily controlled through the principles of Dew point control (for capacities>8KL)
- CFC free cooling system consisting of hermetically sealed compressor coupled with evaporation coil & condenser
- System is made up of split type condenser unit in well-ventilated area to avoid throw of hot air in the room
- Stand by humidity system with booster humidification
- Complete Operations driven through PLC with data logging capacity of upto 1000 readings
- High speed Ethernet based communication
- All operations through a single 7" Color Touch Screen
- High quality imported make T/Rh combo sensor with 4-20 mA output
- Safety devices: Low & High temperature cut-off settable thermostats
- Audio/Visual alarms for deviations
- Complete with DQ, IQ, OQ, PQ & SOP & Maintenance Manual

Power supply: 230/415 volts 50 Hz main supply. Also available with 60 Hz Cycle.

#### **SPECIFICATIONS**

Temperature Range : 20°C to 60°C
Temperature Accuracy : ± 0.5°C
Temperature Uniformity : ± 1°C

Humidity Range : 40% Rh to 95% Rh

**tronic**System

**Green Mode Energy Optimisation** 

Humidity Accuracy :  $\pm$  2% Rh Humidity Uniformity :  $\pm$  3% Rh

#### **Optional Accessories**

- ► ICDAS -A Single Software installation for all Newtronic make equipments
- ▶ 8 pt. Temperature & Humidity Scanner
- Stand by Cooling System with auto switch over
- Door Access system (Numeric or Biometric)
- Remote alarm system suitable for upto 4 nos. Newtronic make equipments
- Mobile Alert System

#### Selection Guide

Model	Capacity		Internal Size	External Size	Trays Qty.	Trays Size
	CuFt.	Liter	(H*W*D) mm	(H*W*D) mm		(W*D) mm
NLWH208SI	208	5,848	2000 X 1360 X 2150	2120 X 1480 X 2270	20	900 X 300
NLWH250SI	250	7,017	2400 X 1360 X 2150	2520 X 1480 X 2270	28	900 X 300
NLWH307SU	307	8,600	2000 X 2000 X 2150	2120 X 2120 X 2270	20	900 X 600
NLWH368SU1	368	10,320	2400 X 2000 X 2150	2520 X 2120 X 2270	28	900 X 600
NLWH543SU	543	15,216	2400 X 2000 X 3170	2520 X 2120 X 3290	42	900 X 600
NLWH679SU	679	19,020	2400 X 2500 X 3170	2520 X 2620 X 3290	42	900 X 800
NLWH1092SU1	1092	30,600	2400 X 2500 X 5100	2520 X 2620 X 5220	70	900 X 800
NLWH1787SU1	1787	50,040	3000 X 4000 X 4170	3120 X 4120 X 4290	126	900 X 600
NLWH2857SU	2857	80,019	3000 X 5100 X 5230	3120 X 5220 X 5350	162	900 X 800

\*Custom Build Chambers also available | \* Models with Exterior powder coated GI sheet & Interior stainless steel (304) will be available on request. Standard Inner Heights: 2.0, 2.4, 3.0 Mt | Standard Inner Width: 1.36, 2.0, 2.5, 4.0 Mt | Standard Inner Depths: 2.0, 3.0, 4.0, 5.0 Mt

\* Newtronic reserve the rights to change the product specifications without prior notice.



















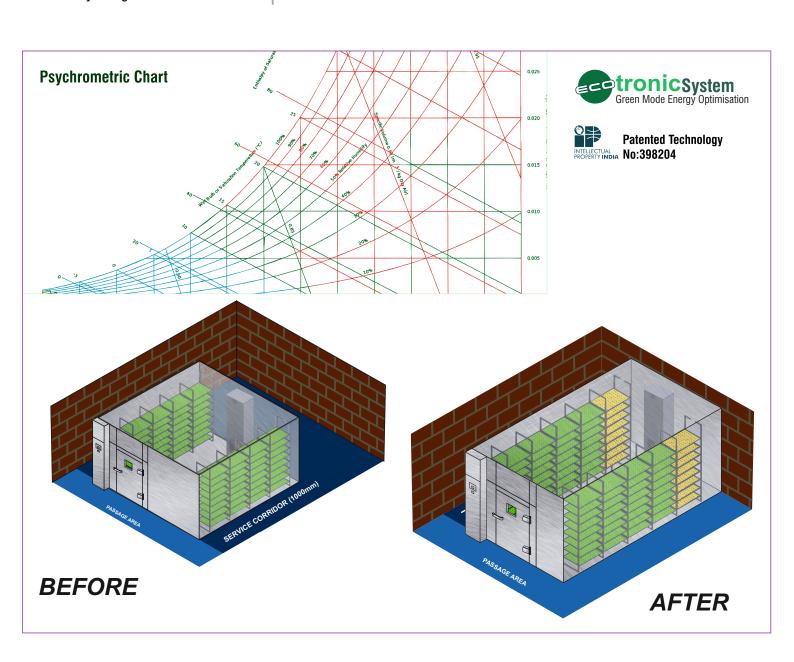






Temperature Range: 20°C to 60°C Humidity Range: 40% Rh to 95% Rh

# **ECOTRONIC Walk-In Stability Chambers**





# Introducing a Patented Technology for Green Mode Energy Optimization



Based on Principles of Dew Point Control



Low Power & Water Consumption



**More Storage Area** 



No short term Deviations



Less Breakdown