

FDA/ICH STABILITY WALK-IN ROOMS

Our stability chambers offer superior environmental control for a variety of applications, and are proven to exceed ICH/FDA stability requirements. For this reason, our FDA/ICH chambers are highly sought. Pharmaceutical shelf-life testing, accelerated stability studies, and testing and storage for cosmetics, animal health products, nutritional supplements, general products, medical devices, packaging materials are just a few applications we service.

Benefits

- Outstanding temperature/humidity control and uniformity. FDA/ICH guidelines concerning control performance is easily exceeded. Our typical stability room will produce mapped and validated results of better than $\pm 0.5^{\circ}\text{C}$ and $\pm 1.0\text{ RH}$ throughout the storage volume of the room. Control at a sensor of $\pm 0.1^{\circ}\text{C}$ and $\pm 0.3\%$ is normal.
- Precision Fluid Temperature Control Unit cooling system utilizes a combination of refrigerant technologies and glycol/water heat exchange technologies.
- A typical 9'W x 10'D x 8' 4"H walk-In stability room will require fewer than 1000 Watts to operate at 25°C/60% and 30°C/65%. At 40°C/75% the efficiency (typically 500 Watts or less) is even better. This savings can be substantial in comparison to competitors (up to \$2500 per year) especially when multiplied by the operation of several rooms.
- Conditioning system can be replaced or relocated quickly due to simple water-type connections.
- Optional on-site validation services that have included multi-point temperature and humidity mapping have repeatedly proven nearly unbelievable uniformity and control results that far surpass FDA/ICH/GMP guidelines. Equipment utilized: Amphenol/ Kaye Validator.
- Rooms that include an optional redundant refrigeration system allow uninterrupted operation upon a refrigeration failure. The room does not need to be taken out of service during repair, as the failed system can be isolated and serviced with no impact upon the chamber operation.
- ADA compliance available with no additional cost to the customer.
- Supplied with vapor proof LED lights which emit significantly more light per unit of input energy than fluorescent bulbs. They also produce less radiant heat, and with less heat used, the cooling requirement for the controlled environment is diminished and the total energy used by an LED-equipped chamber is substantially reduced.



Standard Features

- 4" Polyurethane Insulated Panels, 100% Foamed-In-Place
- Embossed White Aluminum Interior Surface Finish
- Embossed White Galvanized Steel Exterior Surface Finish
- Exceptional Temperature And Humidity Uniformity
- Humidity Control At Sensor: $\pm 0.3\%$
- Temperature Control At Sensor / Set-Point: $\pm 0.1^{\circ}\text{C}$
- High / Low Alarms
- Flexible Configurations
- Complies With LEED Standards
- Energy Efficient Offering-Lowered Maintenance Costs
- Pre-tested, Pre-charged Refrigeration Systems
- Non-proprietary Controls
- UV sterilized ultrasonic humidification
- Temperature Range of 20°C to 40°C
- 25°C/60%, 30°C/60%, 30°C/65%, 40°C/75% capability
- Controls with Auto-tuning, Fuzzy Logic
- Dry Alarm Contacts and Modbus Communication for Connections to Building Management Systems

Optional Features

- Added Dehumidification
- Extended Temperature And Humidity Ranges
- Stainless Steel / Special Surfaces
- Ethernet / Remote Monitoring / Alarming
- Corrosive Resistant Equipment
- Added Redundancy in Controls and/or Conditioning
- Data Logging and/or Chart Recorders
- Water-Cooled Or Air-Cooled Condensers
- Custom Lighting Systems
- High Density Shelving
- Unlimited Door / View Window Sizing
- Insulated Glass View ports
- High Weight Capacity Flooring
- Calibration / Validation / Maintenance Services
- Touch Screen Control Interface
- Electronic Door Lock with Data-Logged Access
- Direct Refrigeration
- Sizes Available to the Nearest Inch

The Darwin Advantage

All installed instrumentation is calibrated to NIST traceable standards and provided with a calibration form. In-house, factory calibrations are performed using state-of-the-art equipment with great accuracies. These reports are three-point verifications with traceable calibration documents.