Envirotronics®

Pharmaceutical Products

›Stability Testing

Test Chambers for Stability Tests on Pharmaceutical Products according to the ICH Q1A and FDA Guidelines

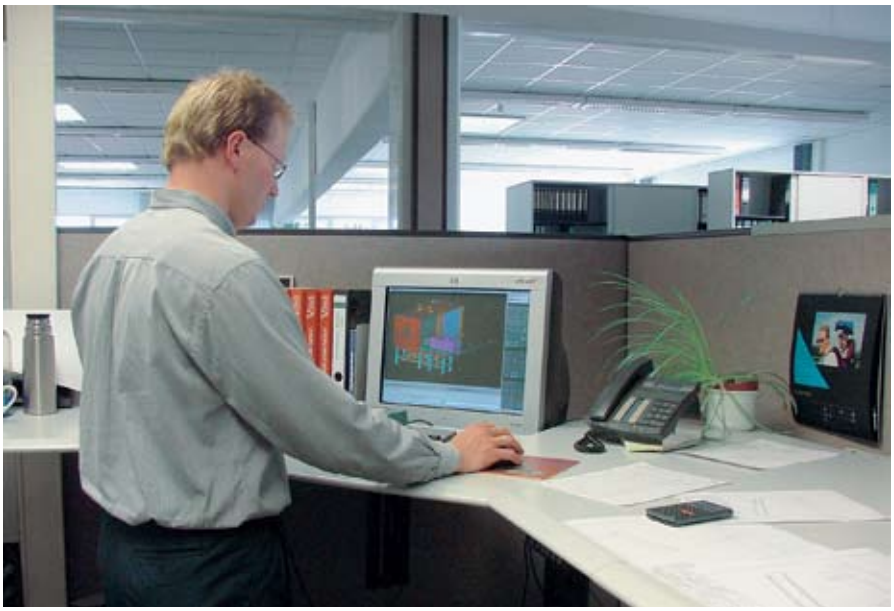
Envirotronics is part of the Weiss Environmental Technology Group. We are one of the most important producers of standard test devices and special test systems for environmental simulation worldwide.

Our range of products is comprised of systems for simulating exposure to weather as well as systems for temperature, humidity, therrmal shock, vibration and corrosion tests. These systems are available in virtually any size for application in research, development, quality assurance and production.

In order to safeguard consistently high quality and the stability of medical and pharmaceutical products, we offer you a comprehensive standard range of stability test chambers. Depending on your requirements, our equipment range can extend to walk-in test chambers and special systems of any size. Envirotronics stability test chambers are based on the GMP, FDA and ICH guidelines.

Our efficient after-sales service ensures optimum support for our customers as well as a high degree of system operation reliability.

Decades of experience in the varied fields of application coupled with an intensive exchange of ideas and experience with our customers from all over the world ensure your lasting partnership with Envirotronics.



›Only Tested Pharmaceuticals get the Required Approval…

To meet the quality criteria of the stability tests, the chemical, microbiological, and physical characteristics of pharmaceutical substances are tested after exposure to temperature and humidity over a defined period.

To that end, the following climate conditions were established for long-term testing, accelerated testing, and testing at intermediate conditions according to the **ICH* Guideline Q1A.**

Testing at intermediate conditions is carried out in case there are deviations between the first two forms of testing.

- **Long-term testing**
  at +25˚C / 60% RH or
  +30˚C / 65% RH
- **Accelerated testing**
  at +40˚C / 75% RH
- **Intermediate testing**
  at +30˚C / 65% RH

The following test conditions were stipulated for substances or pharmaceuticals in semi-permeable packaging:

- **Long-term testing**
  at +25˚C / 40% RH
- **Accelerated testing**
  at +40˚C / <25% RH

During the entire test, the deviation in temperature is stipulated at ±2˚C and the deviation in relative humidity is stipulated at ±5% RH

In the **ICH* Guideline Q1B,** the methods for performing photostability tests are established with an irradiation dose of 1.2 million lxh and an integrated UV part of 200 Wh/m^2.

›Climate Test Chambers with Optimized Storage Areas for Reliable Stability Testing of Pharmaceuticals…

According to the ICH* Guideline Q1A, stability tests have to be performed under defined climatic conditions in order to provide evidence of the stability of active substances and pharmaceuticals.

In cooperation with the pharmaceutical industry, we have developed a specific range of test cabinets and test chambers to meet these requirements.

Stability tests are an important step in the development of new drugs and pharmaceutical substances and an indispensable element in the licensing process defined by federal regulating authorities. However, these tests are just as important for safeguarding the quality of the product within the framework of quality assurance.

Together with committees from the pharmaceutical industry, experts from the licensing authorities (such as the FDA) have developed the ICH* Guidelines for the harmonization of stability tests. These guidelines define standardized storage and batch evaluation as well as the time sequence of the required analytic tests.

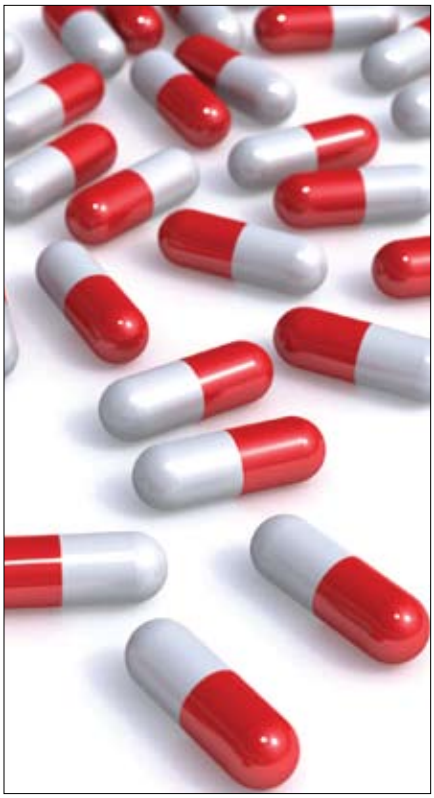
The ICH* Guidelines are valid in the EU, Japan and the USA. For other regions, climate zones have also been established. However, depending on the respective country, the execution of such tests may not be mandatory.

* *International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.*

Attention to Every *Detail*

›Product Diversity

Our comprehensive standard line of climate chambers with workspace ranging from 34 L to 2000 L, as well as custom-sized walk-in test chambers, are available for the execution of stability tests. In specific cases, a stability chamber can be adapted to the actual space that is available.



›Documentation

For recording the measurement values of temperature and humidity, numerous documentation options are available in accordance with the respective requirements. Each of these options is available with independent sensors and, upon request, with the control loop sensors.

In detail these options are as follows:

- Analog line recorder (paper line recorder)
- Digital line recorder (line recorder with memory and display)
- Digital line recorder, complying with FDA 21 CFR Part 11 (line recorder with memory, display and possibility of an electronic signature)
- S!MPATI* **Pharma software package complying with FDA 21 CFR Part 11** for connecting devices and test chambers to a PC.

Additionally, any existing temperature or climate devices can be connected to independent recorders or computers using our S!MPATI* **Pharma** software which complies with FDA 21 CFR Part 11.

›Qualification

Approval of active substances and/or providing evidence of stability tests requires numerous measurements that have to be carried out and confirmed over extremely long periods of time. To provide evidence of compliance with fluctuations in temperature and humidity, it is necessary to ensure the flawless functioning of stability test chambers.

These requirements are documented in a sustainable manner by means of our extensive qualification documentation.

The qualification system is comprised of:

FAT	Factory Acceptance Test
A2LA	Calibration Certificates
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operation Qualification
PQ	Performance Qualification

In addition to this we provide all the required documents such as circuit diagrams, component lists and certificates, e.g. ISO accreditation, maintenance recommendations, etc.

Our trained technicians not only carry out **on-site qualification** on request, but can also utilize the extensive measurement and calibration facilities of our A2LA accredited calibration laboratory. Please contact Envirotronics for more information.

Homogeneous Airflow

Independent Monitoring Center

›Calibration

Various Quality Assurance systems require calibration and monitoring of test equipment that can be traced back to standards which are approved both nationally and internationally.

For this reason, Envirotronics, **accredited by A2LA according to ISO/IEC 17025:2005**, provides calibrations and calibration certificates for the measurable variables of air temperature, dew point temperature and relative humidity.

International acceptance of the A2LA calibration certificates is underlined by the membership of A2LA in ILAC (International Laboratory Accreditation Cooperation), all member countries of which must recognize an A2LA calibration certificate.

Our trained calibration technicians can perform calibrations and spatial measurements of temperature and humidity both in our factory as well as on site.

›Training

Our competent staff would be pleased to advise you on any questions you may have relating to stability testing, qualification, and documentation, as well as questions relating to environmental simulation and heat technology.

We can offer training on all current topics relating to our product range and its application regularly, both in-house and on-site (e.g. FDA 21 CFR Part 11 in practice).

This team also qualifies and trains our service technicians in regular on-the-job-training for performing service, maintenance, calibration and qualification.

›Service and Maintenance

Whether it is maintenance, calibration or repair, **we are available to quickly respond to your needs** through our sevice department.

We will work with you to ensure that a qualified service technician will be on site to respond to your requirements as quickly as possible after we have received a failure notification.

As specialists in the fields of refrigeration, climate and control technology, our technicians are familiar with all the functions and components of your system.

Every technician carries an extensive inventory of spare parts. We also forward spare parts to our technicians and customers every day to ensure availability of the best possible supply of parts.

Our extensive service network guarantees that we will always be able to respond when you need us.

Whether we assist you from our service center or directly at your site – our customers are always given top priority.

›Application

When testing the stability of drugs according to the ICH (International Conference on Harmonization) guidelines, products must be stored under defined climatic conditions.

The test systems Pharma600, Pharma1300 and Pharma2000 were specially developed for use in laboratories and supplement the spacious walk-in chambers that are used in production areas.

Solutions for the Laboratory

- Storage areas of
  2.07 m^2 (600 L)
  4.14 m^2 (1300 L)
  6.21 m^2 (2000 L)
  with 6, 12 or 18 standard shelves
  (additional shelves are available as an option)

The functionality of the cabinets satisfies the basic requirements of the official guidelines as well as the demands of special applications.

The chamber humidification is accomplished through a patented system (Sterile Steam System) which is monitored by an electronic module. The water evaporation is done at 140 °C. The temperature and relative humidity parameters are detected by a PT100 and a capacitive humidity sensor.

The test chamber is equipped with MINCON/32*, a powerful 32-bit control system for monitoring and controlling.

The MINCONTROL terminal with LCD-display offers input and display of values and states.

›Standard Equipment

- Microprocessor monitoring and control with MINCON/32* with terminal MINCONTROL
- Serial interface RS 232
- Humidity input and display in % relative humidity
- Independent adjustable temperature limiter t_{min}/t_{max}
- Calibration of 2 temperature and 2 humidity values with certificate
- Air-cooled refrigeration unit
- Patented steam humidification (Sterile Steam System)
- Capacitive humidity sensor
- Entry port 50 mm ø
- Stainless steel interior
- Water tank (19 L), manual and automatic water supply possible
- Door switch
- Single wing door, lockable
- Mobile on rolling wheels
- Shelves 6, 12 or 18 pieces (depending on workspace volume)

›Important Options

- Color touchscreen
- S!MPATI* or S!MPATI* **Pharma** software
- Networking (RS 485 interface)
- TCP/IP interface
- Registration of temperature and humidity
- Independent sensor for temperature and humidity
- Audible and visual warning signal
- Water-cooled refrigeration unit
- Glass door, heated
- Feet, separately adjustable in height
- Additional shelves
- Additional entry ports
- Demineralization unit for connection to local water supply
- Qualification documentation
- Special voltages

›Technical Data

Type			**Pharma600**		**Pharma1300**		**Pharma2000**	
Shelves 650 x 530 mm		piece	6 [3]		12 [3]		18 [3]	
Storage space standard		m^2	2.07 [3]		4.14 [3]		6.21 [3]	
Temperature range		°C	+10 to +50					
Temperature deviation in time		°C	±0.1 to ±0.5					
Temperature deviation in space		°C	±0.5 to ±1.0					
Temperature gradient [1]		°C	1 to 2					
Humidity range		%	20 to 90					
Humidity deviation in time		%	±1 to ±2					
Calibrated values			+25 °C / 60 % RH and +40 °C / 75 % RH					
External dimensions	Width	mm *in*	740	*29.1*	1460	*57.5*	2155	*84.8*
	Depth	mm *in*	1050	*41.3*	1050	*41.3*	1050	*41.3*
on wheels (standard)	Height	mm *in*	1975	*77.8*	1975	*77.8*	2067	*81.4*
on feet (option)	Height	mm *in*	2030	*79.9*	2030	*79.9*	2112	*83.1*
Test space dimensions	Width	mm *in*	620	*24.4*	1340	*52.8*	2034	*80.1*
	Depth	mm *in*	685	*27.0*	685	*27.0*	685	*27.0*
	Height	mm *in*	1300	*51.2*	1300	*51.2*	1300	*51.2*
Entry port		mm	1 pc. 50 mm diameter, located on right wall					
		in	1 pc. @ 2 in diameter, located on right wall					
Electrical connection			1/N/PE AC 230 V ±10 %, 50 Hz					
Rated power		kW	2.5		3.0		3.5	
Weight		kg	150		250		350	
Noise level [2]		dB(A)	52		52		52	
Humidity water			demineralized water, pH value 6-7 conductivity 5 to 20 Microsiemens/cm					

Performance values refer to +25 °C ambient temperature - [1] In accordance with IEC 60068-3-5. [2] Free field, 1 m distance from the front, as per DIN 45635, part 1, accuracy class 2. [3] Additions possible.

We'll find you a *Solution*

Our slogan, "we'll find you a Solution" says it all about what we do here at Envirotronics.

We find solutions for our customers' environmental test chamber requirements through innovative and intelligent design, quality customer service, and our commitment to excellence.

The images shown here represent a sample of the equipment solutions we provide for our customers. We would be delighted to to discuss your test chamber requirements and how Envirotronics can provide a successful solution for you.

Let Envirotronics find a solution for you!

Temperature and Temperature/Humidity Test Chambers

Environmental Stress Screen Test Chambers

Altitude and Altitude/Humidity Test Chambers

Solid Construction and Modular Panel Construction Walk-In and Drive-In Test Chambers

Salt Spray and Corrosion Test Chambers

Mini- and Benchtop Temperature and Temperature/Humidity Test Chambers

Custom Designed and Manufactured Test Chambers

Solar Panel and Photovoltaic Module Test Chambers

Thermal Shock Test Chambers

Pharmaceutical Stability Chambers

Sand and Dust Test Chambers

Hydraulic Cement and Concrete Moist Cabinet Curing Chamber

AGREE-Style Test Chambers

Pneumatic Vibration Tables

Complete HALT/HASS Test Systems

ENV 1208 PH

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ACCREDITED CALIBRATION LABORATORY Certificate No. 1276-01

Quality System Registered to ISO 9001

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