vötschtechnik
a schunk company

Stability Testing – GMP- and FDA-Compliant

Reliable Solutions for the Pharmaceutical Industry

Our Experience is your Security.

Only tested pharmaceuticals get the required approval.

As quality criteria of the stability tests the stability of chemical, microbiological and physical characteristics of pharmaceutical substances are tested after exposure to the influence of temperature and humidity over a defined period to determine the shelf-life time. 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.

General case

Long Term	25 °C ±2 °C/60 % r.H. ±5 % r.H. or 30 °C ±2 °C/65 % r.H. ±5 % r.H.
Accelerated	40 °C ±2 °C/75 % r.H. ±5 % r.H.
Intermediate	30 °C ±2 °C/65 % r.H. ±5 % r.H.

Semi permeable containers

Long Term	25 °C ±2 °C/40 % r.H. ±5 % r.H. or 30 °C ±2 °C/35 % r.H. ±5 % r.H.
Accelerated	40 °C ±2 °C/not more than 25 % r.H.
Intermediate	30 °C ±2 °C/65 % r.H. ±5 % r.H.

Drug substances intended for storage in a refrigerator

Long Term 5 °C ±3 °C
Accelerated 25 °C ±2 °C/60 % r.H. ±5 % r.H.

Drug substances intended for storage in a freezer

Long term -20 °C ±5 °C

During the entire test the deviation in temperature is stipulated at ±2 °C and the deviation in relative humidity is stipulated at ±5 % r.H.

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 optimised 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 furnish evidence of the stability of active substances and pharmaceuticals. To that end, we have developed a specific range of test cabinets and test chambers together with the pharmaceutical industry. Stability tests are an important step in the course of the development of new drugs and pharmaceutical substances. They are an indispensable element of the process for granting of licences for the product by the authorities, but they are just as important for safeguarding the quality of the product in the framework of quality assurance. Together with committees from the pharmaceutical industry experts from the authorities granting the required licences, such as e.g. the FDA, have developed the ICH* Guidelines for the harmonisation of stability tests which define standardized storage, the evaluation of the batches as well as the time sequence of the required analytic tests. The 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 Harmonisation of Technical Requirements of Pharmaceuticals for Human Use.

Safer and Easier Stability Testing.

Vötsch Industrietechnik offers a complete package of state-of-the-art testing equipment, documentation, qualification, calibration, training and service.

Uni-Flow
Airflow design for best homogenity even in loaded units.

Sterile Steam System
The demineralised water is evaporated at 140 °C to kill eventually available microorganisms.

Integrated Monitoring Centre (IMC)
To record all measurement data of control sensors or from the control loop independent sensors and alarms if an optionally integrated memory is available. The download and reporting of these data are possible with the optional software S!MPATI® Pharma.

Pharma Light
For photostability testing a cold white illumination according to ISO 10977:1993 as well as a UV source from 320 to 400 nm with a maximum between 350 and 370 nm according to ICH Guideline Q1B are integrated.

Exposure Equalisation Filters (EEF)
Due to the fact that fluorescence tubes have the highest intensity in the middle of the tube and lower intensities on the sides the exposure, equalisation filters have been developed to cut the maximum in the middle and therefore get a homogenous illumination of the storage surface.

Qualification Documents
Vötsch Qualification Documents for chambers and rooms and validation documents for software validations are prepared according to the risk-based approach of GAMP.

EU GMP Annex 11 compliance
The computerised system, combined of the controller S!MPAC® and the monitoring software S!MPATI® Pharma, are fully compliant to the requirements of EU GMP Annex 11 for computerised systems according to manufacturer's declaration. This can be proven in the software validation.

FDA 21 CFR Part 11 Compliance
The monitoring software S!MPATI® Pharma is fully compliant to the requirements of FDA 21 CFR Part 11 of the American law for electronic documentation in the pharmaceutical and food industry according to manufacturer's declaration. This can be proven in the software validation.

DAkkS Calibrations
All used measurement systems for temperature and humidity used within Vötsch Industrietechnik for final testing, calibration and qualification on customer side are traceable to a ISO 17025-accredited calibration laboratory of Vötsch Industrietechnik.

The Highest Possible Reliability.

Product diversity

Our comprehensive standard range of climate chambers from 34 l to 2000 l, as well as the walk-in test chambers as standard solutions from 10 m^3 to 300 m^3 are available for the execution of stability tests. In specific cases the stability test chambers can be adjusted to your premises and almost any design. Special sizes, e.g. 400 m^3 or 800 m^3, are also possible.

For testing of photostability we offer you a solution tailor-made specifically for this purpose in the form of a photostability test chamber. Furthermore solutions for continuous operation at 5 °C and -20 °C are available.

Moreover, climate chambers in a version executed as per ATEX are available for tests with preparations containing alcohol. For all these demanding applications we offer individual solutions with regard to volume, safety and design for every customer.

Documentation

For recording of the measurement values regarding temperature, humidity or light, numerous documentation possibilities are available in accordance with the respective requirements, in this context each of these possibilities is available with independent sensors and, upon request, also with the control loop sensors.

In detail these are:

- Integrated datalogger for control, and/or independent sensors for viewing the software S!MPATI® Pharma is necessary.
- **S!MPATI® Pharma** software package complying with FDA 21 CFR Part 11 and EU GMP Annex 11 for connection of test chambers to a PC or server. Moreover, any existing temperature or climate devices can be connected to S!MPATI® Pharma using additional sensors and interfaces.[1]
- Analogue paper recorders
- Digital line recorders complying to FDA 21 CFR Part 11 (line recorder with memory and display)
- To connect the chambers to other monitoring systems, analogue signals 0 to 10 V or 4 to 20 mA from the control loop or additional sensors are possible as option.
- An integration into a LIMS is also possible.

[1]Perhaps options required.

Qualification

For the approval of active substances and/or providing evidence of stability tests, numerous measures have to be carried out and confirmed over extremely long periods of time for the purpose of ensuring flawless functioning of stability test chambers, such as e.g. compliance with fluctuations in temperature and humidity.

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

The entire system qualification comprises:

DAkkS	ISO 17025-accredited calibrations with certificate
DQ	Design Qualification
FAT	Factory Acceptance Test
IQ	Installation Qualification
OQ	Operation Qualification
PQ	Performance Qualification

Alternatively we offer also qualifications according to GAMP 5.

In addition to this we provide all the required documents such as circuit diagrams, component lists and certificates, e.g. ISO accreditation, EC conformity declarations or also maintenance recommendations.
On request, our trained technicians carry out the qualification on site and can complement this with our comprehensive measurement and calibration facilities (also DAkkS calibration).

Our Contribution to Medicinal Safety.

Calibration

Various QM systems require calibration and monitoring of test equipment that can be traced back to national or international standards.

For this reason, Vötsch Industrietechnik offers calibrations with its own laboratory accredited according to ISO 17025 and provides DAkkS calibration certificates for the measurable variables of air temperature, dew point temperature and relative humidity.

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

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

Training

Our competent team of instructors would be pleased to advise you on all questions relating to stability testing, qualification, documentation, as well as relating to environmental simulation and heat technology at any time.

We offer seminars and workshops on all current topics relating to our product range and its application regularly both in our inhouse training centre and on site (e.g. device qualification in actual practise).

Moreover, this team also ensures regular on-the-job training for our service technicians through workshops regarding service, maintenance, calibration and qualification.

Service and maintenance

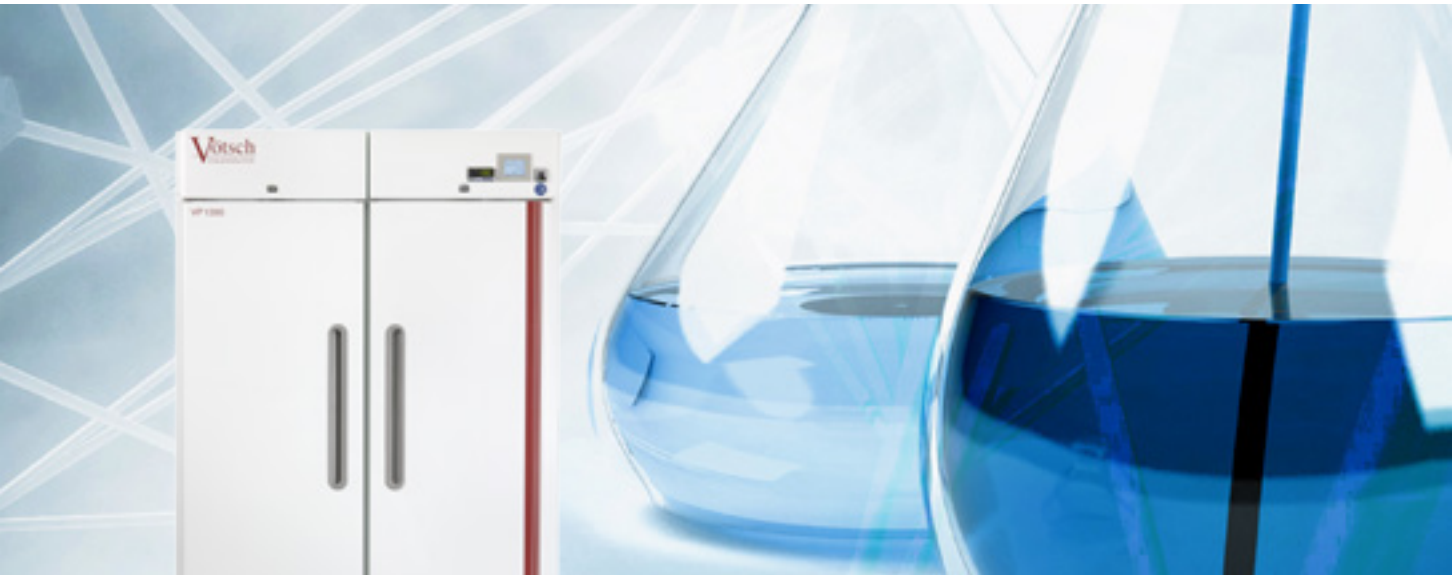
Whether it is maintenance, calibration or repair, we are available round the clock through our service centre. On demand, we guarantee that a service technician will be on site within 24 hours after we have received a failure notification on weekdays in Germany.

In addition to this, we offer maintenance contracts with a provision regarding a response time of 24 hours also on weekends.

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

In addition to the range of spare parts which our technicians have on site, we forward spare parts to our technicians as well as customers every day in order to ensure the best possible supply with spare parts.

Our extensive service network with more than 300 technicians worldwide ensures that we are always there when you need us. Whether we assist you from the service centre or directly on site – our customers are always given top priority.



Stability Testing According to ICH Guideline Q1A.

VP Series 280 | 280-T | 600 | 600-T | 1300 | 1300-T | 2000 | 2000-T

Vötsch pharmaceutical cabinets have been specially developed to meet the requirements of test laboratories in the pharmaceutical industry. VP Series Cabinets come in four sizes and can provide a constant climate (Types 280, 600, 1300 and 2000) or just a constant temperature (Types 280-T, 600-T, 1300-T and 2000-T). The exceptional build quality, innovative product features, accuracy and smart controls allow for the safest and easiest stability testing.

The working range of the cabinets easily meets the requirements of the ICH Guideline Q1A. Furthermore the systems are designed to work at 5 °C continuously without defrosting. The cabinets also permit the implementation of tests with other specifications in the performance range of the respective system. Controlling of temperature and humidity is performed with highly precise sensors in combination with a specially designed control unit. The control system responds quickly in order to correct set-point variations caused by:

- Influence of the cabinet's contents (absorption or emission of water vapour by the test specimens or their packaging)
- External influences (e.g. laboratory temperature, opening of door)

Standard scope of delivery

- Microprocessor monitoring and control S!MPAC® with 3.5" colour touch panel for entering of set-point values
- Ethernet interface
- Fully integrated user management in the control panel[3]
- Calibration of 2 temperature and 2 humidity[1] values
- Software temperature limiter for min. and max. test space temperatures
- Alarm system according to GAMP
- Interior fittings are entirely made of stainless steel
- Door contact switch
- Water tank with automatic and manual water supply of demineralised humidification water[1]
- Lockable doors
- 4 castors of which 2 have brakes[2]
- Air-cooled refrigeration unit with low noise emission
- Patented vapour humidification system (Sterile Steam System)[1]
- Capacitive humidity sensor[1]
- Entry port, Ø 50 mm, in the right side panel
- Operating manual
- Multi-language touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)
- 280-l units on 6 feet
- 280-l units are stackable

[1]Not applicable for Pharma Series 280-T, 600-T, 1300-T and 2000-T.
[2]Not applicable for Pharma Series 280 and 280-T.
[3]User management is possible in conjunction with S!MPATI®.

Technical data

VP Series Cabinet Type			280	600	1300	2000
SHELVES	Number (max.)	-	2 (16)	6 (36)	12 (72)	18 (108)
	Width (net)	mm	530	530	530	530
	Depth	mm	650	650	650	650
	Storage area (max.)	m²	0.69 (5.52)	2.07 (12.4)	4.14 (24.8)	6.21 (37.2)
	Load per shelf	kg	40 (distributed load)			
	Max load total	kg	160	250	400	600
EXTERNAL DIMENSIONS	Width	mm	1159	782	1440	2156
	Depth	mm	872	1040	1040	1040
	Height (with castors)	mm	-	1995	1995	2001
	Height (with feet)	mm	1017	2050	2050	2050
WEIGHT		kg	135	150	250	350
TEST SPACE DIMENSIONS	Width	mm	620	620	1340	2034
	Depth	mm	673	685	685	685
	Height	mm	641	1300	1300	1300
ENTRY PORT			Entry port, Ø 50 mm, in the right side panel			
TEMPERATURE	Working range	°C	+5 to +60			
	Fluctuation (in time)	K	±0.1 to ±0.2			
	Homogeneity (in space)	K	±0.3 to ±1.0			
	Gradient (acc. to IEC 60068-3-5)	K	1 to 2			
HUMIDITY**	Humidity range	% r.H.	20 to 90			
	RH fluctuation (in time)	% r.H.	±0.5 to ±1.0			
	Dew point temp. range	°C	+5 to +40			
	Water supply		Automatically via built-in water tank and/or external supply			
		l	Water tank, 13	Water tank, 19		
	Water specification		Demineralised water pH value 6 to 7, conductivity 5 to 20 microsiemens/cm			
CALIBRATION VALUES			+25 °C/60 % r.H. and +40 °C/75 % r.H.			
POWER	Mains		1/N/PE, AC 220/230 V ±10 %, 50/60 Hz			
	Nominal	kW	1.1	1.2	1.4	2.0
NOISE LEVEL*		dB(A)	52			

This data is based on an ambient temperature of +25 °C, 230 V, 50 Hz nominal voltage, without specimen, without additional equipment and heat compensation. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more.
*Measured in 1.6 m height under free field conditions at 1 m distance from the front of the system.
**Not applicable for Pharma Series 280-T, 600-T, 1300-T and 2000-T.

Most important options

- Software package S!MPATI® Pharma for recording and processing of measurement values
- Integrated datalogger
- Networking of several systems
- Serial interface RS 232 C
- Registration of temperature and/or humidity[1]
- Integrated UPS to keep the recording alive during a power failure
- Additional temperature and/or humidity[1] sensor
- Acoustic and optical warning signal
- Refrigeration unit, water-cooled
- Glass door, heated[2]
- Height-adjustable feet[3]
- Additional shelves
- Additional entry ports
- Demineralisation unit with exchangeable cartridges for connection to local water supply[1]
- Qualification documentation for equipment and S!MPATI® software
- Special voltages
- Analogue outputs
- Maintenance contracts with defined response time

[1]For types 280-T, 600-T, 1300-T and 2000-T only temperature.
[2]Not for 280-I models.
[3]Standard in 280-I models.

Photostability Testing According to ICH Guideline Q1B.

VP Series 250-L | 250-LT | 500-L | 500-LT

Vötsch VP Series photostability cabinets come in two sizes and can provide a constant climate (types 250-L and 500-L) or just a constant temperature (Types 250-LT and 500-LT). The photostability testing cabinets are characterised by an ideal light, UV, temperature and humidity (types 250-L and 500-L) distribution and can thus guarantee absolutely reproducible light, UV and climatic conditions. The lighting equipment used complies with the ICH Guideline Q1B Option 2 and enables photostability tests to be carried out in less than 100 hours.

One of the most important requirements in photostability tests is the homogeneous irradiation of the specimens. For this reason, all the specimens have to be positioned at the same distance from the light source. The inhomogeneous emission of light by fluorescent lamps is compensated with the help of special light and UV filter systems, thus a homogeneous irradiation of the entire storage area is achieved. For recording of the illumination and UV irradiance this system can be equipped with corresponding light and UV sensors. With this option, entering of set-point values in lxh and Wh/m^2, e.g. 1.2 million lxh and 200 Wh/m^2, is made possible to have a fully automated and with S!MPATI® Pharma also fully documented process. Vötsch photostability testing cabinets offer innovative product features, high accuracy, intelligent controls and an exceptional build quality.

Standard scope of delivery

- Microprocessor monitoring and control S!MPAC® with 3.5" colour touch panel for entering of set-point values
- Fully integrated user management in the control panel[3]
- Shelves illuminated with UV light
- Shelves illuminated with white light
- Light and UV timer
- Light and UV filter for optimum distribution (EEF)
- Software temperature limiter for min. and max. test space temperatures
- Alarm system according to GAMP
- Interior fittings are entirely made of stainless steel
- Calibration of 2 temperature and 2 humidity values[1]
- Alarm output (potential-free contact) for monitoring of tolerance band ±2 °C ±5 % r.H.[1]
- Water storage reservoir with automatic and manual supply of demineralised humidification water[1]
- Door contact switch
- Lockable doors
- Counter for total operating hours
- 4 castors of which 2 have brakes[2]
- Air-cooled refrigeration unit with low noise emission
- Patented vapour humidification system (SSS Sterile Steam System)[1]
- Capacitive humidity sensor[1]
- Entry port, Ø 50 mm, in the right side panel
- Operating manual
- Multi-language touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

[1]Except for types 250-LT and 500-LT. [2]Except for types 250-L and 250-LT.
[3]User management is possible in conjunction with S!MPATI®.

Technical data

VP Series Cabinet Type			250-L	500-L	250-LT	500-LT
SHELVES	Number	–	2 shelves: 1 UV 1 white light	4 shelves: 2 UV 2 white light	2 shelves: 1 UV 1 white light	4 shelves: 2 UV 2 white light
	Storage area	m²	0.71	1.45	0.71	1.45
	Load per shelf	kg	25 (distributed load)			
	Max. total load	kg	50	100	50	100
EXTERNAL DIMENSIONS	Width	mm	1159	740	1159	740
	Depth	mm	872	1050	872	1050
	Height (with castors)	mm	–	2070	–	2070
	Height (with feet)	mm	1017	2070	1017	2070
WEIGHT APPROX.		kg	160	250	160	250
TEST SPACE DIMENSIONS	Width	mm	530	530	530	530
	Depth	mm	673	685	673	685
	Height	mm	641	1305	641	1305
	Useful storage space	L	Approx. 235	Approx. 460	Approx. 235	Approx. 460
ENTRY PORT			Entry port, Ø 50 mm, in the right side panel			
TEMPERATURE	Working range	°C	Without radiation: +10 to +50 With radiation: +15 to +50			
	Fluctuation (in time)	K	±0.1 to ±0.5			
	Homogeneity (in space)	K	±0.5 to ±1.0 (1.5 with radiation)			
	Gradient (acc. to IEC 60068-3-5)	K	1 ... 2			
HUMIDITY	Humidity range	% r.H.	20 to 90			
	RH fluctuation (in time)	% r.H.	±1 to ±2			
	Dew point temp. range	°C	+5 to +40			
	Water supply		Automatically via built-in water tank and/or external supply			
		l	Water tank, 13	Water tank, 19		
	Water specification		Demineralised water pH value 6 to 7 conductivity 5 to 20 microsiemens/cm			
LIGHT	Intensity of light	lx	Approx. 15,000 at +15 °C Approx. 18,000 at +25 °C Approx. 25,000 at +45 °C			
	Intensity of UV	W/m²	1.75 at +15 °C 3.0 at +25 °C 3.7 at +45 °C			
	Homogeneity (in space)	K	±0.5 ... ±1.0 (1.5 with radiation)			
	Light distribution	%	Approx. ±8	Approx. ±8	Approx. ±8	Approx. ±8
	UV distribution	%	Approx. ±12	Approx. ±12	Approx. ±12	Approx. ±12
CALIBRATION VALUES			+25 °C/60 % r.H. and +40 °C/75 % r.H.			
POWER	Mains		1/N/PE, AC 220/230 V ±10 %, 50/60 Hz			
	Nominal	kW	1.4	2.6	1.4	2.6
NOISE LEVEL*		dB(A)	52			

This data is based on an ambient temperature of +25 °C, 230 V, 50 Hz nominal voltage, without specimen, without additional equipment and heat compensation. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more.
*Measured in 1.6 m height under free field conditions at 1 m distance from the front of the system.

Shelf with UV light

Shelf with white light

Most important options

- Software package S!MPATI® Pharma
- Integrated datalogger for recording and processing of measurement values
- Networking of several systems
- Serial interface RS 232 C
- Integrated UPS to keep the recording alive during a power failure
- Registration of temperature and/or humidity[1]
- UV and Lux sensors with automatic measurement value integration
- Mapping of light distribution
- Additional temperature and/or humidity[1] sensor
- Acoustic and optical warning signal
- Refrigeration unit, water-cooled
- Glass door, heated
- Additional entry ports
- Demineralisation unit with exchangeable cartridges for shelf with white lights
- Connection to local water supply[1]
- Qualification documentation for equipment and S!MPATI® software
- Special voltages
- Analogue outputs
- Maintenance contracts with defined response time
- Operation at 5 °C with full illumination

[1]Except for types 250-LT and 500-LT.

Walk-in Test Chambers.

For stability testing according to ICH Guideline Q1A.

Walk-in test chambers for stability tests

The extremely accurate and reliable stability test chambers of Vötsch Industrietechnik can be validated and are designed specifically to help you meet the requirements of the ICH Guideline Q1A. The insulation elements of the chambers can be optimally adapted to an existing building structure since adherence to standard dimensions is not necessary. The standard height is 2700 mm; other dimensions are possible. Chamber volumes from 10 m^2 up to 300 m^2 can be supplied by Vötsch Industrietechnik.

Standard scope of delivery

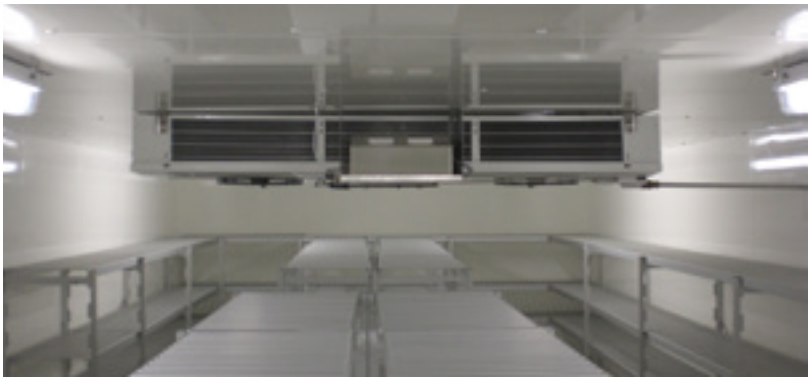
- An excellent mechanical rigidity and optimum thermal insulation are ensured thanks to PU insulation chamber elements (CFC-free) with easy-to-clean, corrosion-resistant double-sided metal plate coating. Panels on the inside and outside are painted RAL 9010.
- Insulated heavy duty floor construction covered with slip-resistant, chequered plate stainless steel.
- Lockable test chamber door with insulated observation window and emergency opening facility. The door frame heater prevents the forming of condensate during high humidity operation.
- A pressure relief valve is fitted to the chamber wall.
- Heating and cooling system consisting of ceiling evaporator with integrated electrical heater and air-cooled refrigeration unit.
- Powerful axial fans ensure continuous intensive air circulation as well as uniform air distribution and temperature conditioning.
- Climate conditioning system with energy-saving ultrasonic humidifier and separate dehumidifier.
- Micro-processor-controlled control system corresponding to GAMP Guide and FDA 21 CFR Part 11 and EU GMP Annex 11, with maintenance-free electronic temperature/humidity sensor.
- Fully integrated user management in the control panel.*
- The switch cabinet incorporates the complete electrical section with fuses, protection, switch, control and regulation appliances. Wiring and electrics are strictly conform to safety regulations for electrical installation and materials according to the European Machinery Directive.
- Safety temperature limiter for electrical heater and test chamber.
- Specimen protection thermostat tmin./tmax. and over humidity protection.
- Multi-language touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean).

*User management is possible in conjunction with S!MPATI®.

Technical data

Temperature working range	°C	+20 to +45
Temperature fluctuation (in time)	K	±0.1 to ±0.5
Temp. homogeneity (in space)	K	±0.5 to ±1 acc. to IEC 60068-3-5
Temperature gradient	K	1 to 2 acc. to IEC 60068-3-5
Humidity range	% r. H.	20 to 80
RH fluctuation (in time)	% r. H.	±1 to ±3
Dew point temp. range	°C	+9 to +41

The performance values refer to an ambient temperature of +10 °C to +32 °C. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more.



Most important options

- Software package S!MPATI® Pharma for recording and processing of measurement values
- Integrated datalogger
- Networking of several systems
- Serial interface RS 232 C
- Additional temperature and/or humidity sensor
- Acoustic and optical warning signals
- Refrigeration unit, water-cooled
- Connection to customer-provided chilled water circuit (e.g. +6 °C)
- Additional entry ports
- Demineralisation unit with exchangeable cartridges for connection to local water supply
- Constant temperature chamber (without controlled humidity)
- Shelf systems
- One-point calibration
- Spatial calibration
- Qualification documentation for equipment and S!MPATI® software
- Special voltages
- Analogue outputs
- Maintenance contracts with defined response time
- Further options available on request

Special Solutions for your Special Applications.

Vötsch VC³/0 Series | Vötsch VTL and VCL Series

If safety matters: Climate Test Chambers of the VC³/0 Series.

In case you test samples containing alcohol and cannot exclude the possibility of leakage of vapours with certainty, you have to carry out a risk analysis and take corresponding safety precautions according to the classification as per ATEX.
With the VC³/0, Vötsch Industrietechnik has developed a series of climate test chambers for real-time tests or tests under different climate conditions. The VC³/0 Series is characterised by very low energy requirements and operation at low noise levels and which can also comprise safety precautions as per ATEX upon a request to that end. The VC³ series is also available with temperature ranges from -40 °C to 180 °C and -70 °C to 180 °C and can be used for stress test or freeze thaw cycles without explosion protection.

Technical data

Vötsch VC³/0 Series		Vötsch VTL/VCL Series
Approx. 190 ... 1540	Test space volume (litres)	Approx. 34, 64 and 100
Performance for temperature tests		
- 10 to +90/- 5 to +90/0 to +90	Temperature working range (°C)	- 70 to +180/- 40 to +180/+10 to +180
±0.1 to ±0.5	Temperature fluctuation (in time) (K)	VTL: ±0.3 to ±1.0, VCL: ±0.3 to ±0.5
±0.5 to ±1.0	Temp. homogeneity (in space)[2] (K)	VTL: ±0.5 to ±2.0, VCL: ±0.5 to ±1.5
1 to 2 acc. to IEC 60068-3-5	Temperature gradient (K)	1 ... 2 acc. to IEC 60068-3-5
+4 and +90	Calibration values (°C)	+23 and +80
Performance for climatic tests		
+10 to +90	Temperature working range[2] (°C)	+10 to +95
±0.1 to ±0.3	Temperature fluctuation[2] (in time) (K)	±0.3 to ±0.5
±0.5 to ±1.0	Temp. homogeneity[1, 2] (in space) (K)	±0.5 to ±1.5
10 to 98	Humidity working range[2] (% r. H.)	10 to 98
±1 to ±3	RH fluctuation (in time)[2, 3] (% r. H.)	±1 to ±3
+4 to +89.5	Dew point temp. range[2] (°C)	+5.5 to +94
+25 °C/60 % r. H. and +40 °C/75 % r. H.	Calibration values acc. to ICH Guidelines	+23 °C/50 % r. H. and +95 °C/50 % r. H.
General data		
1/N/PE, AC 220/230 V ±10 %, 50/60 Hz, safety plug	Electrical connection	1/N/PE, AC 220/230 V ±10 %, 50 Hz
2.3	Max. installed load (kW)	1.8 to 3.5
Height: 1805 to 2005, Width: 875 to 1395, Depth: 1545 to 2610	Overall dimensions (mm)	Height: 980 to 1880, Width: 640 to 780, Depth: 750 to 1105
420 to 920	Weight (kg)	110 to 210
<46	Noise level[4] (dB[A])	<59

This data is based on an ambient temperature of +25 °C, 230 V, 50 Hz nominal voltage, without specimen, without additional equipment and heat compensation. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more. [1]Relative to the set-point value in temperature range from minimal temperature to +150 °C measured. [2]Not applicable for VTL. [3]For VC³ measured in the middle of the test space. [4]Measured in 1.6 m height under free field conditions at 1 m distance from the front of the system.

If Available Space is Limited.

Temperature Test Chambers VTL.
Climate Test Chambers VCL.

Compact, quiet, yet powerful units are required to tackle special laboratory conditions that include limited space, even smaller specimens and the need to conduct re-producible tests on a laboratory scale or stability tests according to ICH Guideline Q1A tests directly at the workplace. The VTL and VCL series of temperature and climatic test chambers are ideally suited to such applications. These systems have a volume of 34 l, 64 l and 100 l respectively and provide an optimum solution where space is limited.

Humidity is generated by a temperated waterbath in a manner free of aerosols. The devices of the VTL and VCL series are suitable for program and constant set point operation, e.g. for stress tests and freeze thaw cycles and are equipped with a state-of-the-art efficient 32-bit S!MPAC® control and communications system. Up to 100 test programmes can be stored and retrieved.

With regard to the technical data the temperature and climate devices fulfil test standards, such as e.g. DIN, ISO, MIL, IEC, DEF or ASTM.

Standard scope of delivery

- 32-bit control system S!MPAC® with 3.5" colour touch panel
- Fully integrated user management in the control panel*
- Observation window
- Test space lighting
- Independent adjustable temperature limiter tmin./tmax.
- Potential-free contact for test specimen switch-off
- Ethernet interface
- USB interface for documentation of measuring data via USB stick
- Air-cooled refrigeration circuit
- 1 shelf
- 1 entry port, Ø 50 mm
- Calibration of 2 temperature values for VTL and 2 climatic values for VCL/VC³/0
- Automatic water supply (VCL and VC³/0 only)
- Multi-language touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

Most important options

- S!MPATI® software package
- Integrated datalogger
- Temperature measurement on test specimen
- Capacitive humidity measurement
- Interface RS 485/RS232C
- Compressed air dryer
- Additional entry ports
- Additional shelves
- Frame with castors (except for VCL/VTL -70 °C/34 l)
- Demineralisation unit (VCL and VC³/0)
- Special voltages

* User management is possible in conjunction with S!MPATI®.

VT 3050 Pharma.

The VT 3050 Pharma is the alternative to a -20 °C freezer as well as usable for freeze thaw cycles and temperature stress test.

500-l temperature test space that takes up less than 1 m² floor space.

Technical data

Test space volume	l	500
Temperature range	°C	-30/+100
Temperature fluctuation[1]	K	±0.5
Deviation in space	K	±1.5
Temperature gradient[1]	K	3
Temperature rate of change[1]		
Heating	K/min.	2.0
Cooling	K/min.	1.4[2]
Heat compensation max.	W	650
Calibrated values	°C	+23/+80
Test space dimensions	mm	width 710/depth 590/height 1250
External dimensions	mm	width 940/depth 1030/height 1955
Noise level[3]	dB(A)	<60
Rated power	kW	1.9
Electrical connection		1/N/PE, AC 230 V ±10 %, 50 Hz

The performance values refer to +25 °C ambient temperature. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more.
[1] In accordance with IEC 60068-3-5.
[2] With option 3 K/min.
[3] Free field, 1 m distance from the front, as per DIN 45635, part 1, accuracy class 2.

Application

Reliable temperature tests ranging from -30 °C to +100 °C for a large variety of applications are possible with the VT 3050:

- Constant temperature tests
- Changing temperature tests
- Freeze thaw cycles
- -20 °C freezer*

Features

- Adjustable software temperature limiter min./max.
- Independent, adjustable temperature limiter tmin./tmax.
- Potential-free contact
- Test space illumination
- Mobile design
- 1 entry port 80 mm
- 1 stainless steel shelf
- Air-cooled refrigeration unit
- WKD calibration of 2 temperature values
- Ethernet interface
- Multi-language 3.5" touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

Options

- Software S!MPATI® Pharma
- Integrated datalogger
- Qualification documents
- Temperature measuring on test specimen
- Other entry ports and shelves
- Glazed door
- Special voltage
- Reinforced cooling unit
- Water-cooled design
- Compressed air dryer*

*For continuous operation with negative temperatures the option compressed air dryer as well as compressed air are necessary to avoid icing.

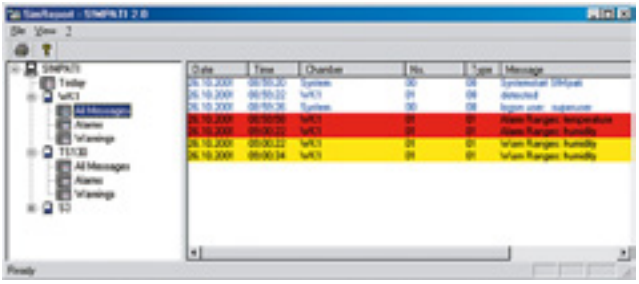
Simple and Secure.

S!MPATI® Pharma software.

Our control and documentation software S!MPATI® Pharma enables you to make even better use of your devices and systems. S!MPATI® Pharma allows for simple and secure recording and archiving of data.

All warning and alarm messages are recorded and, if necessary, transmit an alarm signal to the person in charge of the system. Access rights can be specifically defined for every user; the recording and storage of data are manipulation-safe but can still be used for further processing, e.g. in Excel.

It goes without saying that the S!MPATI® Pharma software complies with FDA 21 CFR Part 11 and EU GMP Annex 11 according to manufacturer's declaration. Validation documents are also provided for the S!MPATI® Pharma monitoring system.

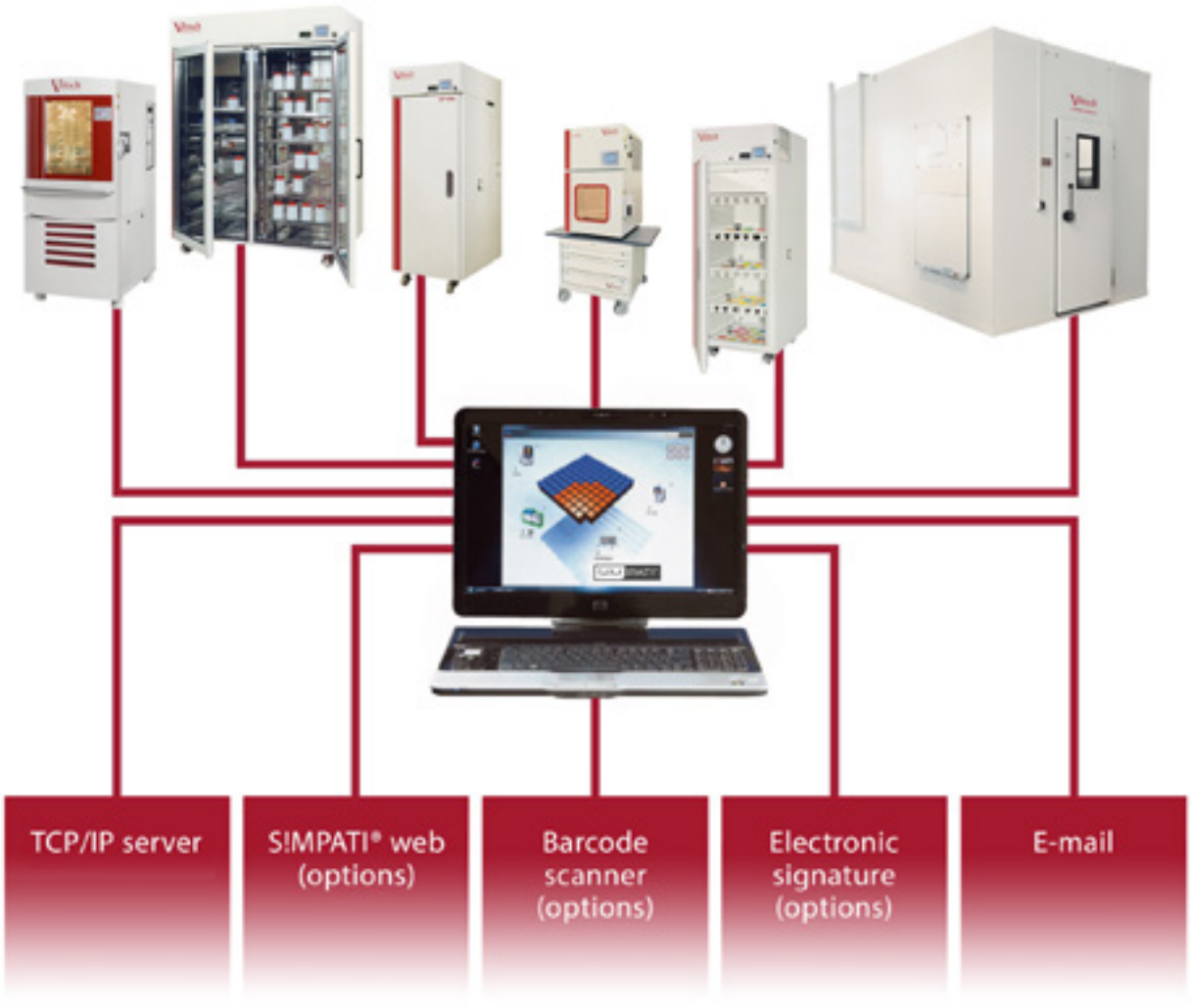


Audit trail

Operation of our systems is simple and time-saving. S!MPATI® can be integrated into your PC network[1] and enables operation at individual stations without requiring special software – simply by using your Internet browser. Furthermore S!MPATI® can be installed on virtual servers.

[1]Perhaps options required.

Connections



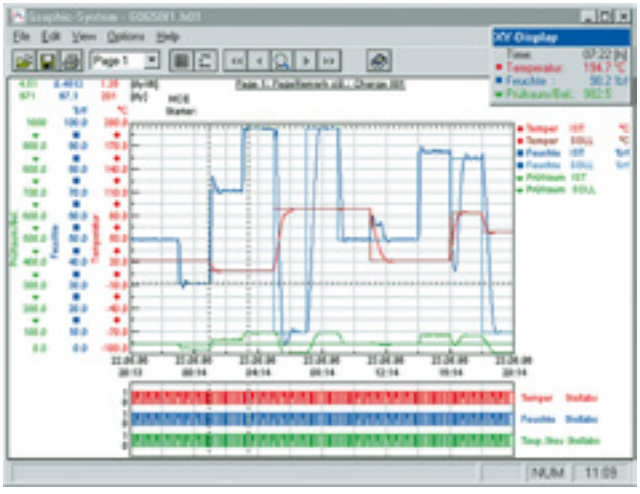
The Most Important Functions and Possibilities.

- Recording and archiving of all test data
- Manipulation-safe data registration
- Administration of multi-level access rights (user management)
- Password alteration
- Compliance with FDA 21 CFR Part 11 according to manufacturer's declaration
- Compliance with EU GMP Annex 11 according to manufacturer's declaration
- Audit trail
- Up to 99 units can be linked via the serial interface or Ethernet interface (TCP/IP)
- Alarm output via e-mail, SMS, phone
- Recording of door openings and documentation of opening times
- Recording of alarms
- Recording of temperature and humidity curves
- Recording of light and UV intensity during photostability tests
- Mobile solutions for site-independent monitoring of devices, e.g. by means of a PDA within the range of the installed WLAN
- Data recording via a special system network as well as via a TCP/IP network is possible
- Documentation of climate chambers and rooms irrespective of manufacturer[1]
- Considering the alarm system of the connected devices S!MPATI® Pharma fulfils the complete 5 steps risk-based approach according to GAMP 5
- Category 3 software according to GAMP
- Available in German, English, French, Czech, Russian, Spanish, Chinese, Korean

In some cases further options or special infrastructure at the customer's facilities are required for the functions described.

Options:

- S!MPATI® e-Sign: Electronic signature with recording of biometric data
- Barcode reader for batch management



Graphical recording

User management

[1]Perhaps options required.

S!MPATI® Barcode Scan.

Batch registration using barcode scanners.

Optional barcode scanning technology can also be used for batch registration and storage management in the system. This optional module must always be adapted on the individual data structures of the user.
An automatic report can be created.

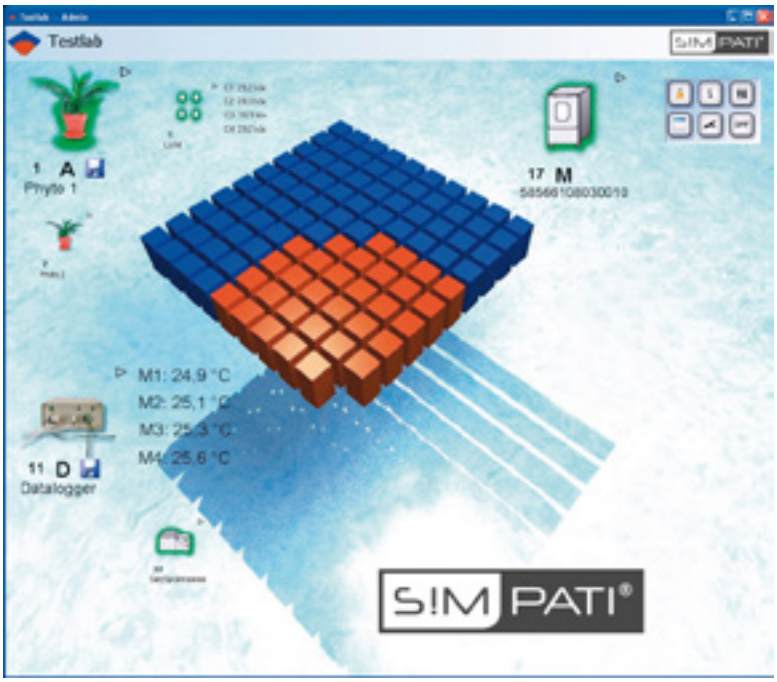
Advantages

- Simple to use – even in clean room conditions
- "Fault-free" input of lot numbers and product IDs
- Scanning of process data
- Automatic assignment of process cycles to existing products
- Wireless scanner technology scans and transfers the information, e.g. during the loading of test chambers

Always in Control

Wherever you are!

S!MPATI® provides a comfortable means of operating and monitoring from your desktop PC. S!MPATI® also supports the modern possibilities of Internet communication for monitoring via Internet browser[1] and information via e-mail. S!MPATI® not only provides process information at your desktop PC but also virtually anywhere in the Internet. It is ensured that you can permanently recall actual data via the cellular phone network (option).



[1]Perhaps options required.

S!MPATI® e-Sign.

Biometric data based on your handwriting.

The consistent solution from electronic documentation of measurement values through to the delivery of electronic documents to the authorities.

Many lawyers would like to see the introduction of a truly **active biometric component** to identify persons. In their opinion, a hand-written electronic signature is the only real active declaration of intent that could never be given unwillingly or by force.
S!MPATI® e-Sign as a supplement to the software package compliant with FDA 21 CFR Part 11 and EU GMP Annex 11 according to manufacturer's declaration. S!MPATI® Pharma enables signing all measurement data whilst capturing biometric data based on your handwriting.

S!MPATI® e-Sign offers legal security, whereby the undersigned is clearly identifiable!

In order to also be able to identify the undersigned at a later date, there are special software graphic components which, in case of dispute, could be used by handwriting experts. Because comparable conclusions can be reached from these components as from a hand-written signature on paper. Functional security was verified, based on more than 200,000 signatures.

All aspects from FDA 21 CFR Part 11 and EU GMP Annex 11 are complied with according to manufacturer's declaration. The system can be easily qualified.

This system is based on a state-of-the-art electronic signature which is accepted for all documents which do not explicitly require the written form by law (such as the German Civil Code), directives or standards.
For all legally valid internal company signatures, i.e. including those in the laboratory, this way of signing is sufficient and also compliant with FDA 21 CFR Part 11 and EU GMP Annex 11 according to manufacturer's declaration.

The data are encoded using a multi-stage asymmetrical encoding process. This code is filed in the document. A hash value (checksum) is formed over the signed document and stored. Even the transmission from the high-resolution graphic tablet to the PC is encoded. A so-called public key/private key infrastructure (PKI) is used when sealing the document. These codes, however, must be generated from an independent office and, for legal security purposes, the private key must be stored in the same place. The storage of the data is carried out in accordance with ISO 19005 in a generally readable data format, with no possibility of changes being made to it, suitable for long-term storage.

Our Customers and Partners Include the “Who’s Who” of the Pharmaceutical Industry.

Around the world, companies profit from solutions developed by Weiss Technik to meet the specific processes and product requirements of each customer. Please ask for our references.

vötschtechnik
Test it. Heat it. Cool it.

Our solutions are deployed around the world in research, development, production and quality assurance of numerous products. Our experts are available at 22 locations in 14 countries, ready to provide support services to ensure high operational reliability of your systems.

Vötsch Industrietechnik is a subsidiary of Weiss Technik, one of the most innovative and pre-eminent manufacturers of environmental simulation systems. With these testing systems, we can simulate all climate conditions around the globe, and beyond in time lapse. Whether temperature, climate, corrosion, dust or combined shock testing: We have the proper solution. We supply systems in all sizes, from standard versions up to customised, process-integrated facilities – for high reproducibility and precise test results.

Vötsch Wärmetechnik, a subsidiary of Vötsch Industrietechnik, offers a wide product portfolio in the field of heat technology. With an experienced team of engineers and designers, we develop, plan and produce high-quality and reliable heat technology systems for virtually any field of application. Products include heating/drying ovens, clean-room drying ovens, hot-air sterilisers, microwave systems and oven systems. The programme reaches from technologically sophisticated standard versions to customised solutions for individual production operations.

Furthermore, Weiss Klimatechnik also offers reliable climate solutions wherever people and machinery are challenged: in industrial production processes, hospitals, mobile operating tents or in the area of IT and telecommunications technology. As one of the leading providers of professional clean-room and climate solutions, we deliver effective and energy-saving solutions and expertly guide you through your entire project, from planning to implementation.

Weiss Pharmatechnik, a subsidiary of Weiss Technik, is a competent provider of sophisticated clean-room and containment solutions. The product range includes barrier systems, laminar flow facilities, security work benches, isolators and double door systems. The company emerged from Weiss GWE and BDK Luft- und Reinraum-technik and disposes of over 30 years of experience in clean-room technology.

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