

In Compliance with GMP and FDA...



... you can be assured of that!

We guarantee reliable state-of-the-art products for the pharmaceutical industry

# Absolute Confidence ...

## Stability testing...

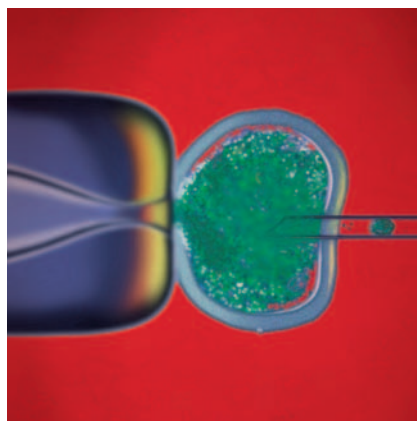
Absolute confidence becomes reality with Vötsch systems dedicated to the fields of pharmacy, medicine, gene technology, biotechnology, foodstuffs industry and all industries involved in the intensive research of life sciences.

Regardless of whether you require stability test systems for the pharmaceutical industry or climate chambers for substances or medicines, heating and drying ovens or hot air sterilizers for production purposes, Vötsch Industrietechnik offers you a full range of systems to meet your requirements.

**GMP** (Good Manufacturing Practice) and **FDA** (Food and Drug Administration) define the demands on functionality, performance and documentation in the **ICH** guidelines (International Conference on Harmonization).

Europe, Japan and USA agreed to a common stability tests. The objective of these tests is to gather information in order to make recommendations regarding the stability of substances or medications. The ultimate goal is proof of the drugs' effectiveness after its exposure to temperature and humidity over a defined period.

In the Q1A guideline a long-term test, an accelerated test and a test with intermediate stress values were laid down. The latter is only applied when the first two tests deliver differing results.



- **Long-term condition**

Temperature +25 °C  
Humidity 60 % r.h.  
Duration 12 months

- **Accelerated condition**

Temperature +40 °C  
Humidity 75 % r.h.  
Duration 6 months

- **Intermediate condition**

Temperature +30 °C  
Humidity 60 %  
Duration 6 months

The deviation for temperature and humidity during the entire testing period is defined as  $\pm 2$  K and  $\pm 5$  % r.h. respectively.

The above mentioned guideline defines not only the number of batches but also the sequence of the necessary analytic tests.

The synthesis of a new substance through to its approval as a medicine is a process which today takes approx. 12 years. In the seventies, this process took about 10 years.

Although this period cannot be reduced considerably by using climate chambers, the confidence level of the result is higher. For this objective, Vötsch supplies highly accurate and reliable test systems.

Each physical/chemical system is subjected to changes due to the thermal movement of particles. For drugs these changes can be divided into 3 groups:

### Physical changes

- Mechanical stability, decay period of tablets, suppositories
- Polymorphism and pseudo polymorphism (solubility changes)
- Change in state of aggregate (eutectic solutions)

### Chemical changes

- Caused by hydrolysis, oxidization, reduction, decarboxylation, esterification, polymerization etc.

### Microbiological changes

- Contamination as defined in DAB 9 as well as observation of the microbiological processes.



It is stipulated that substances that are extremely sensitive to temperature must be tested to the following conditions:

- **Long-term condition**  
Temperature +5 °C  
Duration 12 months
- **Accelerated condition**  
Temperature +25 °C  
Humidity 60 % r.h.  
Duration 6 months

The effectiveness of substances and drugs in semi-permeable packaging is tested as follows:

- Long-term condition  
Temperature +25 °C  
Humidity 40 % r.h.  
Duration 12 months
- Accelerated condition  
Temperature +40 °C  
Humidity 15 % r.h.  
Duration 6 months

The ICH guidelines also include the **Q1B** test "Photostability", which subjects substances, inscription and packing to light.



## Qualification

The design of our products, along with their outstanding performance capabilities to maintain highly accurate temperature and humidity conditions over an extremely long period of time is certified in our qualification documentation.

### The entire system qualification comprises:

- DQ** Design qualification
- IQ** Installation qualification
- OQ** Operation qualification
- CQ** Certification qualification  
Certificates and check lists

These qualifications confirm that the units were manufactured as per the construction diagrams and manufacturers specifications that comply with **DIN EN ISO 90001** and that all tests were verified according to the specified standards.

The coordination of function and design as well as the confirmed performance features complement the overall package.

**"Meliora cogito"** (I strive for the best), is the motto that prevails at Vötsch Industrietechnik.

Our cabinets with the corresponding documentation bring you one step ahead.

It goes without saying that both product sectors of Vötsch Industrietechnik GmbH are certified as per **DIN EN ISO 90001**.

# Drug testing ...

## The application

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

### The test systems

VP 600  
VP 1300 and  
VP 2000

were specially developed for use in laboratories and supplement the spacious walk-in chambers that are used in production areas.

### Our solution for the laboratory, available in three sizes:

- Storage space of  
2.07 m<sup>2</sup> (600 l)  
4.14 m<sup>2</sup> (1300 l)  
6.21 m<sup>2</sup> (2000 l)  
with 6, 12 or 18 standard shelves.

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

The chamber humidification is a patented system which is permanently monitored by an electronic module.

The parameters temperature and relative humidity are detected by a PT100 and capacitive measuring sensors.

For monitoring and controlling the test chamber is equipped with a powerful 32-bit control system **MINCON/32**.

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



## Standard equipment ...

- Microprocessor monitoring and control unit **MINCON/32**
- Humidity input and display in % rel. humidity
- Independent adjustable temperature limiter  $t_{\min}/t_{\max}$
- Calibration of 2 temperature and humidity values
- Air-cooled refrigeration unit
- Capacitive humidity measuring sensor
- Steam humidification
- Entry port NW 50 mm, right-hand side
- Test space stainless steel
- Single wing door, lockable
- Mobile design, wheels (with 2 locking castors)
- Shelves made of stainless steel 6, 12 or 18 pieces

## Technical Data

Type			VP 600	VP 1300	VP 2000
Shelves 650 x 530 mm	Piece		6	12	18
Storage space	m <sup>2</sup>		2.07	4.14	6.21
Temperature range	°C		+10 to +50		
Temperature fluctuation 1)	K		±0.5		
Deviation in space	K		±1		
Temperature gradient 1)	K		2		
Humidity range	% r. h.		30 to 90		
Dew point range			5 to 40		
Humidity fluctuation in time	% r. h.		±2		
Calibrated values			+25 °C / 60 % r.h. and +40 °C / 75 % r.h.		
External dimensions	Width	mm	740	1460	2155
	Depth	mm	1050	1050	1050
on wheels (standard)	Height	mm	1975	1975	2067
on feet (option)	Height	mm	2030	2030	2112
Test space dimensions	Width	mm	530	1245	1880
	Depth	mm	650	650	650
	Height	mm	1300	1300	1300
Entry port	mm		1 pce. 50 mm diameter, on the right		
Electrical connection			1/N/PE AC, 230 V ±10 %, 50Hz		
Rated power	kw		2.5	3.0	3.5
Weight	kg		150	250	350
Noise level					
1 m distance from the front 2)	dB(A)		52	52	52
Humidification water			demineralized water, pH-value 6-7 conductivity max. 20 Microsiemens/cm		

Performance data refer +25 °C ambient temperature. 1) as per IEC 60068-3-5

2) For free field measurements as per DIN 45635, part 1, accuracy class 2

**Subject to technical alterations. Some units illustrated with options**

## Possible options

- Software SIMPATI\*
- Networking of test systems
- Registration of temperature and humidity
- Independent sensor for temperature and humidity
- Temperature sensor (PT100 Class A)
- Door opening contact
- Glass door, lockable
- Feet separately adjustable in height
- Additional insert shelves
- Additional entry ports
- Demineralization unit for connection to domestic water supply
- Qualification documentation



# Stability tests ...



## Bio Line Pharma series ...

The Bio Line Pharma series (VB...) is used for stability testing of drugs, e.g. as per the ICH guideline of 27<sup>th</sup> October 1993 "Stability Testing of New Drug Substances and Products".

The VB ... series provides maximum storage area where minimum space is available. The spacious shelf system of stainless steel provides you with the same storage conditions on all 15 or 30 shelves thanks to the patented horizontal airflow system using an airflow fiber.

The airflow fiber and the germ-free humidification system ensure clean ICH climate conditions. The storage space is easy to clean and the airflow fiber is washable.

The logging of temperature and humidity is possible via the RS 232 interface.

An alarm system provides the necessary safety. Low energy consumption and a thick layer of thermal insulation ensure economical long-term operation.

### Technical details:

- Temperature range for climatic mode +5 °C to +45 °C
- Temperature fluctuation, in time ±0.5 K
- Humidity range 40 % to 95 % r.h.
- Humidity fluctuation ±3 % to ±5 % r.h.
- Shelf system of stainless steel
- Shelves, maximum 15 or 30 pce. respectively
- Storage area 9.6 m<sup>2</sup> or 19.2 m<sup>2</sup>
- Electrical connection 1/NE AC, 230 V ±10 %, 50Hz
- Dimensions Width x depth x height in mm

#### Typ VB 0714

Test space 970 x 750 x 1400  
Housing 1980 x 850 x 1970

#### Typ VB 1514

Test space 1990 x 750 x 1400  
Housing 3000 x 850 x 1970

## Climate conditioning at its best ...

For even higher demands, we offer our climate chambers of the VC 0 ... series

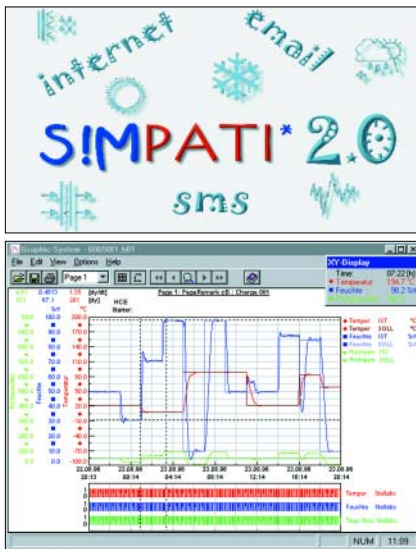
The desired climate is produced reliably and exactly to your requirements. Long-term tests in climate chambers are the quickest way to optimize and secure your product quality. Stability tests as per the ICH guideline, constant climatic tests as per DIN 50014 and IEC 60068-2-3, ..-56, ..-67 and ..-78 can be easily performed.

### Technical details:

- Temperature ranges: -10 °C to +90 °C (600 l -5 °C to +90 °C from 1000 l ±0°C/+90 °C)
- Humidity range 10 % to 98 % r.h.
- Test space volumes 190 to 1540 l
- Calibration values as per ICH + 25 °C / 60 % r.h. + 40 °C / 75 % r.h.
- Independent, adjustable temperature limiter  $t_{min}/t_{max}$
- RS 232 interface
- Air-cooled cooling unit

### Additional leaflets available (Environmental Simulation Balingen)

"Stability tests for pharmaceut. agents" "Constant climate", Series VC 0...



## SIMPATI\* Software

SIMPATI\* the control and test management software (option) enables you to make even better use of your systems.

Operation of the cabinets is simple and time-saving. The evaluation and documentation of the test and sterilization cycles as well as the incorporation of your special measuring data ensure a high quality standard.

SIMPATI\* can be integrated in your PC network and enables you to operate through various PCs without requiring special software - simply by using your Internet browser.

It goes without saying that our controls SIMCON and MINCON as well as our software SIMPATI\* 2.0 comply with the "21 CFR Part II Compliance" guidelines.

We also provide a qualification document for our control and test management software SIMPATI\*.



## Safe and reliable sterilization

If you wish to sterilize products in a quick, safe and cost-saving manner, then hot air sterilization is an alternative method. The only requirement is that the product to be sterilized is temperature-resistant. Receptacles, ampoules and vials can be sterilized at high temperatures with pyrogenes being removed using this method.

The higher the temperature, the shorter the sterilization procedure, thus this method is particularly time-saving and economical.

### Technical details:

- Temperature range 70 °C to 350 °C depending on the series
- Sterilization under clean room conditions (Class 100 and 10.000)
- Horizontal airflow for series ST, NTS, NTSF, vertical for the STR series
- Compliance with GMP/FDA
- Monitoring of internal pressure

### Additional leaflets available (Heat Technology Reiskirchen)

„Safe and reliable sterilization...“



## Vacuum drying

Vacuum drying today has become indispensable in the many drying processes used in the pharmaceutical, biotech, chemical and cosmetics sectors. Active agents and end products, e.g. granulates, powder and pastes can be dried gently under vacuum at low temperatures.

Heat-sensitive pharmaceutical products can be dried quicker and more economically in this manner by lowering the pressure in the vacuum chamber. Powders are not disturbed due to the absence of convection currents. Evaporating fluids, such as combustible solvents, can be recovered.

The vacuum dryers comply with recognized guidelines, e.g. FDA. All safety regulations as well as the rules of good manufacturing practise (GMP) are observed. Rotary vane vacuum pumps which are used for condensation of solvents are a part of the accessories as well as charging systems, special materials and a tailor-made software.

“Vacuum heating and drying ovens”

# Walk-in chamber for the pharmaceutical industry ...



## Walk-in climate chambers for stability testing

Stability chambers produced by Vötsch Industrietechnik GmbH are qualifiable and designed to meet your individual requirements. Thanks to flexible design and construction techniques, the walk-in chambers can be integrated into existing structures.

Technical details on request.



## Long-term tests of drugs

Two test rooms, with conditioning provided by external standard climatic systems for storing drugs for climate zones I (temperate 21 °C, 45 % r.h.) and II (Mediterranean 25 °C, 60 % r.h.). Medicines in gelatine capsules are packed in blister packs, cans or jars and then stored (some of which for 3 years) to fulfill the requirements of BGA (Federal Health Office) and FDA.



## Hot air sterilizers for the pharmaceutical industry

Our heat technology product range offers turn-key sterilization systems in the clean room versions, Class 100 and 10.000 in compliance with GMP/FDA. Technical information on request. We also offer systems for continuous drying/heating sterilization specially for the pharmaceutical industry.

**VIT-E 8/01** 6C 05.03 N SV

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