ASM 2000

High performance CCIT solution for the pharmaceutical industry based on helium mass spectrometry


Syringes


Blister


Vials

PFEIFFER VACUUM

ASM 2000

High performance CCIT solution for the pharmaceutical industry based on helium mass spectrometry

High sensitive measurements for project and validation studies of new containers

Your added value

Turnkey solution

Our know-how

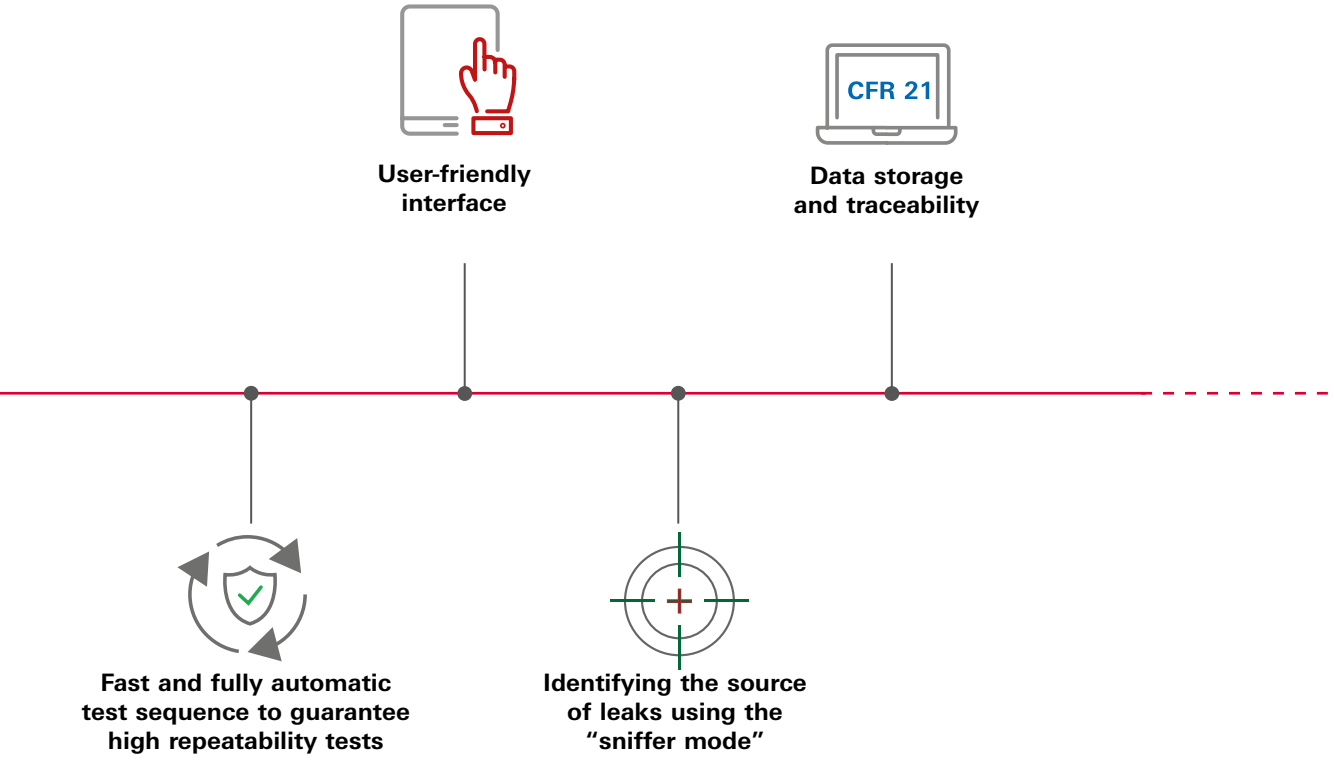
Pfeiffer Vacuum is one of the world´s leading providers of vacuum and testing solutions. The product portfolio comprises vacuum pumps, measurement and analysis devices, components, as well as vacuum chambers and high performance detection systems. Furthermore, we offer a unique portfolio of equipments based on three technologies that are dedicated to the pharmaceutical and medical markets. Leak testing and CCIT can be performed on a large variety of drug/container combinations.

Integrity challenges

Contamination such as humidity, oxygen or microbiological ingress can impact drug stability throughout the product life cycle. To prevent the risks of stability failure of highly moisture-sensitive drugs (e.g. dry powder for inhalation), or the risk of biological ingress of parenteral drugs, integrity tests with a high sensitivity are required. Most test methods are very challenging in regards to time effort, complexity or the limitation of sensitivity and detection range.

A proven solution

Helium mass spectrometry based upon ASTM F 2391-05[1)] is applicable to non-porous packaging such as vials, syringes and cartridges. Currently, the helium leak test, a deterministic method, is being established as the gold standard for its sensitivity and versatility. Furthermore, helium leak detection offers the capability to also locate the position of a leak.



Key features

ASM 2000 is a comprehensive solution completely adapted to the needs of pharma industry. ASM 2000 is the perfect solution for the validation and qualification of new containers. Based on a high performance helium mass spectrometer leak detector, it also includes a helium charging module, and can be equipped with custom fixtures for the particular container formats. The instrument is calibrated against NIST[2)]-traceable standard leaks.

Dependable, fast and sensitive

Further advantages of the ASM 2000 are its high helium pumping, its integrated automatic helium charging module as well as the optimized free internal volumes. Those features guarantee high performance measurements on helium filled sealed containers and open sub-assemblies.The ASM 2000 sustains very high throughput, ensures the accuracy and the reproducibility of the measurement results, and allows ultra fast cycle time.

Advanced software

The software proposes intuitive menus easy to navigate. User log in is required to operate the equipment and four access levels are available (operator, advanced user, maintenance, administrator). Test recipes can be managed for each part format. At the end of the test sequence, the result is clearly displayed and PDF test and calibration reports are automatically generated at the batch closure.

[1)] American Standard for Testing and Materials
[2)] US National Institute of Standards and Technology

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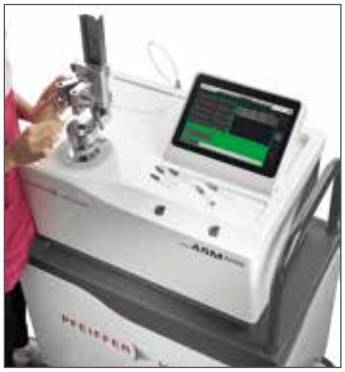
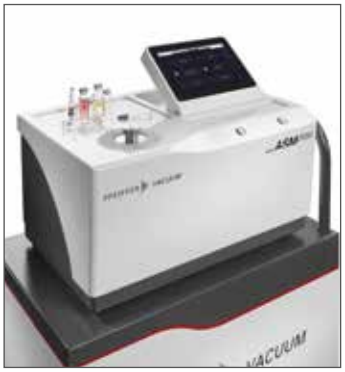
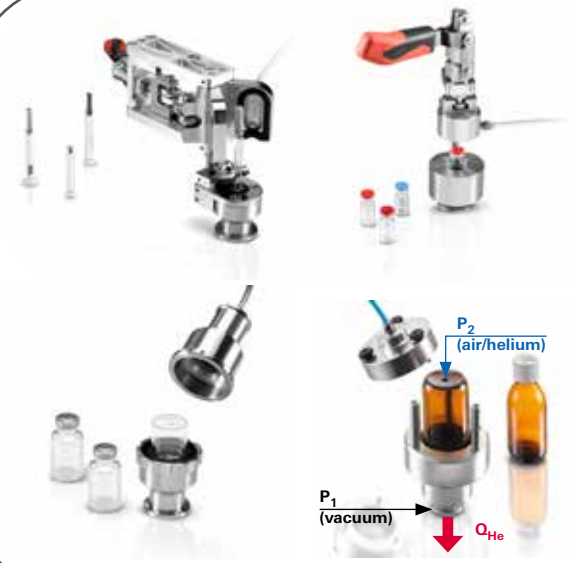
[1] The laptop is not provided by Pfeiffer Vacuum

Operation

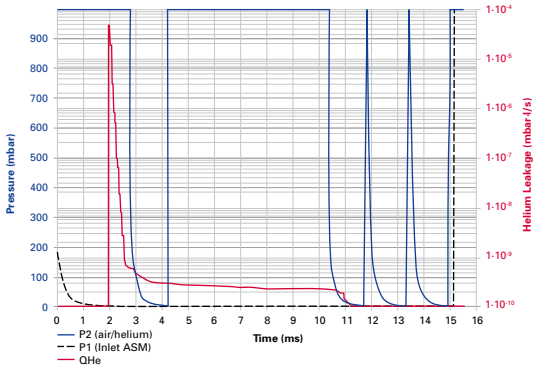




High performance helium leak testing for validation and qualification of new packagings.



- Specific tooling's according container design
- Automatic test sequence including He charging
- Massive leak detection prior to He charging
- Test duration < 20 sec.



Test of open containers

Sniffer probe for leak localization

Helium spray gun for charging vials

Test of He pre-filled containers

- Vacuum test chamber according container design
- Test chamber volume: 3 liters max.
- Typical test duration < 8 sec. (depend on free volume)

Dry Chiller Module

Mastering Integrity
Under Cold Storage Conditions

The Dry Chiller Module is a versatile addition to both new and existing leak detection systems. Serving as an external cooling component, it is compatible with the ASM 2000 for helium pre-filled containers and the AMI 1000 without any sample preparation, utilizing naturally present gas. This module sets new benchmarks in delivering reliable data for testing container closure integrity at low temperatures. Benefit from real-time results of temperature and leak rate, optimizing your process without wasting cycle time.

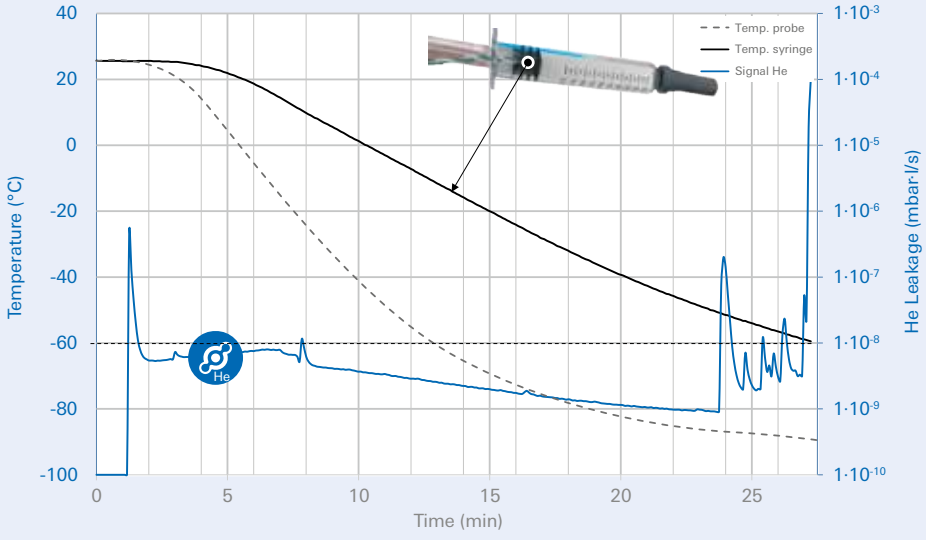
The Dry Chiller Module is designed to prove that the container closure system maintains integrity at deep cold storage temperatures, either at -80 °C (-112 °F) or even lower. It ensures the quality of substances requiring cold storage conditions, particularly in medical and pharmaceutical environments. Its flexibility ensures that the Dry Chiller Module can be integrated seamlessly into existing equipment.

Fast cool down and heat up

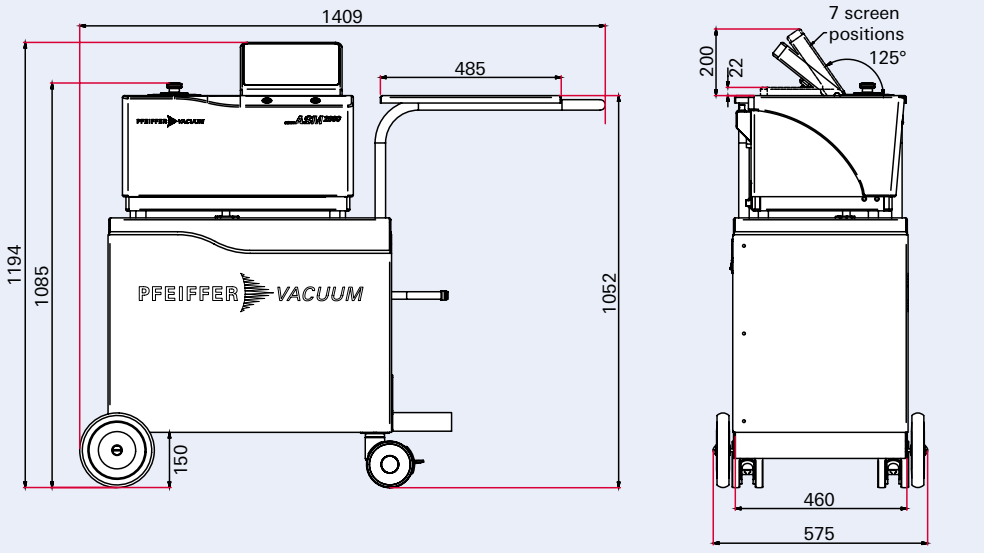
Control over entire temperature profile

Continuous leak rate measurement

ASM 2000: Low temperature test on He pre-filled syringe



Dimensions



Dimensions in mm

Technical data

	ASM 2000
Test methods	Vacuum and sniffing leak detection
Measurement range (vacuum test)	
Quantitative range – Fine leak Helium	< 10^{-9} – 10^{-5} mbar l/s
Qualitative range – Gross leak Helium	10^{-5} – 10^{-3} mbar l/s
Qualitative range – Massive leak Air	> 10^{-3} mbar l/s
Minimum detectable He leakage (sniffing test)	> 10^{-5} mbar l/s
Power supply	90-250 V AC / 50–60 Hz
Typical power consumption	3,750 W
CDA supply	Required for operation
Quality	(1.3.1 according to ISO 8573-1)
Pressure (min./max.)	4.5/10 bar rel. – 65/145 psig
Helium supply	Required for operation
Pressure (min./max.)	4.5/10 bar rel. – 65/145 psig
Nitrogen supply	Required for operation
Pressure (min./max.)	4.5/10 bar rel. – 65/145 psig
User interface	10“ Multi-touch Full HD color screen
Software	21 CFR part 11 compliance PDF GMP test and calibration reports authentication local or domain (LDAP)
Operating system	Windows 10
Network connection	1 x LAN (RJ45)
Interfaces (printer, bar code reader, data export)	2 x USB 3.0 (ext.), 1 x HDMI
Operating conditions	
Temperature (min./max.)	15–25 °C
Humidity (min./max.)	30–80 %
Dimensions (l x w x h) (Including trolley)	1,409 x 575 x 1,194 mm 55.5 x 22.6 x 47 inch
Weight, (Including trolley)	140 kg/308 lbs.
Noise level	< 53 dB(A)

ASM 2000

<10^{-9} – 10^{-5} mbar l/s

Quantitative range – Fine leak Helium

CFR 21 part 11

Compliant software

Order information

Please contact your local Pfeiffer Vacuum sales adminstration

Your Success. Our Passion.

We give our best for you every day – worldwide!

Are you looking for an optimal vacuum solution? Please contact us:

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