



ASM 2000

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

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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 2391-05²⁾ 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.

²⁾ American Standard for Testing and Materials

Application examples





¹⁾ The laptop is not provided by Pfeiffer Vacuum

Customer benefits

- High sensitivity measurements required for design and validation studies of new containers
- Turnkey solution including high performances helium leak detector, helium charging module and customized tooling
- User-friendly interface
- Fast and fully automatic test sequence to guarantee high repeatability tests
- Data storage and traceability
- Identifying the source of leaks using the “sniffer mode”

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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 NIST³⁾-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.

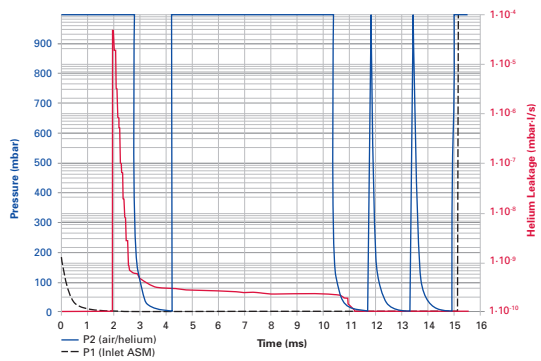
³⁾ US National Institute of Standards and Technology

Operation





- 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)

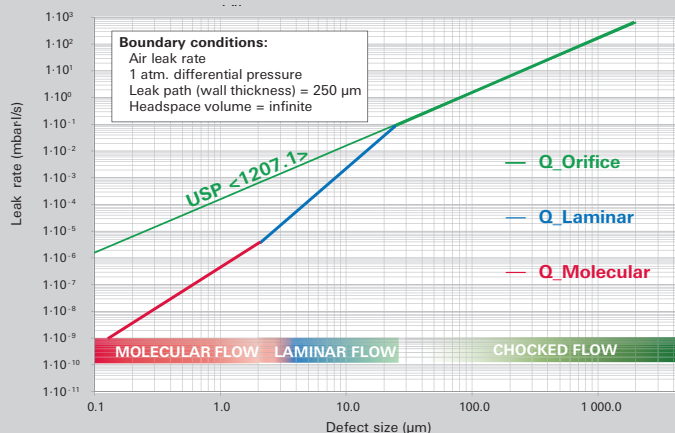
Equivalence between defect size & air leak rate

Leak rate versus defect size

Historically, dye ingress testing has been the container closure integrity test of choice. The detection limit of this method is around 20 μm . Since the test is strictly visual, the detection limit has experimentally been determined by using orifices of known diameter. As a consequence, tightness criteria in pharmaceutical industry are usually expressed as an equivalent hole diameter in μm . However, an equivalent hole diameter is not enough to define the tightness criterion of a packaging. Depending on the diameter of the hole, the leak path (length) must be considered in order to define a leak rate ($\text{atm} \cdot \text{cc/s}$) which corresponds to a tightness criterion.

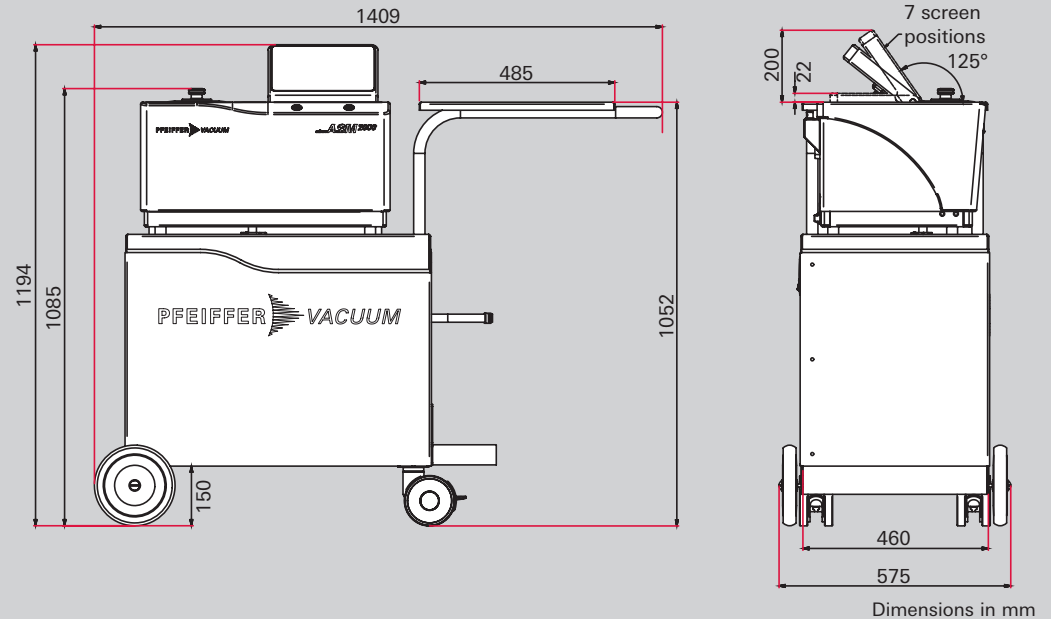
- For large diameters (typically $> 100 \mu\text{m}$), the leak can be generally considered as orifice (leak path of negligible length) as defined in USP <1207.1> section 3.9. This corresponds to the "CHOKED FLOW" regime and the leak rate is directly proportional to the surface of the orifice (green curve). For smaller diameters, the leak path (wall thickness) also needs to be considered. Therefore, the leak rate is not a function of the square of the equivalent hole diameter anymore. Moreover, different flow regimes must be considered for calculation of the leak rate.
- In "LAMINAR FLOW", the viscosity of the gas (depending on the gas temperature) is the parameter which determines gas-to-gas variations of media transfer through the leak.
- In the region of smallest diameters there is another flow transition. In "MOLECULAR FLOW" regime the molecular mass of the gas and its temperature are the driving parameters. As shown on the attached graph, the difference between the USP <1207> orifice calculation and the real geometry of the leak is very important for holes with very small diameters.

General introduction (Leakrate / defect size)



$$Q_{\text{Air}} \text{ (mbar} \cdot \text{l/s)} = f[\text{defect size } (\mu\text{m})]$$

Dimensions



Technical data

Features	ASM 2000
Test methods	Vacuum and sniffing leak detection
Measurement range (vacuum test)	
Quantitative range – Fine leak Helium	10^{-8} – 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)

Order information

Please contact your local Pfeiffer Vacuum sales administration

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