Vacuum and Pressure Decay CCI Technology

Non-destructive, deterministic Testing Technologies

PDA Europe
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AGENDA

- Vacuum and Pressure decay, the Basics
- Vacuum and Pressure decay, Capabilities and Challenges
- Combined Solutions
- Conclusions

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Vacuum – Pressure decay

General definition	Leak Ø in µm (approx.)	Leakage in mbar.l.s^{-1}	Method with corresponding detection limit
Water tight	5-10 µm	10^{-2}	**High Voltage/Pressure and Vacuum decay**
Vapor tight	2-5 µm	10^{-3}	**deep vacuum decay**
Bacterial tight	1 µm	10^{-4}	**Head Space Analysis**
Virus tight	0,1 µm	10^{-6}	**Mass spectroscopy**

Smallest leak to allow microbial ingress: 6.1 x 10^{-6} mbar.l.s^{-1}

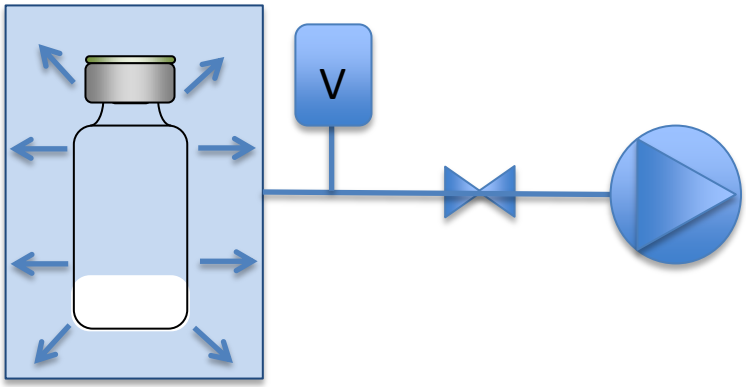
Source: Lee Kirsch, et al, PDA Pharm Science & Technology,Vol51, No.5, 1997[4]

Vacuum – Pressure decay

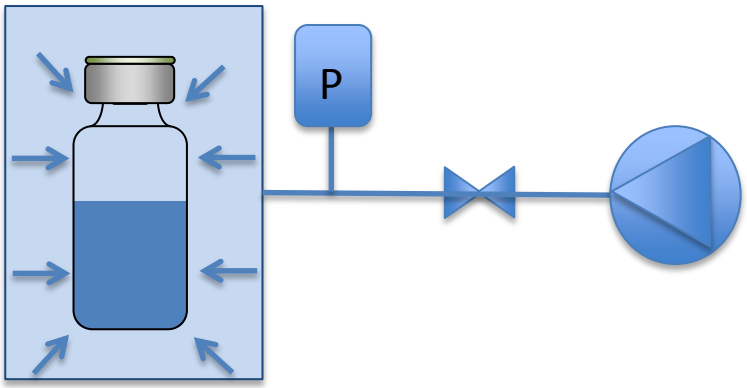
20 ml Vial prepared with capillary, pressurized with 1000mbar:

1.6 x 10^{-2} mbar*l/sec => 8µm

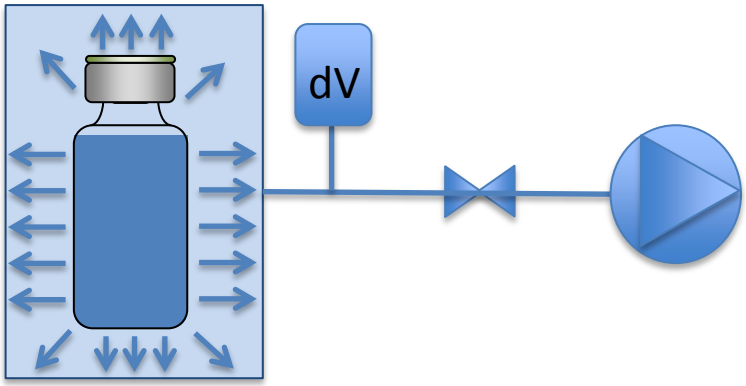
Vacuum – Pressure decay



Vacuum decay

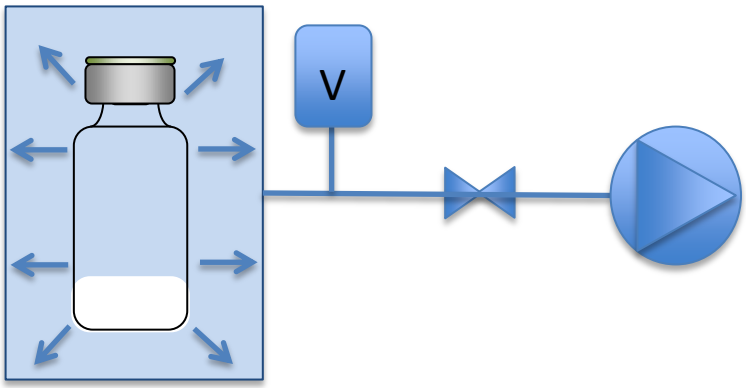


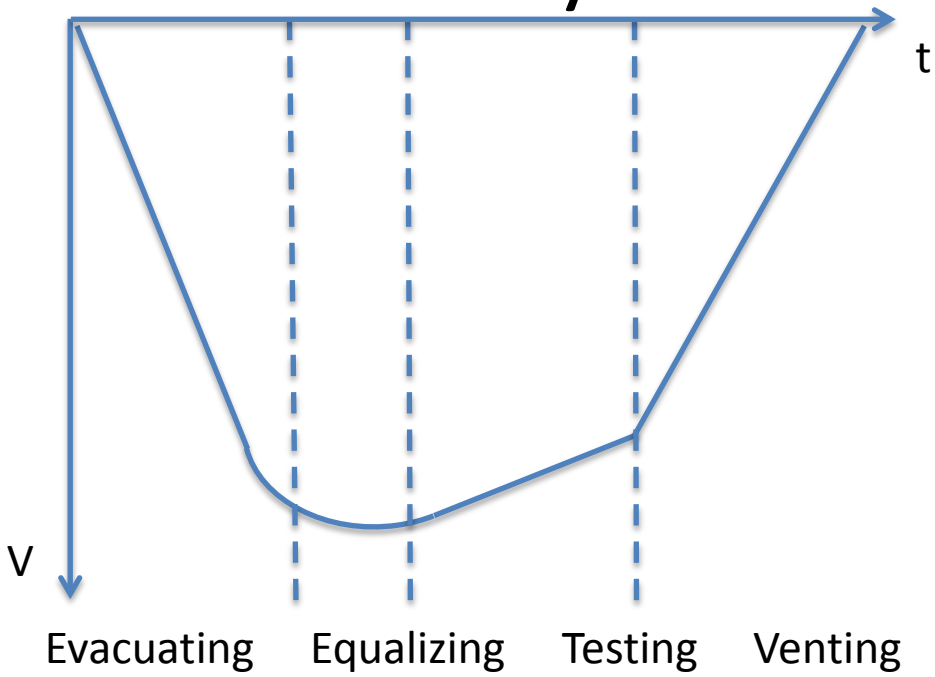
Pressure decay



Deep Vacuum decay

Vacuum – Pressure decay



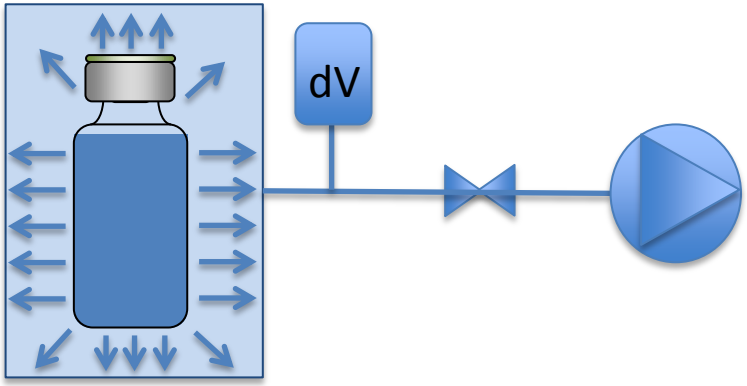


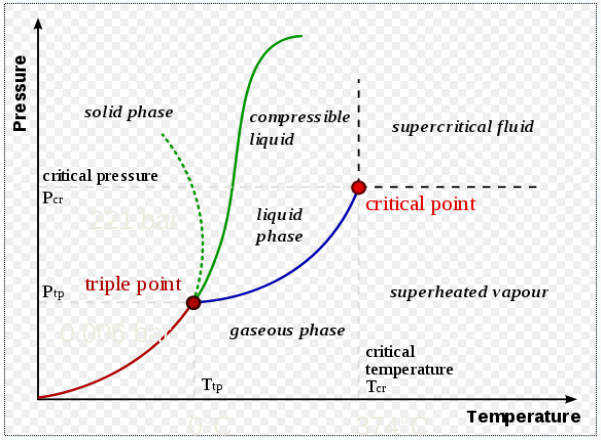
Standard vacuum decay => vacuum levels between 300 – 900 mbar

4 Phases => Complete testing cycle of approx. 6 sec. for 10 µm for in-lie applications or 5 µm with single station

Vacuum – Pressure decay

Vacuum – Pressure decay

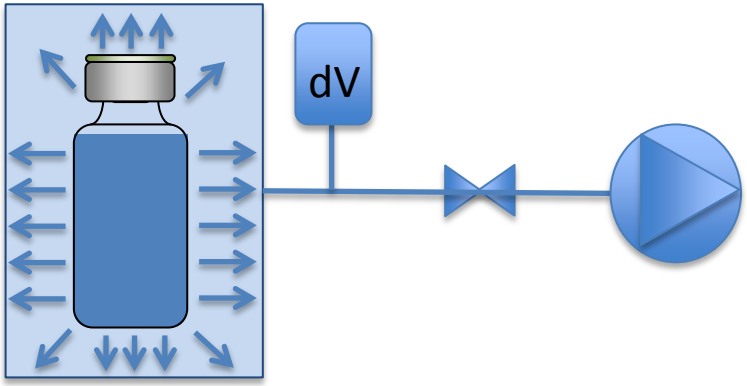


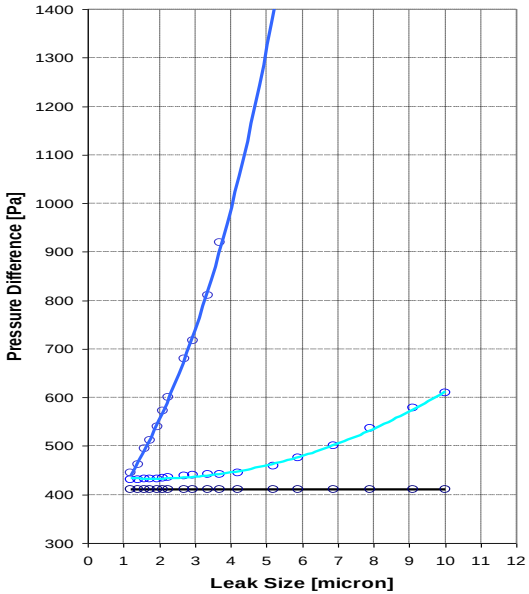


Deep vacuum decay => absolute testing pressure below tripe point of water

4 Phases => Capabilities of detecting leaks down to 8 µm for in-line application

Vacuum – Pressure decay





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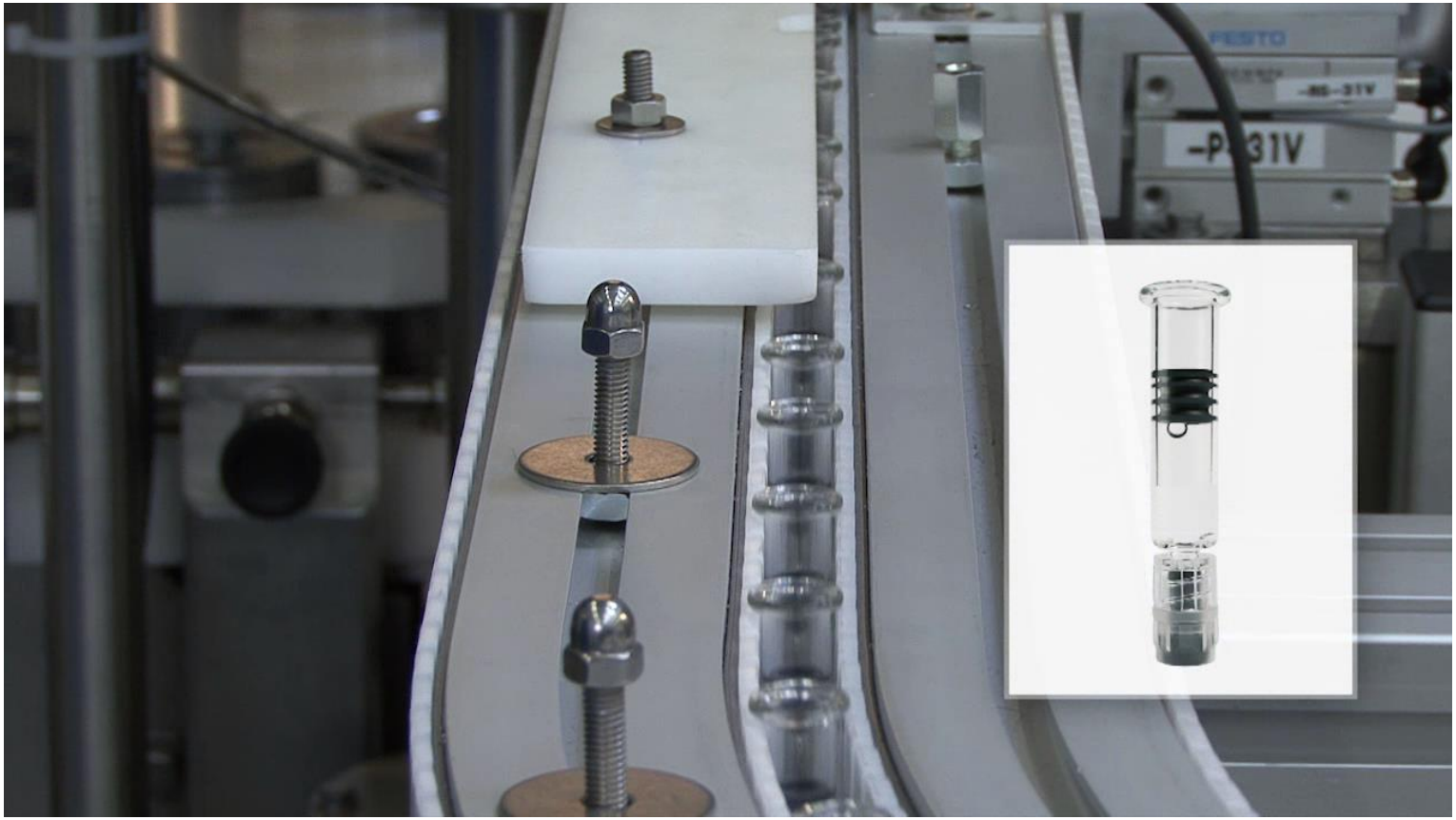

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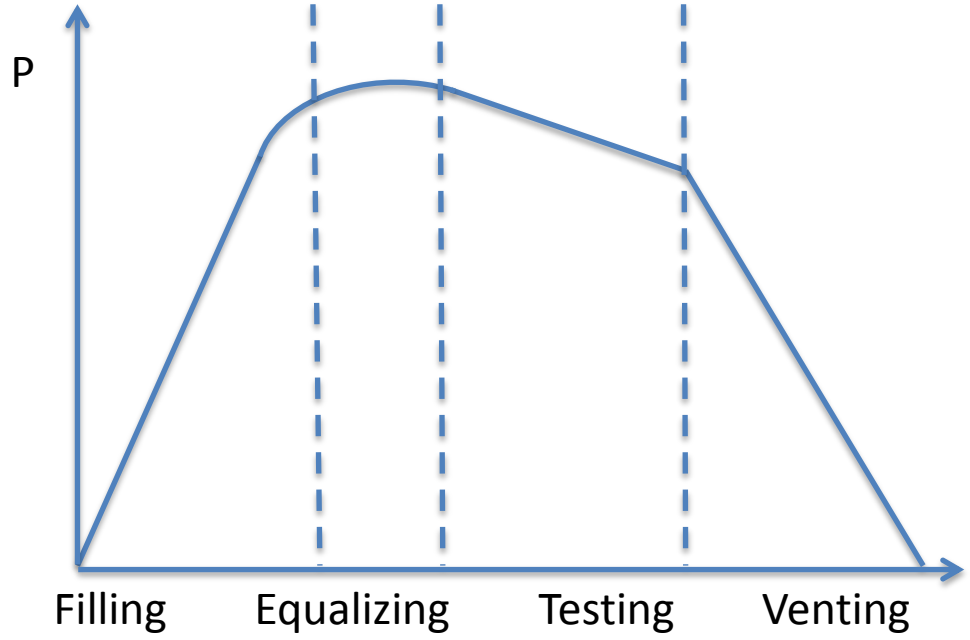

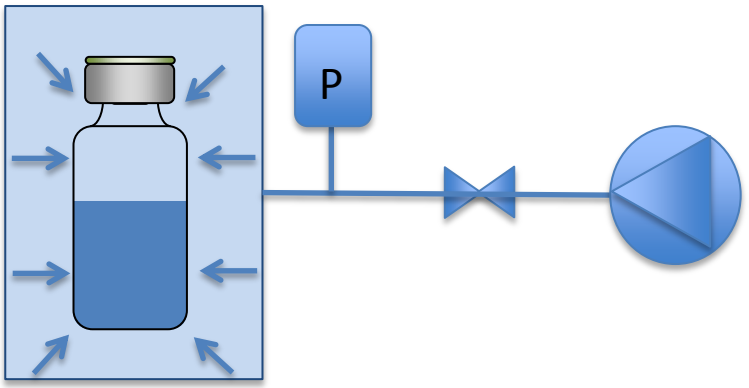

Pressure decay => pressure levels between 300 – 900 mbar

4 Phases => Complete testing cycle of approx. 6 seconds for 10 µm

Vacuum – Pressure decay

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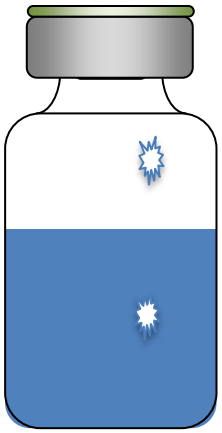

Pressure decay	Vacuum decay	Deep vacuum decay
8-10 um	8-10 um	8-10 um
8-10 um	For freeze dried products 8-10 um	5-8 um
Headspace volume required	Headspace volume required	Regardless of headspace

- Trapped air effect
- Clogging effect due to proteinaceous solutions as well as sucrose or salts
- Positive controls like laser drilled holes or capillaries with use of real product

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Combined Applications

			
Format Sizes	2R – 100H	2R – 20R	1ml – 30ml
Product	Liquid water based	Freeze Dried N_2 overlay	Liquid oil based
Inspection Technology	Deep vacuum decay	Head Space Analysis Vacuum decay Near Infrared	Pressure decay
Inspection type	CCIT	CCIT Residual O2 Freeze Dried cake defects	CCIT

Combined Applications

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PDA Parenteral Drug Association

Conclusions

- Non-destructive, deterministic CCI Technology
- Single stations, High-speed solutions
- Validatable
- Suitable to be combined with other CCI Technologies or PAT

Acknowledgement

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