



# Combined Deterministic Technologies for 100% inspection

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# Guidelines, USP 1207

## **USP 1207**

No single package leak test or package seal quality test method is applicable to all product-package systems.

Test method selection is made on a product-package on a case-by-case basis.

A deterministic leak test method having the ability to detect leaks at the product's maximum allowable leakage limit is preferred when establishing the inherent integrity of a container closure integrity.

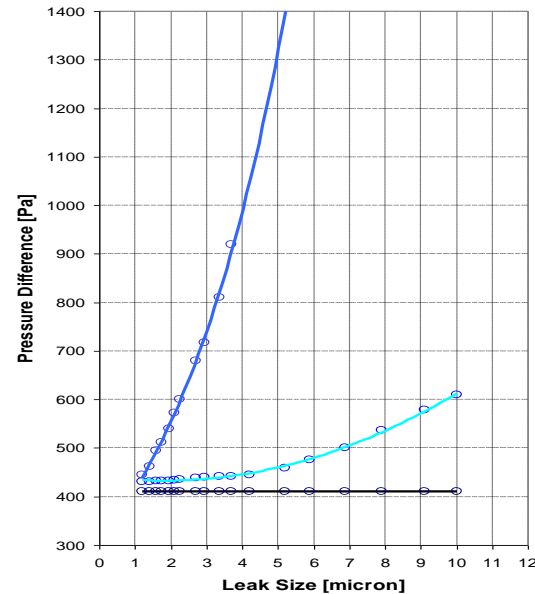
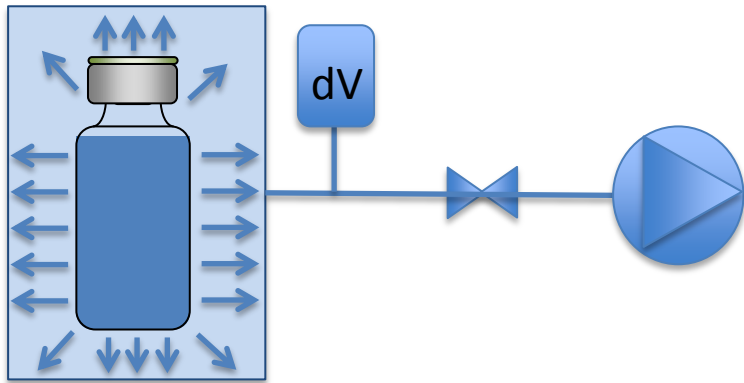


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On-line leak testing is commonly integrated into a continuous fill and seal product-package manufacturing process. A pre-requisite for an on-line leak test method for entire lot testing is that it be nondestructive to the package and its contents.

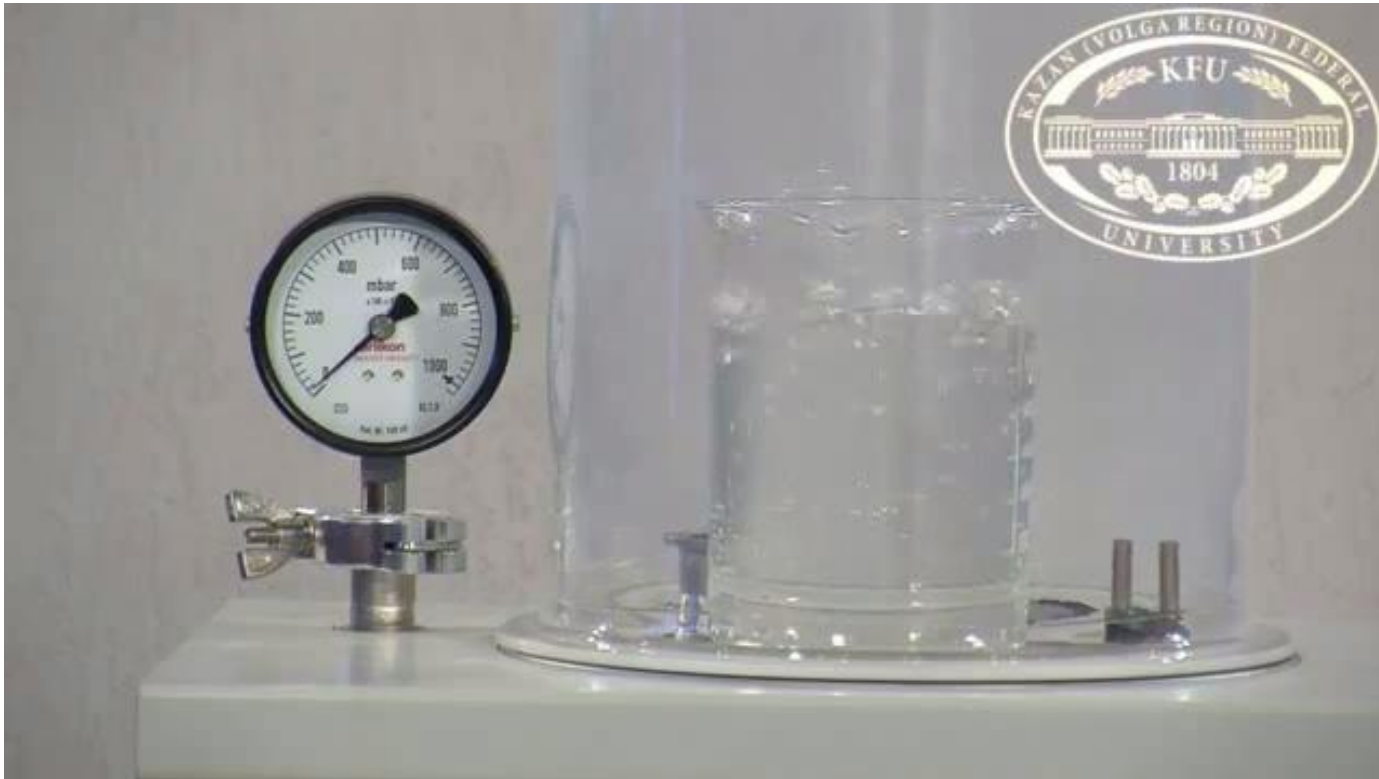
Often more than one test method is employed during a given product's life cycle.



Deep vacuum decay

Testing pressure below the triple point of water, applicable for liquid filled containers

gross leaks detection for powder containers as a key element for combined solution or for dual chamber container

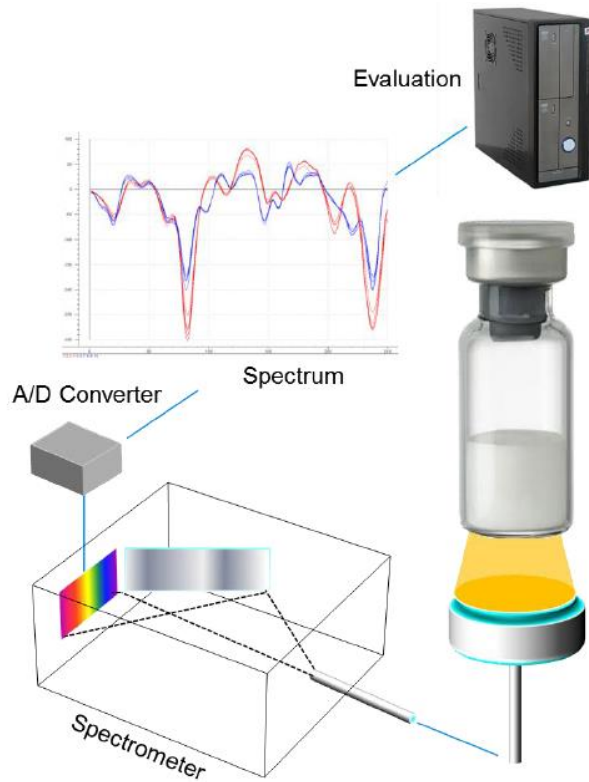




Headspace Analyzer

Laser absorption spectroscopy

Measuring of oxygen partial pressure or total pressure as per consequence of filling/stoppering failures or leakages

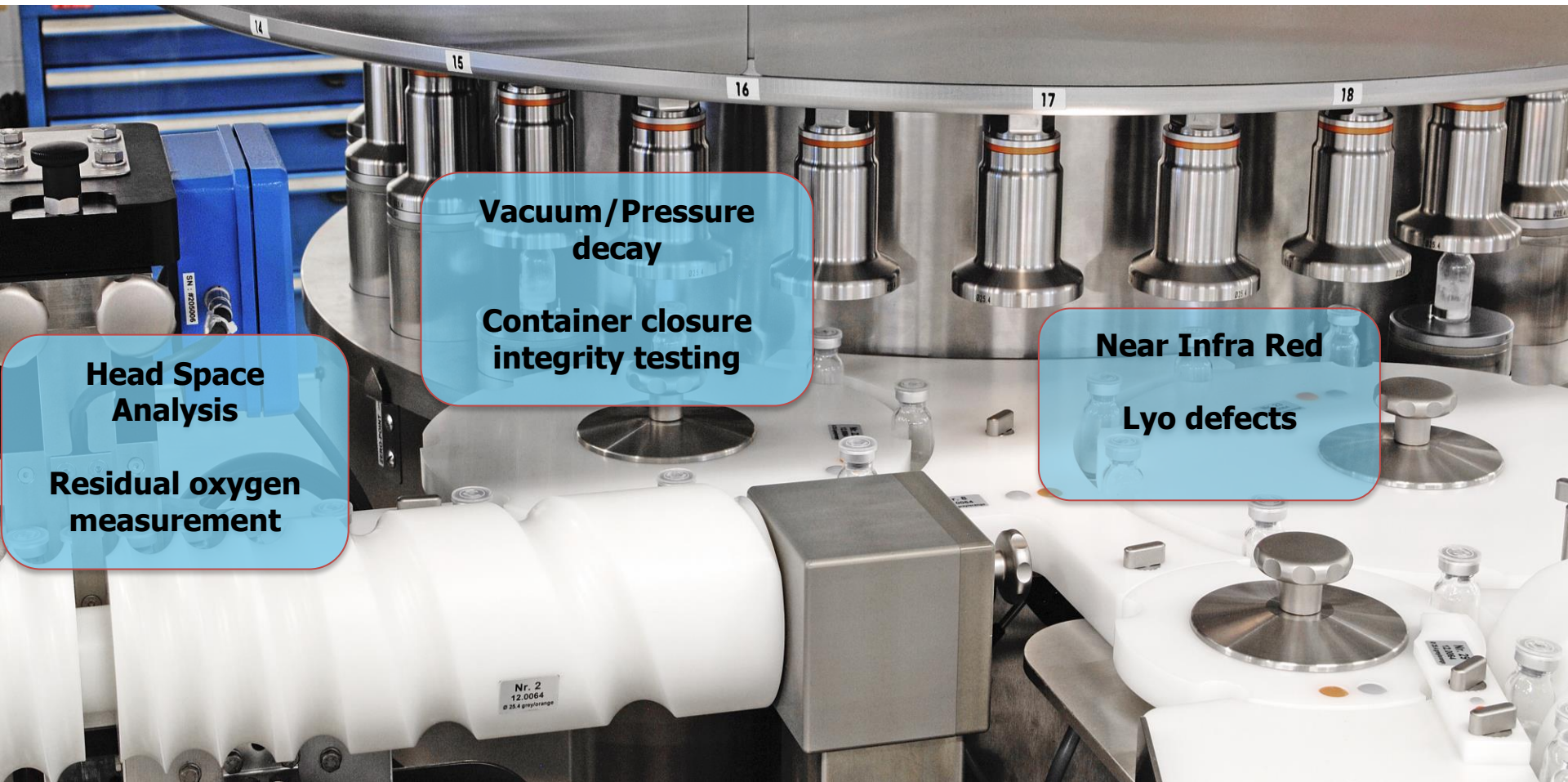


## PAT Technology, NIR

The light source is used to generate electromagnetic radiation which has in a specific wavelength range a high intensity.

In the NIR spectroscopy usually tungsten-halogen lamps are used. The radiation emitted by the source hits the sample. After crossing this sample, the radiation is focused onto an entrance slit and then encounters a holographic reflection grating.

The principal set up is to achieve the NIR spectra in reflection mode.



**Head Space  
Analysis**

**Residual oxygen  
measurement**

**Vacuum/Pressure  
decay**

**Container closure  
integrity testing**

**Near Infra Red**

**Lyo defects**



Testing capacity	300 vpm
CCIT sensitivity	10-15 $\mu\text{m}$
HSA sensitivity	1,8 % O <sub>2</sub> Separation @10 SD
NIR	4% Cake humidity
Formats	Ampoules, Liquid filled vials, Freeze dried vials
Up-stream process	Visual Inspection
Down-stream process	Labelling

Validation for CCIT

with positive samples

During operational condition, needle valve

Validation for HSA

with positive samples

During operational condition, standars

Validation for NIR

with positive samples and standards

During operational condition, standars

## **Restrictions by using real leaky samples**

The detection evidence of real leaky samples is only reliably guaranteed once this is used only once.

In case that the real leaky sample is used repeatedly, the gas flow through the leak may be varied. This is valid for leaks in the headspace area as well as in the liquid area of a vial.

A drop formation on the outside surface of a leak may impede or obstruct the gas flow.

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