Ampoule Headspace Oxygen

Many parenteral drugs are filled in glass containers like vials, ampoules, and pre-filled syringes. Oxygen sensitive drugs need to be produced and filled with low residual oxygen in the headspace of the container. Often a nitrogen overlay is used during the aseptic filling process. Multiple vacuum / nitrogen cycles are used for even lower residual oxygen levels. The GMP (Good Manufacturing Practice) regulations requesting a verification of the effectiveness of the process. The instrument GPX1500 Vial enables an accurate and fast non-destructive measurement of the residual oxygen in the headspace of the container.

Application Example

The specific format part is installed without using any tools. Once connected, all required measurement parameters are stored within the format part, and no changes of the parameters are requested by the operator. The ampoule is placed into the format part. The measure button in pressed to start the measurement. The laser beam is passing the headspace of the ampoule to perform TDLAS based, non-destructive and precise measurement of the residual oxygen in the headspace.

GPX1500 Vial

Easy to use oxygen HSA for vials, ampoules & PFSs

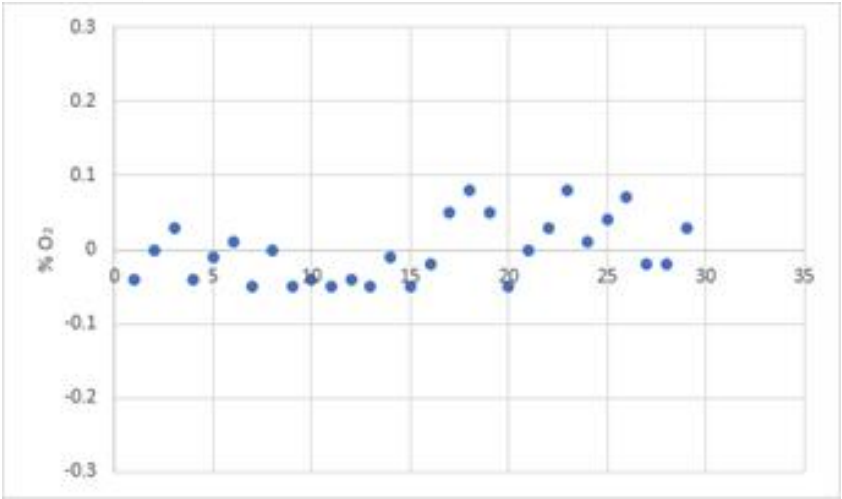
- Laser based measurement
- Possible to measure low headspace
- GMP Compliant

Parameters:

Product:	ISO 20 ml Ampoule
Gas:	Residual O_2 in N_2
Measurement time:	2 seconds
Sample handling:	No vial movement and no gas flushing

Performance:

The ampoule was removed for each measurement and re-inserted in the format part. This shows the instrument performance including the influence of the container itself. All values are within a band of ± 0.065% O2.



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