

Application Note

Residual Vial Headspace Oxygen

Gasporox presents GPX1500 Vial for headspace oxygen measurements of pharmaceutical vials.

Many parenteral drugs are filled in glass containers like vials. Oxygen sensitive drugs need to be produced and filled with a 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 vial.



Application description

The specific vial holder is installed without using any tools. With installing the vial holder all parameters are set. No parameter settings are required for the operator. The vial is placed in vial holder. The measure button is pressed to start the measurement. The laser beam is passing the headspace of the vial to perform TDLAS based, non-destructive and precise measurement of the residual oxygen in the headspace.

Parameters:

Product:	10 R Vial
Gas:	Residual O ₂ in N ₂
Measurement time:	2 seconds
Sample handling:	No vial movement and no gas flushing



Performance

The vial was removed for each measurement and re-inserted in the vial holder. This shows the instrument performance including the influence of the vial itself. All values are within a band of +/- 0.03% O₂.

