



# Headspace Measurement Services

## PRODUCT NOTE

Headspace measurement services are carried out by LIGHTHOUSE laboratory facilities in Charlottesville, Virginia and Amsterdam, The Netherlands. Clients requiring rapid non-destructive headspace analysis can choose from several service options. Samples can be sent to LIGHTHOUSE for analysis, equipment can be brought to the client and analysis performed on site by LIGHTHOUSE Application Scientists, or equipment can be implemented at the client on a project basis for a short term lease. Headspace systems from LIGHTHOUSE utilize a patented laser absorption technique developed with funding from the Food and Drug Administration and have been implemented & validated by the industry for more than a decade. Measurement Services clients take advantage of the expertise at LIGHTHOUSE gained from analyzing millions of samples from ster-



ile drug facilities all over the world to address the following applications:

### Applications include:

- Container closure integrity inspection and leak rate modeling
- Headspace oxygen stability studies
- Nitrogen purge optimization & validation
- Lyo chamber moisture mapping
- Lyo cycle optimization
- Packaging permeation studies

### MEASUREMENT SERVICE OPTIONS

Lab based measurement services	Samples sent to LIGHTHOUSE lab facility
On site measurement services	Benchtop equipment brought on site by LIGHTHOUSE Application Scientist
Short term lease	Benchtop or automated systems leased on a per project basis

### MEASUREMENT CAPABILITIES

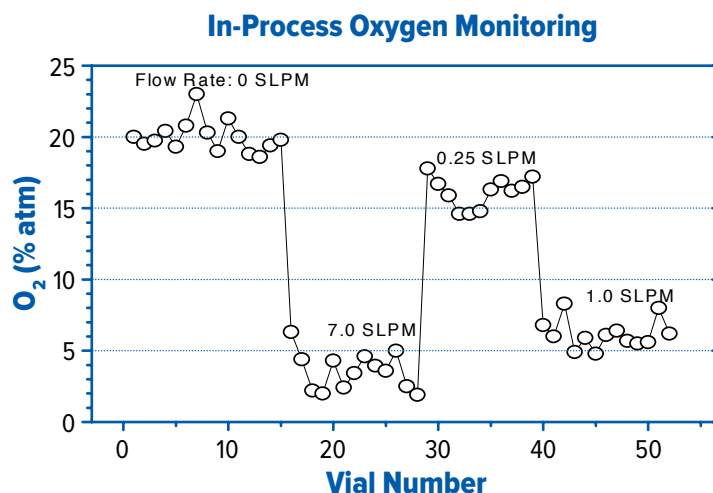
Headspace parameters	Headspace oxygen, moisture, and pressure (vacuum)
Containers	Sealed vials, ampoules, bottles, syringes (tubing, molded, clear, amber, clear plastic)



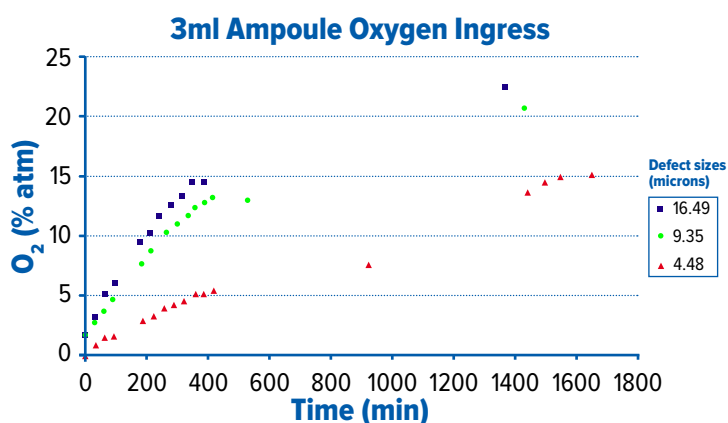
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Laser-based headspace measurements are rapid and non-destructive making the technique ideal for developing and optimizing parenteral drug processes and for performing 100% inspection to help guarantee the stability and quality of finished product. Case studies described here show how headspace measurements give clients deep insight into processes and product quality while saving time and resource. A client requiring 100% leak detection on a purged ampoule product wanted to prove laser-based headspace inspection could be used for this application. To demonstrate the headspace oxygen inspection solution, LIGHT-



**Figure 2: Monitoring headspace oxygen levels on a filling line as the nitrogen purge rate is varied between 0 and 7 standard liters per minute (SLPM).**



**Figure 1: The rise in oxygen levels in purged ampoules measured with the non-destructive headspace oxygen method from LIGHTHOUSE.**

HOUSE performed a leak detection study by monitoring oxygen ingress into product ampoules having laser-drilled defects of known sizes (see Figure 1). Numerous clients have also used LIGHTHOUSE headspace measurements to qualify purging systems on filling lines and verify that headspace oxygen levels meet specification. Figure 2 shows how headspace oxygen analysis can give immediate feedback on the oxygen levels during filling as a function of the nitrogen flow rate.

