PRODUCT NOTE

FMS-OXYGEN
Headspace Analyzer

LIGHTHOUSE
The Science of Pharmaceutical Manufacturing

The FMS-Oxygen is a non-destructive headspace oxygen analyzer from LIGHTHOUSE, the industry leader in laser-based headspace analysis. The compact benchtop instrument utilizes a patented laser absorption technique developed with funding from the Food and Drug Administration. This rapid and versatile technology addresses a wide range of applications that span the full product life cycle.

APPLICATIONS

- Leak detection
- Container closure integrity studies
- IPC monitoring of oxygen levels during the filling of oxygen-sensitive product
- Optimization and validation of purging systems on filling lines
- Oxygen degradation studies
- Stability trends, end-of-shelf-life studies
- Package permeation studies

KEY FEATURES

- Non-destructive, quantitative measurement method
- High-sensitivity signal analysis delivers an accurate measurement in seconds
- Custom change parts provide consistent positioning of sample for optimal measurement across a wide range of container types and sizes
- NIST-certified oxygen standards for calibration and verification ensure accurate results
- Easy-to-use hardware and software requires minimal user training
- Full validation package and 21 CFR Part 11 compliant software

SYSTEM SPECIFICATIONS

- Measurement range: 0.0 – 25.0% Oxygen
- Measurement time: 0.5 – 5.0 seconds
- Sample type: syringe, ampoule, vial, bottle
- Sample size: 6.0 – 86.0 mm in diameter (1ml syringe to 200ml bottle)
- Dimensions: 30.5 x 30.5 x 29.2 cm
- Weight: 13.6 kg
- Power requirements: 110 - 240 VAC, 50/60 Hz, 60W
- Interface: PC
- Safety Standards: IEC/EN 61010, 61326, 60825; US CDRH 21 CFR 1040; Declaration of Conformity available

APPLICATION SPOTLIGHT

The versatility of the headspace oxygen measurement enables the collection of analytical data for a wide range of applications, providing an opportunity for process optimization and improvements to product quality. The following study results highlight examples of data that can be gathered using the FMS-Oxygen system.

CONTAINER CLOSURE INTEGRITY TESTING

Headspace oxygen analysis offers the ability to test container closure by measuring the increase in oxygen when air enters the container through a leak. This graph presents the increase in measured headspace oxygen over time for 15ml

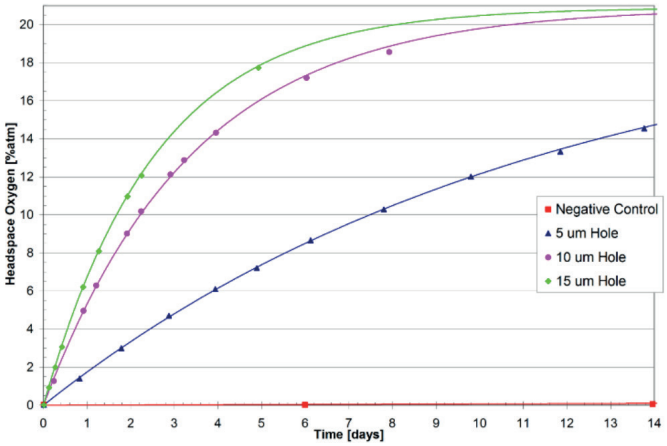

Figure 1: Container Closure Integrity Testing. Increase in headspace oxygen levels over time for 15 ml positive control vials.

positive control vials (Figure 1). The positive controls were created with idealized defect diameters of 5, 10 and 15 microns and initially sealed with a nitrogen headspace prior to analysis.

OXYGEN DEGRADATION STUDIES

With a non-destructive measurement, a single sample can be prepared and analyzed at different intervals to observe a change in the headspace oxygen content. In this example (Figure 2), the rate of oxygen consumption was determined for two different antioxidants, with each sample

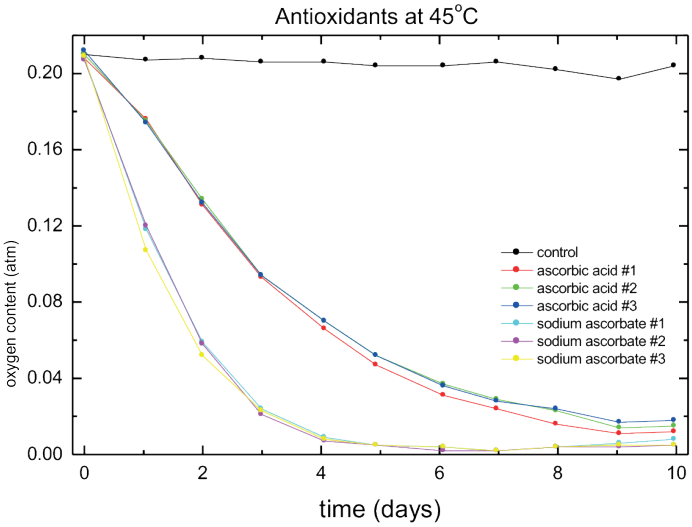

Figure 2: Oxygen Degradation Studies. The headspace oxygen concentration is used to determine the rate of oxygen consumption for two different antioxidants.

measured once per day for ten days. Very little product was needed to determine full product oxidation curves.

IPC MONITORING OF OXYGEN LEVELS

An FMS-Oxygen system installed at a liquid filling line offers rapid feedback on the efficiency of the purging system. Changes to the process, such as the varying purge flow rates shown here (Figure 3), or process upsets are quickly detected by in-process measurements of the resulting headspace oxygen levels without wasting expensive finished product.

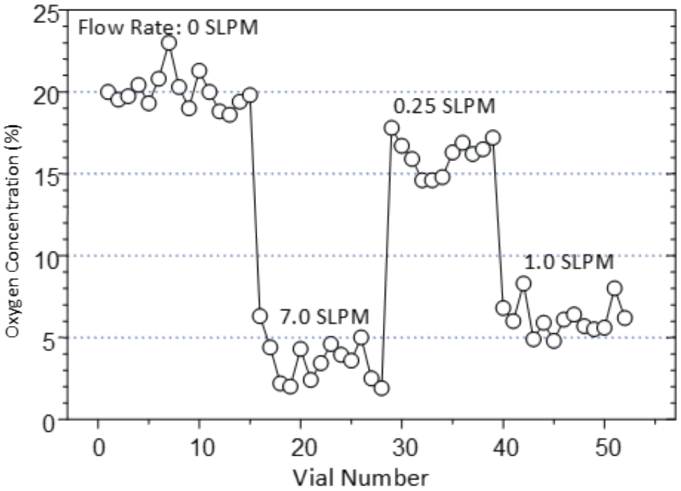

Figure 3: IPC Monitoring of Oxygen Levels. Headspace oxygen levels are measured while the purge flow rate is adjusted.

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