PRODUCT NOTE

FMS-CARBON DIOXIDE Headspace Analyzer

LIGHTHOUSE
The Science of Pharmaceutical Manufacturing

The FMS-Carbon Dioxide is a non-destructive headspace carbon dioxide 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

- Container closure integrity testing of frozen product stored on dry ice for transport
- General container closure integrity testing when the test method uses carbon dioxide as a tracer gas
- IPC monitoring of carbon dioxide levels during the filling of product purged with carbon dioxide in the headspace
- Microbial growth detection in media vials

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 carbon dioxide standards for calibration and verification to 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 – 1.0 atm
- 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 carbon dioxide 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 generated using the FMS-Carbon Dioxide system.

CONTAINER CLOSURE INTEGRITY TESTING

The use of carbon dioxide as a tracer gas provides a high-sensitivity leak detection method. After using a LIGHTHOUSE CCI Test Vessel to expose vials to carbon dioxide, the positive controls with idealized 5-micron defects were easily identified by the significant increase in headspace carbon dioxide (Figure 1). Initial levels near zero increased to almost 1 atm (760 torr) of carbon dioxide in the leaking positive control vials.

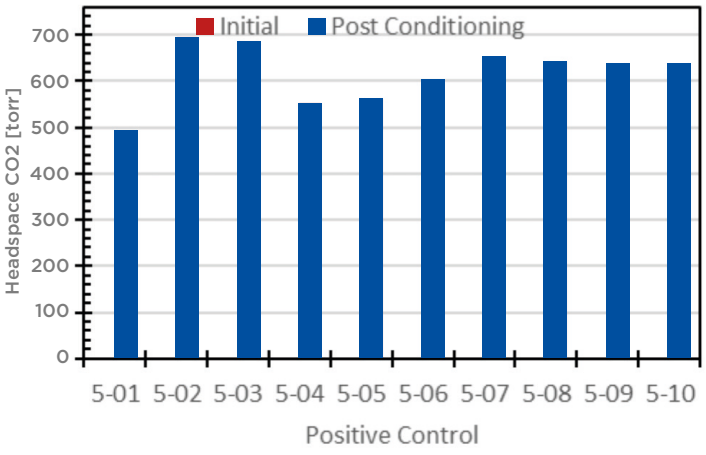

Figure 1: Container Closure Integrity Testing. After exposure to carbon dioxide in the CCI Test Vessel, positive control defects are easily identified by the increase in headspace carbon dioxide.

CCI TESTING ON DRY ICE

The loss of rubber stopper elasticity under deep cold storage poses an increased risk of seal integrity failure. A leak that develops in dry ice storage will allow the ingress of the surrounding carbon dioxide gas. After storage on dry ice for seven days, 3 of the 20 product samples in this study exhibited an increase in the headspace carbon dioxide (Figure 2).

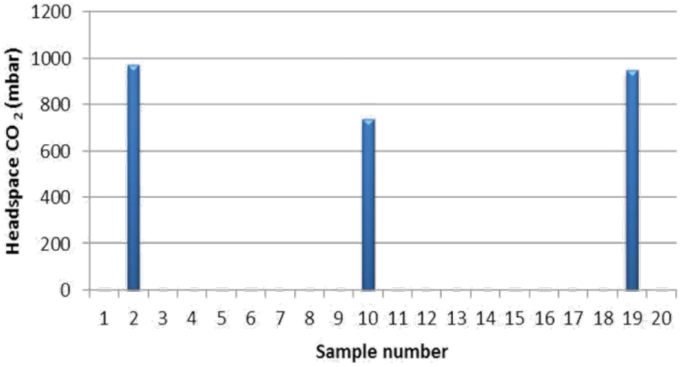

Figure 2: CCI Testing on Dry Ice. After storage on dry ice, 3 samples reveal elevated headspace carbon dioxide levels due to loss of seal integrity.

MICROBIAL GROWTH DETECTION IN MEDIA VIALS

Aerobic microbial growth within a media vial will result in the consumption of oxygen and the release of carbon dioxide. A contaminated media vial will exhibit an increase in carbon dioxide during the standard incubation period, providing a rapid and quantitative method for media fill inspection. This result has been observed in a wide range of microorganisms, including the B. spizizenii samples shown here (Figure 3), where rising carbon dioxide and falling oxygen were detected within three days of incubation.

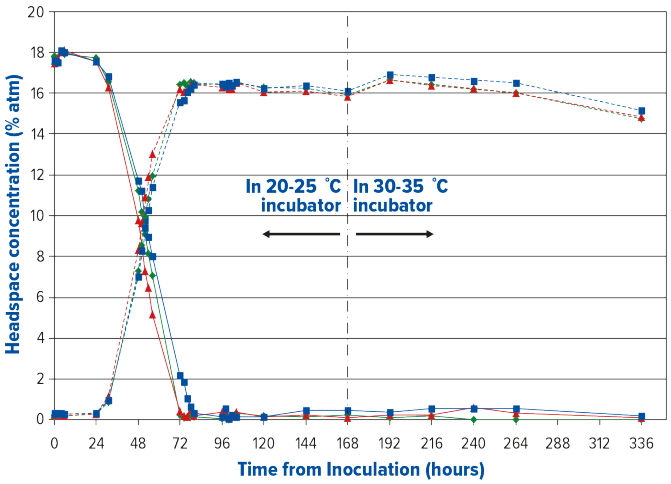

Figure 3: Microbial Growth Detection in Media Vials. Headspace oxygen (solid-line) and carbon dioxide (dashed-line) concentrations in media vials injected with B. spizizenii. Growth is detected after 24 hrs, with headspace conditions changing drastically in the first 72 hours.

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