LIGHTHOUSE

THE SCIENCE
OF PHARMACEUTICAL
MANUFACTURING

PRODUCT NOTE

FMS-MOISTURE/PRESSURE
Headspace Analyzer



The FMS-Moisture/Pressure is a non-destructive headspace moisture and pressure 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

- Vacuum leak detection
- Container closure integrity studies
- Moisture determination of lyo product
- Lyo chamber moisture mapping for cycle optimization.
- Water vapor permeation studies
- Moisture degradation 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 moisture and pressure 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 (total pressure), 0.0 – 0.03 atm (moisture partial pressure)
- Measurement time: 0.5 – 5.0 seconds
- Sample type: ampoule, vial, bottle
- Sample size: 6.0 – 86.0 mm in diameter (1ml vial to 500ml bottle)
- Dimensions: 30.5 × 30.5 × 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 moisture and pressure measurements 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-Moisture/Pressure system.

CONTAINER CLOSURE INTEGRITY TESTING

Headspace pressure analysis offers the ability to test container closure by measuring the increase in pressure when vacuum is lost through a leak. In this study (Figure 1), an investigation of lyophilized product revealed a high incidence of elevated headspace pressure for vials sealed with coated stoppers, demonstrating an increased risk of raised stoppers after exiting the freeze dryer.

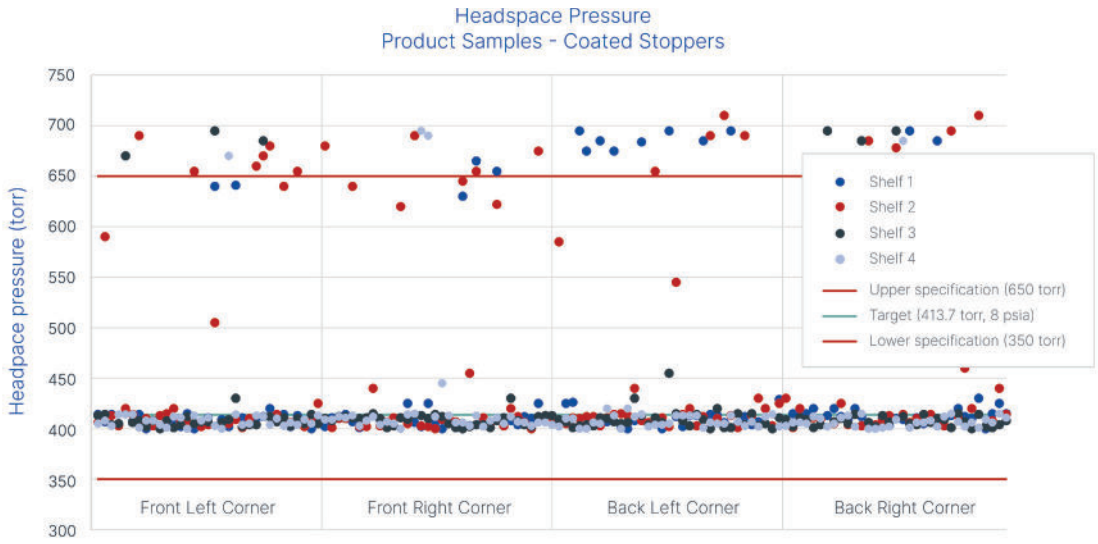

Figure 1. Container Closure Integrity Testing. Lyophilized product sealed with coated stoppers are investigated after freeze drying. The high incidence of elevated headspace pressure levels demonstrate an increased risk of raised stoppers after exiting the chamber.

MOISTURE DETERMINATION OF LYO PRODUCT

Headspace moisture analysis provides a faster and simpler alternative to Karl Fischer titration for product moisture measurements. Data collected using both methods demonstrates a correlation between the headspace moisture and total moisture (Figure 2), offering an opportunity to replace the destructive and time consuming Karl Fischer measurement method.

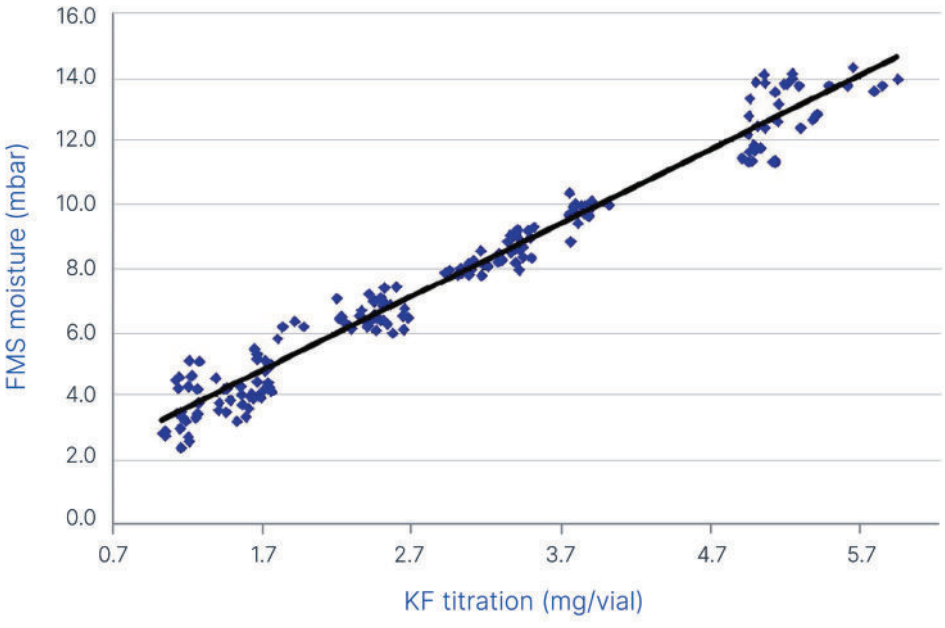

Figure 2. Moisture Determination of Lyo Product. Correlation of headspace moisture levels to residual product moisture content as measured by Karl Fischer.



LYO CHAMBER MOISTURE MAPPING

A rapid non-destructive moisture measurement enables the analysis of an entire batch of freeze dried product. Correlating the measured moisture to the location in the lyo chamber provides insight into freeze dryer performance and the freeze drying cycle; for example, the region of high moisture discovered at the center of the shelf in this study (Figure 3).

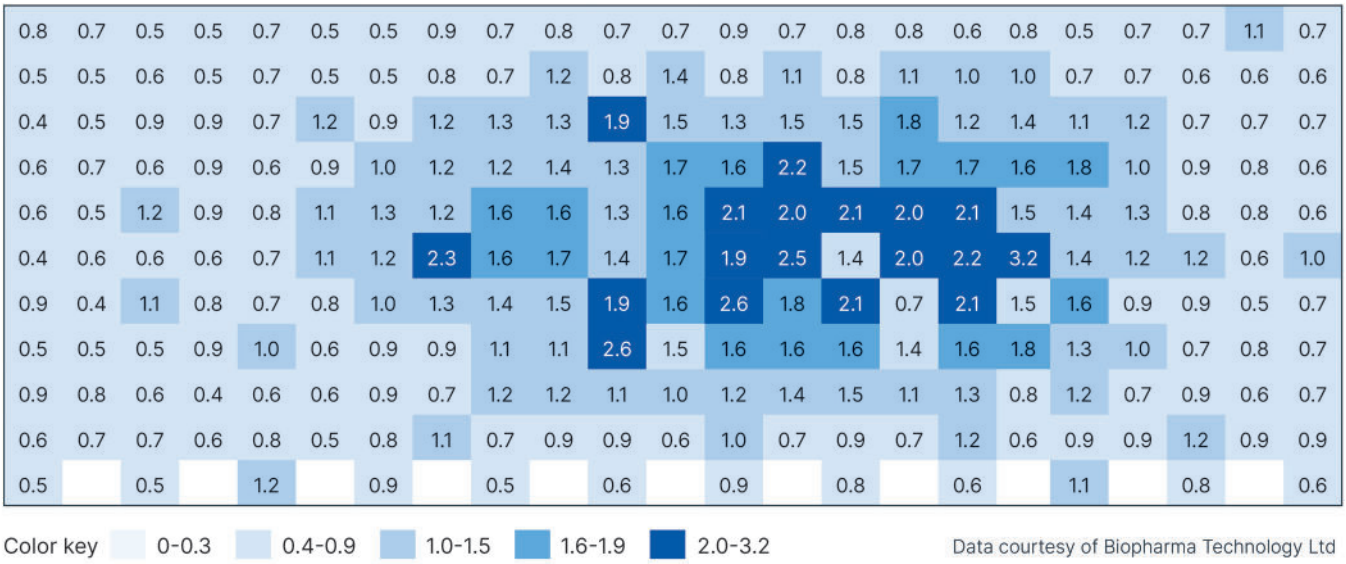

Figure 3. Lyo Chamber Moisture Mapping. Moisture map showing a wet spot in the center of the freeze dryer shelf.

CONTACT US

- Lighthouse Instruments, LLC
  2050 Avon Court
  Charlottesville, Virginia 22902
  United States of America
  Office • +1 (434) 293-3081
  Email • info@lighthouseinstruments.com

  www.lighthouseinstruments.com

- Lighthouse Instruments, B.V.
  Wisselwerking 22
  1112 XP Diemen
  The Netherlands
  Office • +31 (0)20 7051 050
  Email • euinfo@lighthouseinstruments.com