LIGHTHOUSE

THE SCIENCE
OF PHARMACEUTICAL
MANUFACTURING

Company Brochure

Introduction

LIGHTHOUSE offers solutions for headspace oxygen monitoring of oxygen sensitive formulations, container closure integrity (CCI) testing, moisture determination of freeze-dried product, sterile powders and solid dosage forms, and the inspection of media fills. We deliver non-destructive laser based headspace analysis platforms and analytical lab services to generate statistica! process and product data in all stages of the product life cycle.

From Development to Manufacturing and Quality Control, science-based data needs to be generated on both the product and the process to ensure overall quality. Both the stability and sterility of finished parenteral drug product are critical objectives. In addition, ensuring process design quality and generating in process control (IPC) data to monitor process robustness is required.

As the leading provider of headspace analysis platforms and measurement services, LIGHTHOUSE supports clients in their parenteral drug activities. Our offering includes feasibility studies, process and packaging studies, stability studies, automated and benchtop headspace platforms, method development, method validation protocols, on-site trouble shooting and support.

Our Application Solutions

Rapid, non-destructive, laser-based headspace analysis is a powerful measurement technique suitable for applications specific to the sterile pharmaceutical industry, including:

OXYGEN MONITORING

The need to monitor headspace oxygen levels in parenteral containers arises from the requirement to ensure the stability and potency of oxygen-sensitive product.

Besides a loss of efficacy and reduction in shelf life, exposure of such products to oxygen can result in product discoloration, changes in dissolution rate and profile, and even toxicity or other pharmacological properties associated with negative side effects.

We offer oxygen monitoring solutions for:

- Stability testing
- Packaging studies
- Permeation studies
- Characterizing Nitrogen Purging systems (In-Process Control)
- Nitrogen Purge Optimization and Validation
- 100% Oxygen Analysis of Finished Product
- Release Testing of Oxygen Sensitive Product
- Troubleshooting and Investigations of Oxygen Sensitive Product

CONTAINER CLOSURE INTEGRITY (CCI) TESTING

Loss of CCI can occur due to component defects (e.g. cracks in glass, out of specification stopper dimensions or improper vial/stopper combinations) or process defects (e.g. stopper pop-up prior to capping, misaligned tooling, rough handing). Rapid, non-destructive, headspace analysis enables at-line and in-line leak detection by monitoring changes in headspace gas composition or changes in total headspace pressure.

We offer CCI solutions for:

- CCI Test Method Development and Validation
- Cold Storage Studies
- Transport Studies
- Vacuum Maintenance
- CCI testing in lieu of sterility testing
- CCI qualification of Filling, Freeze Drying and Packaging lines
- Validation of Raised Stopper Limits
- 100% Finished Product Inspection
- Batch Troubleshooting and Investigations

MOISTURE DETERMINATION

Residual product moisture content is a critical parameter when considering the stability and shelf life of lyophilized pharmaceutical product, sterile powders, or solid dosage product. Moisture analysis is traditionally performed using Karl Fischer titration or thermo-gravimetrie analysis (TGA) methods, which are destructive and labor & time intensive. Replacing these slow traditional methods with a rapid, non-destructive method will streamline moisture analysis efforts and help improve the quality of finished product.

We offer moisture determination solutions for:

- Rubber stopper moisture studies
- Lyophilization cycle optimization
- Characterizing freeze dyers for moisture distribution (moisture mapping)
- Water activity measurements of solid dosage product
- 100% moisture inspection of commercial freeze-dried product
- Troubleshooting and investigations of dry product

MEDIA FILL INSPECTION

The manual visual inspection process used to inspect media fills for signs of contamination is considered to be tedious and time consuming. Since visual inspection is performed by operators, there is always a risk of human error, due to subjectivity and fatigue. In addition, difficult-to-inspect containers such as molded or colored glass, or certain plastic containers, can present a particular challenge for operators.

An inspection method that is analytical and automated improves the media fill inspection and fits with the industry trend of removing human subjectivity from the process. Studies have demonstrated that laser-based headspace inspection platforms measuring the levels of headspace oxygen and carbon dioxide can detect microbial growth in media-filled pharmaceutical containers.

The implementation of a 100% headspace inspection machine enables an automated analytical media fill inspection process that has numerous advantages over current manual processes.

Our Products & Services

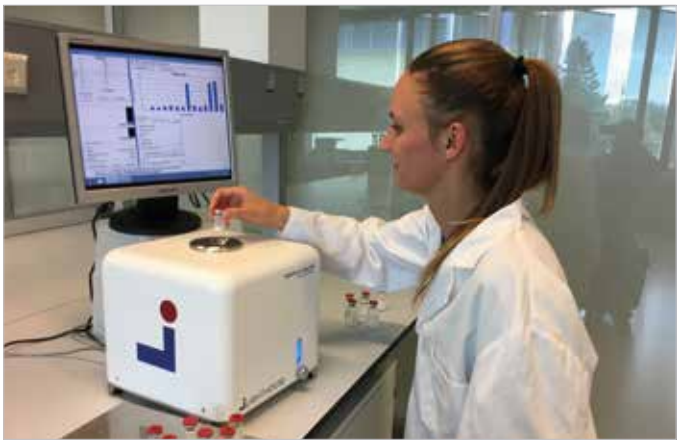
LIGHTHOUSE Instruments is the leading provider of headspace analysis platforms and analytical lab services.

Platforms for rapid, nondestructive, laser-based headspace analysis were developed with the help of funding from the Food and Drug Administration. Our equipment product lines include benchtop FMS-analyzers and automated PULSAR inspection machines for characterizing headspace oxygen, moisture, pressure, and carbon dioxide. Equipment is delivered with data integrity compliant solutions and comprehensive qualification packages.

As a science-based company, we also offer headspace measurement services carried out by application scientists and engineers from our laboratory facilities in Charlottesville, Virginia and Amsterdam, The Netherlands. Samples can be sent to LIGHTHOUSE facilities for analysis as part of an outsourced scientific study. LIGHTHOUSE application scientists can also bring equipment and perform analysis on-site, or LIGHTHOUSE application engineers can install and qualify equipment on a project basis and train operators as part of a short-term equipment lease.

Clients can take advantage of a broad range of services including:

- Feasibility studies
- Process and Package studies
- Method Development
- Method Validation Protocols and support for method transfer
- Lease of benchtop systems and automated machines
- Onsite troubleshooting and support



Headspace measurements carried out by a Lighthouse Application Scientist.

Benchtop FMS-analyzers.

Automated Pulsar inspection machine.

Our Technology

LIGHTHOUSE scientists pioneered the use of diode laser absorption spectroscopy for performing headspace analysis of pharmaceutical packages.

Commercialized with funding from the Food & Drug Administration, patented platforms from LIGHTHOUSE make use of a high-sensitivity laser absorption technique called Frequency Modulation Spectroscopy (FMS). The technique measures a number of physical parameters within the headspace of a parenteral container including gas concentration (oxygen, carbon dioxide and moisture) and total headspace pressure (vacuum level).

Rapid and non-destructive headspace analysis is accomplished by transmitting diode laser light through the container headspace at a wavelength matching the absorption wavelength of the molecule of interest. Applying sophisticated modulation and signal processing techniques, the systems achieve measurement sensitivities that are 10,000 times greater than standard NIR absorption.

A wide variety of containers can be inspected using laser absorption spectroscopy including tubing, molded, clear and amber glass vials & ampoules, bottles, cartridges, syringes, and translucent plastic containers.

Diode laser light being transmitted through a container for headspace characterization.

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