LyoinMSTrack®

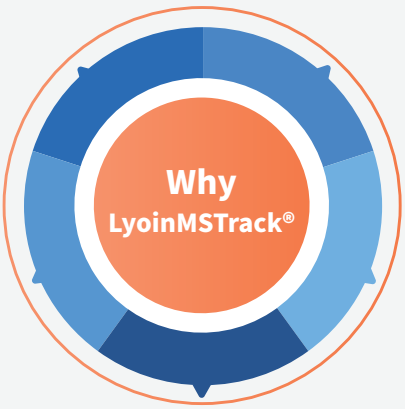
Real-Time Mass Spectrometry for Freeze-Drying Process Control



LyoinMSTrack®

Real-Time Mass Spectrometry for Freeze-Drying Process Control

LyoinMSTrack® seamlessly integrates with your existing freeze-dryer, and revolutionizes freeze drying with in-line Mass Spectrometry as a Process Analytical Technology(PAT), offering real-time, high-precision and non-invasive analysis of moisture, solvent vapor and volatile compounds within the chamber during lyophilization, ensuring the safety and quality of the final products. Engineered for compactness and reliability, it empowers researchers and manufacturers to optimize processes, ensure product quality, and reduce development time—all without disrupting your workflow.



- **Online Analysis**

  Continuously monitor the vapor level in real - time until the completion of the drying process. There is no requirement to sample during the lyophilization process or conduct additional analyses.

- **Batch Monitor Tool**

  Monitor the state of the entire batch of products rather than that of a single vial.

- **PAT for All Size equipments**

  Applicable to all types of freeze dryers, ranging from benchtop research models to production - scale equipment.

- **Plug - and - Play Integration**

  Compatible with the majority of freeze - dryer brands through standard vacuum line connections; no complex modifications are necessary.

- **Compliance - Ready**

  Complies with FDA 21 CFR Part 11 and GMP guidelines regarding data integrity.

What can LyoinMSTrack® do?



Process monitor

The end point of primary and secondary drying determination

Quality control

Silicon oil and impurities detection and ensure the safety and quality of the products

Performance monitor

System leakage detection of the equipment, saving both time and money

Target component monitor

Not only for water detection, but also for analyzing non-aqueous solvents, volatile compounds, and potential impurities.

Technical parameters

Parameters	Description
Type	High performance quadrupole mass spectrometer system
Mass range	1–200 AMU (or 1–300 AMU optional)
Detection Limit	Water vapor: Better than 1×10-5mbar (or ppmv level);Silicone oil characteristic peak: Ability to detect ⩽ 10 ppmv changes
Response Time	Full-spectrum scan response ⩽ 1s
Stability & Drift	Zero drift < 1% F.S. over 24 hours
Sampling System	Molecular beam inlet with heated, anti-contamination transfer line (maintained >120°C to prevent condensation)
Interface Materials	Full inert flow path to minimize adsorption and memory effects
Connection	Standard ISO-KF or CF flange for direct mounting to lyophilizer sampling port
Differential Pumping	Integrated at least two-stage vacuum system to maintain analyzer under high vacuum while sampling from variable chamber pressure
Software	Dedicated process monitoring software with real-time trending, multi-component display, alarm setting, data logging, and export
Calibration	Automated zeroing capability; supports online single/multi-point calibration with standard gases
Regulatory Compliance	Supports cGMP data integrity requirements and 21 CFR Part 11 compliance (user access control, audit trail, electronic signatures)

Key Features

- **Compact Design**

  The LyoinMSTrack® can be seamlessly integrated into laboratory and production scale freeze dryer, demanding minimal space.

- **Real - Time Monitoring of the Freeze - Drying Process**

  It provides continuous data on the concentrations of water vapors, as well as the detection of primary and secondary drying endpoints, facilitating prompt process adjustments.

- **Multicomponent synchronous analysis**

  It encompasses water vapor, oxygen, nitrogen, residual solvents, and other process - related volatiles. All datas can be obtained via a single experiment.

- **Contamination Control**

  Acquire real-time data regarding silicone oil leakage within the product chamber and safeguard the products.

- **High Sensitivity**

  It enables the sensing of species concentrations down to parts per million (ppm) levels.

- **Intuitive Software**

  User-friendly interface with automated data logging, and exportable reports.





End point determination of drying

The RGA mass spectrum - H_2O curve exhibits a high degree of consistency with the Pirani curve, precisely and clearly reflecting the trend of water vapor content variations within the vacuum chamber.

The primary and secondary drying processes are distinctly manifested in the RGA mass spectrometry - H_2O curve. In comparison to the Pirani curve, it demonstrates higher sensitivity, which is conducive to determining the end point of the drying process. When the moisture content decreases, the Pirani signal experiences a reduction of approximately 39%, whereas the RGA signal shows a 96% reduction.

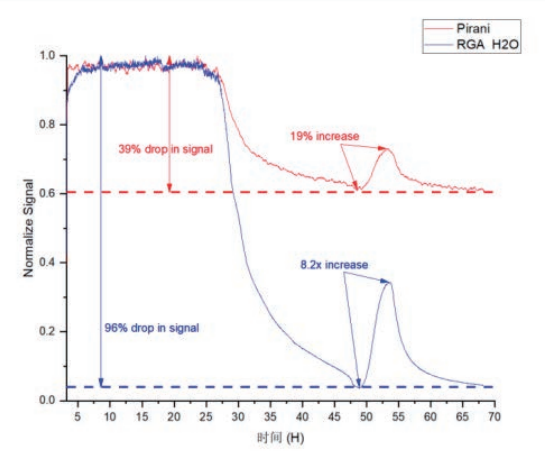


Fig 1.

Plot of Plot of cycle data including RGA water signal for 5% w/v sucrose solution

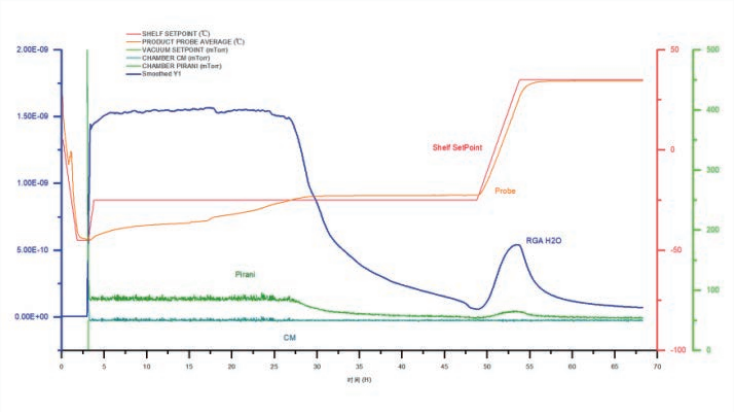


Fig 2.

Comparison of the normalized RGA mass spectrometer and Pirani gauge signal during the lyo cycle.

Applications

Pharmaceutical Development

Monitor API stability and residual solvent levels in lyophilized drugs.

Biotechnology

Optimize freeze-drying cycles for proteins, vaccines, and cell therapies.



Food Science

Analyze volatile profiles in dehydrated foods to enhance flavor retention.

Material Science

Characterize sublimation behavior of advanced materials (e.g., aerogels).

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