

LYOPLUS® MONITORING FOR LYOPHILIZATION.

The LYOPLUS® mass spectrometer is a multipurpose measurement device for pharmaceutical freeze drying.



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Originally developed to detect very small traces of silicone oil inside freeze dryers, the LYOPLUS® mass spectrometer is fitted with advanced software that facilitates the collection and measurement of data that wouldn't be possible with ordinary equipment.

The system is able to work alongside any existing PLC/SCADA system as a standalone unit or can be fully integrated into the control system. It can also be operated independently as a monitoring device that does not interfere with any qualified processes. In addition to being able to detect trace levels of silicone oil, thereby preventing product contamination, LYOPLUS® is also able to monitor the moisture content in the freeze drying chamber during the drying cycle. Not only does this help to define primary and secondary drying endpoints, it reduces leak detection times down to just one hour.

LYOPLUS® performs all these three tests in one single unit, improving productivity, reducing power consumption and the environmental impact of the process, and saving the owner time and money.

Silicone oil detection

Silicone oil is used to transfer heat energy to the product. After years of operation, the harsh conditions in the dryer can lead to small leaks and, as a consequence, product contamination. Eventually, as the leak increases, silicone oil is detected during end product testing in quality control. But how many batches have been contaminated? With LYOPLUS®, it's possible to detect even small traces of silicone oil in situ. No additional product is put at risk as the leak is detected immediately.

Moisture content (PAT)

At the start of the drying process, the chamber fills with product derived vapor. During the later stages, however, the moisture level decreases significantly. LYOPLUS® measures this drop and correlates the data with the average product moisture levels in the vials. This information can be used to refine drying recipes, avoid any unnecessary drying time and predict product drying curves based on the chamber's moisture content.

System leak tests

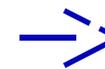
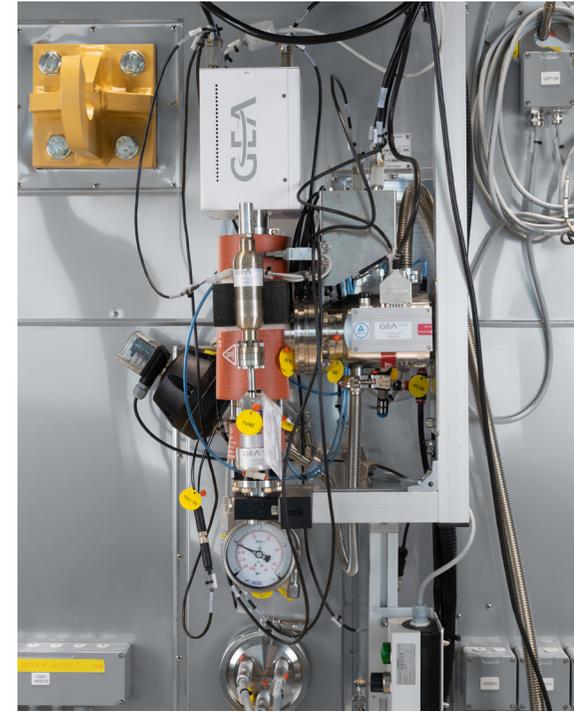
To prevent leak-based contamination, it is mandatory to perform a leak test after each critical process. Using LYOPLUS®,

it's possible to reduce the time for this standard procedure down from four hours, for example, to approximately one hour, owing to its very high sensitivity. And, as LYOPLUS® is permanently connected to the system, helium leak tests can begin instantly, improving detection times and productivity.

In short, LYOPLUS® detects impurities before quality problems arise, saving both time and money, and plays a key role in maintaining high standards of safety, quality and productivity.

Technical Data

- Fully automated
- Fail-safe operation to ensure sterility and protect the lyophilization equipment and the measurement device
- Standalone or optional full SCADA implementation
- High performance quadrupole mass spectrometer system
- Mass range: 1–100 standard
- (1–200 AMU or 1–300 AMU optional)
- High conductance inlet system
- Max. operating pressure: 1 mbar
- Detection limit: 1 ppm of non-interfering species.



Further information

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