GEA LYOSENSE® STATION

A fast, effective and mobile sensor for
on-the-go online moisture control

engineering for
a better world

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The lyophilization of pharmaceutical products such as vaccines enhances their stability and shelf-life. However, these properties can only be maintained when the resulting cake has a residual moisture level of 0.2–5.0%. For this reason, regulatory guidance indicates that this parameter must be controlled and determined. Until now, however, techniques to measure such properties have been destructive, time-consuming and, therefore, uneconomical.

Real-Time Characterization of Lyophilized Products

The LYOSENSE® STATION was designed for the quick, accurate and mobile testing of pharmaceutical glass vials for residual moisture. Based on the well-known NIR test method, GEA has developed a test device that allows the user to examine vials.

Based on multipoint NIR measurements, the LYOSENSE® STATION enables the comprehensive and non-destructive evaluation of freeze-dried product cakes in real-time. This easy-to-install and use online measuring device is a fast and non-invasive solution to moisture determination, enabling the effortless detection of residual moisture.

Functions and Features

The LYOSENSE® STATION automatically measures the residual moisture content in lyophilized glass vials, which are manually loaded via a tray on the infeed turntable. Process parameters such as vial speed can be controlled using an integrated touchscreen and residual moisture limits can be controlled by laptop via an interface. Checked vials are stored on the outfeed table and can be collected manually on the infeed tray.

The NIR sensors measure the vials from the side and/or from below. The results are sent to an external computer, which is isolated from the process area and reports any out-of-specification data. Rejected vials are collected in a container adjacent to the conveyor.

This miniaturized probe is simple to calibrate and enhances product development by facilitating Quality by Design. It also offers the following benefits:

- fast measurement and evaluation (5 ms)
- no required consumables
- simple and easy user interface and operation
- single person operation
- accurate analysis of residual moisture (0.2–5.0% water content)
- 100% vial inspection (from 16.25–33.00 mm) at a rate of up to 100 per minute
- rejection of out-of-specification vials.

Mounted on wheels for easy maneuverability, the LYOSENSE® STATION is 900 mm wide and can readily pass through the doors and corridors of most pharmaceutical production areas.

Documentation and Testing

The LYOSENSE® STATION is tested before delivery in a factory acceptance test (FAT). The results comprise part of the documentation package. The LYOSENSE® STATION is designed to comply with the European Union's CE Guidelines and is also supplied with a manual, safety instructions and wiring diagram.

Technical data

In an experiment to compare the LYOSENSE® STATION with a Karl Fischer sensor, the data in Table I were obtained.

Product	Filling Volume	Layer Height	Residual Moisture LYOSENSE®	Residual Moisture Karl-Fischer	Difference between LYOSENSE® and Karl-Fischer
Mannitol (3%)	5,5 ml	15 mm	**0,9655%**	**0,94%**	0,03%
Mannitol (3%)	5,5 ml	15 mm	**0,9660%**	**0,96%**	0,01%
Mannitol (3%)	5,5 ml	15 mm	**0,8112%**	**0,91%**	-0,10%
Mannitol (3%)	5,5 ml	15 mm	**1,0332%**	**1,00%**	0,03%
Mannitol (3%)	5,5 ml	15 mm	**0,8970%**	**0,99%**	-0,09%
Mannitol (3%)	5,5 ml	15 mm	**1,0040%**	**0,95%**	0,05%
Mannitol (3%)	5,5 ml	15 mm	**0,8499%**	**0,99%**	-0,14%
Mannitol (3%)	5,5 ml	15 mm	**0,9502%**	**1,04%**	-0,09%
Mannitol (3%)	5,5 ml	15 mm	**0,9645%**	**0,98%**	-0,02%

Table I: *LYOSENSE® versus a Karl Fischer sensor*

Similarly, predicted versus recorded measurements were compared for mannitol and sucrose, using the LYOSENSE® STATION, and are shown in Figure 1.

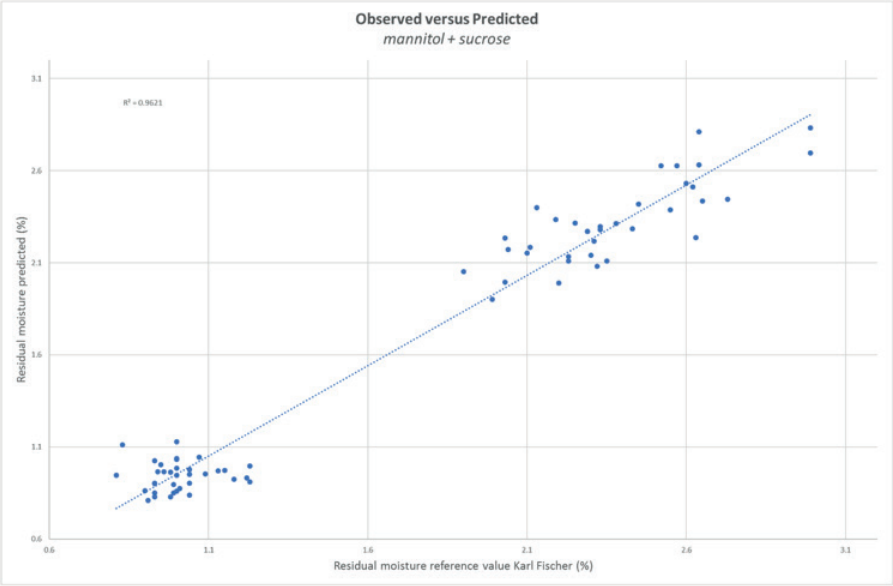

Figure 1: *Predicted and observed residual moisture content*

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