



GEA LYOSENSE®

A fast and effective sensor for online moisture control

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 water 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 both destructive and time-consuming, and thereby uneconomical.

Real-Time Characterization of Lyophilized Products

LYOSENSE® from GEA, based on multipoint NIR measurements, provides 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 control, enabling the effortless detection of

- residual moisture
- cake homogeneity
- API concentration.

Other critical process parameters, such as porosity, melt and glass particles, can also be assessed.

For 100% vial inspection, machine communication capabilities and easy integration into both lab and production environments, this miniaturized probe is simple to calibrate and enhances product development by facilitating Quality by Design.

Fully GMP and 21 CFR Part 11 compliant and supplied with IQ/OQ/PQ support, the LYOSENSE® provides the following benefits:

- whole cake assessment with multipoint measurement
- fast measurement and evaluation (5 ms)
- no required consumables
- simple and easy user interface and operation.

LYOSENSE® is compatible with other GEA innovations such as LYODATA™ for continuous monitoring and full traceability, and the ALUSTM automatic loading and unloading system.

Technical data

In an experiment to compare the LYONSENSE® with a Karl Fischer sensor, the data in Table I was obtained.

Product	Filling volume	Layer height	Residual Moisture LYONSENSE®	Residual Moisture Karl-Fischer	Difference between LYONSENSE® and Karl-Fischer	Weighted sample Karl-Fischer
Mannitol (3%)	5,5 ml	15 mm	0,9655%	0,94%	0,03%	0,06691g
Mannitol (3%)	5,5 ml	15 mm	0,9660%	0,96%	0,01%	0,06862g
Mannitol (3%)	5,5 ml	15 mm	0,8112%	0,91%	-0,10%	0,08897g
Mannitol (3%)	5,5 ml	15 mm	1,0332%	1,00%	0,03%	0,05580g
Mannitol (3%)	5,5 ml	15 mm	0,8970%	0,99%	-0,09%	0,03957g
Mannitol (3%)	5,5 ml	15 mm	1,0040%	0,95%	0,05%	0,04799g
Mannitol (3%)	5,5 ml	15 mm	0,8499%	0,99%	-0,14%	0,02641g
Mannitol (3%)	5,5 ml	15 mm	0,9502%	1,04%	-0,09%	0,04898g
Mannitol (3%)	5,5 ml	15 mm	0,9645%	0,98%	-0,02%	0,07598g

Table I: LYONSENSE® versus a Karl Fischer sensor

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

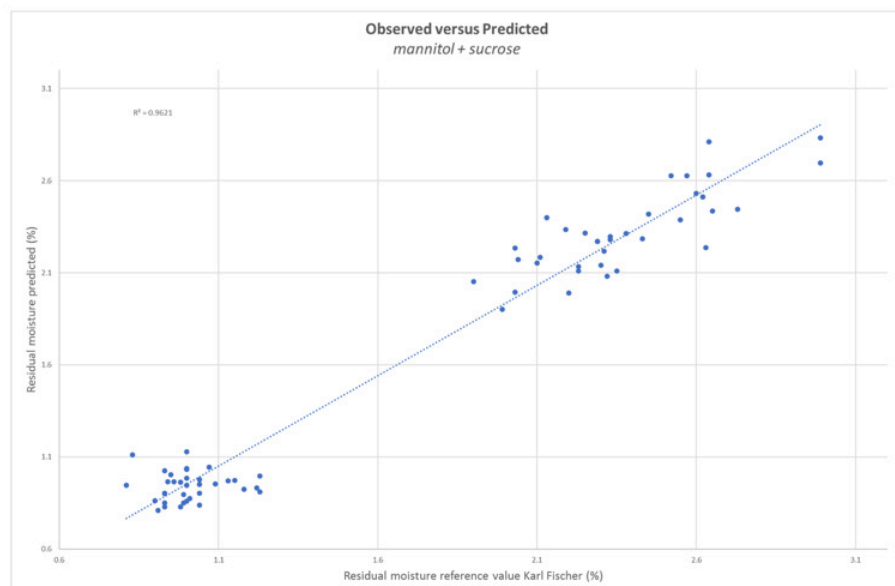


Figure 1: Predicted and observed residual moisture content

