



- Unique method for characterizing freeze-dried products in real time
- Allows non-invasive measurements:
 - Residual moisture content
 - Detection of glass particles
 - API concentration
 - Lyocake homogeneity

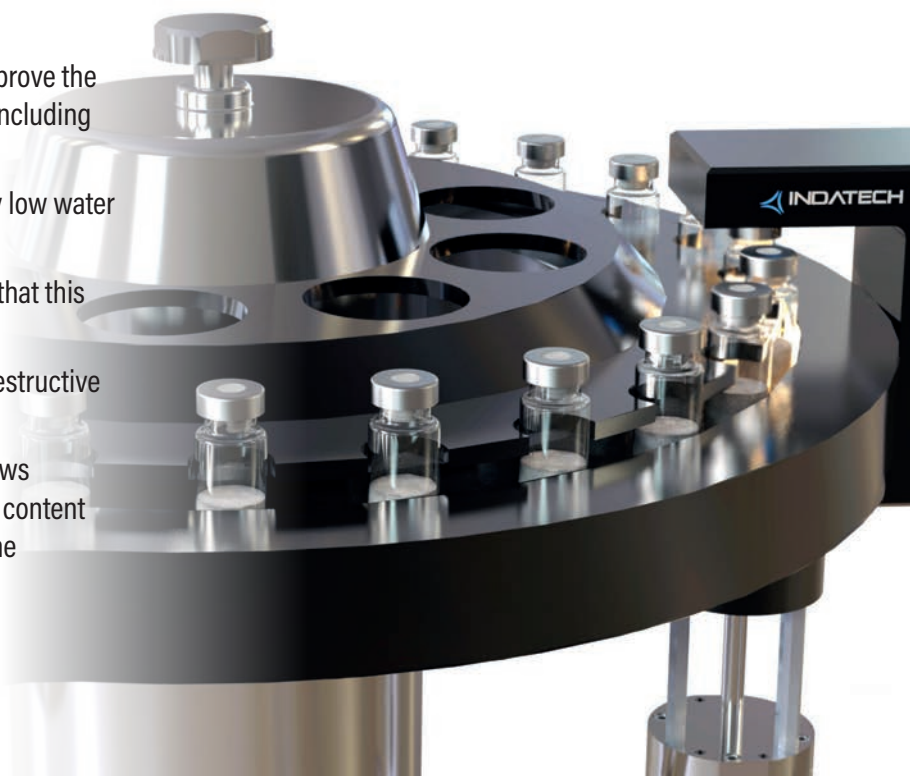
Lyophilization (also called freeze-drying) helps to improve the stability and storage life of a wide range of products, including pharmaceutical vaccines.

It is only possible to guarantee their stability with very low water concentrations (typically below 3 %).

This is why the regulatory recommendations indicate that this parameter's value must be checked and determined.

However, most of the techniques currently used are destructive and particularly time-consuming.

SAM-Spec® Lyo uses a patented technique which allows real-time non-destructive assessment of the moisture content as well as detecting glass particles and meltback in the freeze-dried products.



Packaging line

- 100% inspection
- Automatic vial detection
- Possibilities for integration and automation
- Simple integration & maintenance: miniaturized probe

Process development

- Ideal laboratory setup for Quality-by-Design
- Flexible and easy to use in the laboratory or in the production environment
- Real-time prediction of the parameters of interest

Software

Software integrating all the constraints linked to inline production measurement.

- Our SRS Ready software for acquisition of the spectral data and integrity checks (21 CFR part 11)
- Compatible with data analysis software such as PLS_Toolbox (Eigenvector) and SIMCA (Sartorius) for real-time predictions
- Communication with PLCs via OPC-UA or TCP/IP

Advantages of SAM-Spec® Lyo

- Assessment of the total lyocake volume on the basis of multipoint measurements
- Particularly short analysis time (< 5 ms)
- No consumables required
- Easy to use and to automate
- Precise analysis of the residual moisture content
 - Residual moisture detection threshold : 0.2%
 - Range: water content from 0.2 to 5%
- Assessment of other critical process parameters: API content, lyocake homogeneity, porosity, meltback, collapse or shrinkage, glass particles, etc.



INDATECH's teams will be delighted
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