

SAM-Spec[®] Lyo

Unique real-time characterization
of lyophilized products

Provide non-invasive measurement of:

Water
determination

Glass
particle
detection

Cake
homogeneity

API
concentration



Lyophilization of products enhances the stability and shelf life of many products including pharmaceutical vaccines. Their stability can only be guaranteed if low level water concentrations (0.2 to 5%) are present. For this reason, **regulatory guidance indicates that this parameter must be controlled and determined**. However, most current techniques are destructive and highly time-consuming.

SAM-Spec® Lyo is a new technology that provides you **real-time, non-destructive evaluations of moisture content**, as well as **melt** and **glass particle** detection within freeze-dried products.

The benefits of SAM-Spec® Lyo

- **Whole cake volume** assessment based on 27 multipoint measurements
- **Extremely fast analysis time** (5ms)
- **No consumables** required
- Easy-to-use by standard operator
- **Accurate analysis of residual moisture**
 - **Threshold detection** of residual moisture: 0.2%
 - **Range:** 0.2 - 5% water content
- **Assessment of other Critical Process Parameters:** API, cake homogeneity, porosity, melt, glass particles



Packaging Machine



100% inspection
Automatic vial detection

Machine communication capabilities

Easy integration & maintenance:
miniaturized probe

Process Development



Ideal mounting in the lab for **Quality-by-Design**

Flexible, easy-to-use in both lab and production environments

Ready-to-use calibration

Software	Functions
SRS-Ready® (INDATECH)	Spectral data acquisition and integrity check
PLS_Toolbox®, SIMCA®, The Unscrambler®	CPP calibration, Quality-by-Design, investigation and process understanding
Process Pulse II®	Operator interface, communication with packaging machine, report

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