

Seidenader **NIR Module** for Maximum Process Quality

The Seidenader NIR module allows to utilize near infrared spectroscopy in a production environment, fully embedded in any of Seidenader's automatic inspection machines. The same technology which is widely used for incoming bulk materials can now be integrated into the final packaging process. NIR can be a significant step to add process analytical technologies (PAT) to the filling, packaging and labelling process.

Areas of Applications:

Concentration of active ingredients

A NIR profile of your product allows to monitor the concentration of active ingredients within a defined range at the final point of production.

Residual moisture in lyophilized parenterals

Concentration of residual moisture can be monitored inline on an inspection machine without the usual destructive testing.

Cross contamination

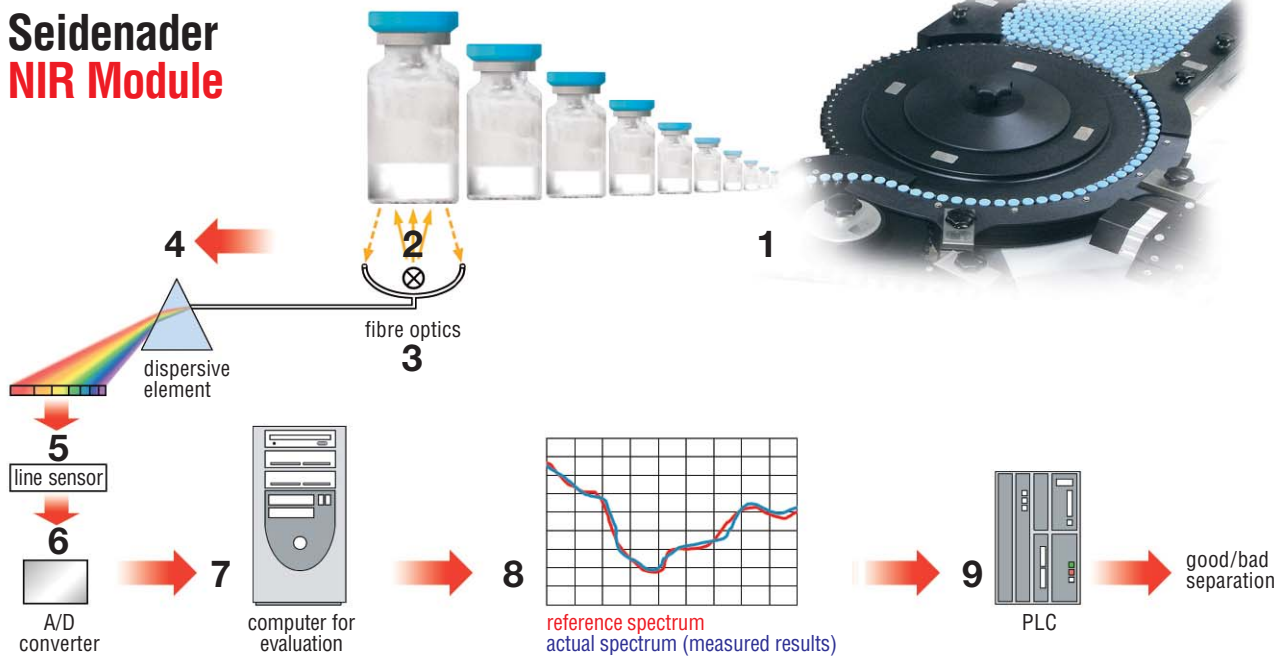
Avoid product mix up by using NIR to document conformity of unlabelled batches of vials or of tablets and capsules.

Advantages:

- Full traceability of active ingredients in liquids, powders and lyophilized products.
- Reduction of laboratory analytical work.
- Inspection of all products – documentation of all inspections.
- Fully embedded in Seidenader inspection machine PLC and HMI structure.
- Higher yield on batches of crystalline suspensions (Insulin).



Seidenader NIR Module



Function

1. Products are passing the NIR inspection unit in a defined position (star wheel, vacuum wheel).
2. A light source emits light to the object to be inspected.
3. The reflected light, which is modulated by the properties of the object under inspection, is transmitted by fibre optics to a dispersive element.
4. The dispersive element is generating a spectrum of the modulated light.
5. A line sensor records this spectrum.
6. The spectrum is digitized
7. and fed into a high performance computer for further analysis.
8. Spectra are compared with reference spectra by sophisticated algorithms to generate a pass/fail signal.
9. Pass/fail signals are sent to PLC which is tracking each product and activates the reject gate if necessary.



Case Studies - History

1997 Seidenader have integrated NIR system in automatic inspection machine for hard gelatine capsules to track concentration of active ingredients – Presentation at AICHEMA 97.

2000 Seidenader developed a system to measure crystal concentration in insulin products.

2003 Seidenader and a major Swiss pharmaceutical manufacturer develop a prototype for inline inspection of freeze dried products to check residual moisture.

2004 After 2 years of practical experience with the prototype Seidenader build a production machine – the Seidenader MPV-NIR – to check

lyophilized products inline at 300/min for residual moisture.
2006 Seidenader present in cooperation with J&M Germany, the NIR module at AICHEMA 06 – a compact module for NIR analysis which can be integrated in Seidenader automatic inspection machines.

Seidenader

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Technical Data S-NIR Module

Diode array spectrometer: transmission grating, 256 pixel for measuring NIR range 1100 - 2100 nm, expandable to UV-VIS-NIR ranges 190 - 2100 nm
Throughput rate: up to 3000 inspections/min depending on application
Dimensions: depending on application
Design: integrated design complies with current GMP recommendations, OSHA regulations, CE requirements, EN 60204-1 and 21 CFR part 11

Since we are constantly working on the improvement of our high-quality machines, the texts, illustrations and figures on these pages are illustrative only and not binding.