

Product Information

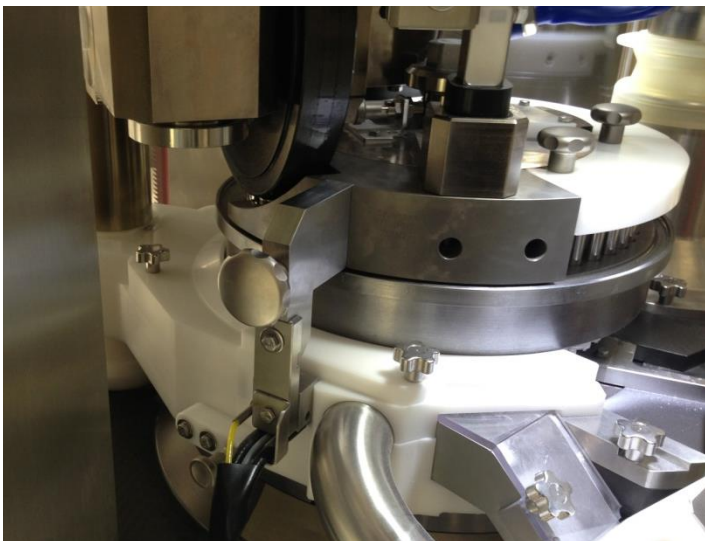
Background

The compacting process of tablets performed on a tablet press is essential for the efficacy of a drug. The content uniformity (CU), right compression force, the degree of humidity in the compound, particle size and other characteristics are critical parameters which are influenced or detectable in this processing step.

An in-line integrated Near Infrared (NIR) system can check for these physical-chemical characteristics to rule out deficiencies. The application is performed in a non-destructive way in real-time. The application was developed together with Fette Compacting, Schwarzenbek, Germany.

VisioNIR LS System

The VisioNIR LS is a high speed Near Infrared spectrometer for Content Uniformity and hardness inspection. The reliable trend monitoring visualizes the CU/hardness prediction value of individual tablets.



Close-up of VisioNIR system measuring head installed into FE35 tablet press

Outliers can be signaled to the tablet press in order to ensure that no bad tablet reaches the marketplace and the results of the in-line check of the CU can be used to support the real-time release approaches.

Individual tablets are scanned in reflection mode directly after the compaction process and the resulting spectra are evaluated by the multivariate data analysis software "The Unscrambler".



HMI visualization of acquired NIR spectra on Fette HMI

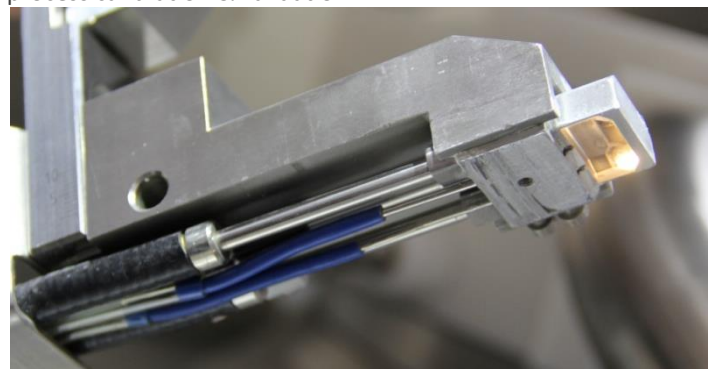
VisioNIR LS is the result of continuous development from customer requirements, process understanding and experience in the pharmaceutical production. As a result of the flexible hardware and intuitive operating software, VisioNIR LS is easy to retrofit and meets the pharmaceutical requirements.

High Speed

VisioNIR LS is a high speed system. The diode array with transmission grid enables rapid and precise data acquisition. As a result of using diode array technology, no moving parts are in use and high scanning rates can be achieved to inspect individual products during the process.

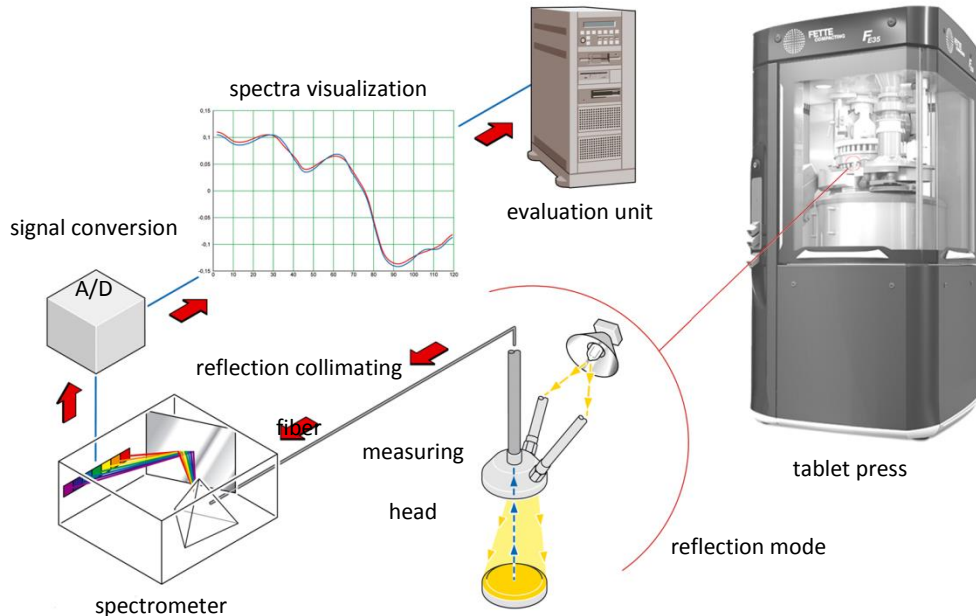
Knowledge and Competence

Visiotec has an excellent team of NIR experts to support you with your application. Our long term experience in method calibration helps to find the best correlation between your process data and your critical quality attributes (CQA). We provide consultancy for the design of experiments (DOE), design space calculation and process calibration & validation.



Close-up of a measuring head and mounting bracket

Functional Principle



Highlights

The tungsten halogen illumination source provides NIR radiation from 700 – 2500 nm and the illumination light fiber transports the radiation to the measuring head. The measuring head focuses the NIR radiation onto the tablet and the reflected NIR radiation with spectral information is captured by the head and coupled into the collimation light fiber. The collimated NIR radiation is transported to the diode array NIR spectrometer and the transmission grid splits the polychromatic NIR radiation into its single wavelengths. The single diodes are counting the number of photons regarding their wavelength range and the AD converter visualizes the NIR spectrum. The spectra will be evaluated in terms of CU or hardness in the evaluation PC with multivariate statistics. The results can be visualized on the trend monitoring screen.

- Sophisticated in-line technique
- High-speed inspection of tablets
- Integration time 0.1 ms – 100 ms (application dependent)
- Diode array technology with 256 pixel
- Wavelength range 850 – 1600 nm or 1100 – 2100 nm
- Integrated or stand-alone solution
- Compact design
- Fiber optics technology
- Multivariate evaluation
- CU and hardness inspection
- Supports Real Time Release approach