

### Product Information

#### Background

PRODITEC and visiotec have partnered to offer a comprehensive inspection/sorting solution which provides 360° optical surface and 100% chemical inspection of pharmaceutical bulk products at high-speed. PRODITEC's automatic vision inspection/sorting systems are featured with visiotec's integrated NIR system VisionNIR LS.

The first combo solution platform was launched at INTERPACK 2008. Besides the features of PRODITEC's optical inspection systems, for the first time in bulk inspection, also the content of bulk products can be ID'ed using high-speed NIR technology - a new way to solve quality challenges cost efficiently before potentially rogue products end up in a patient's bottle or blister.



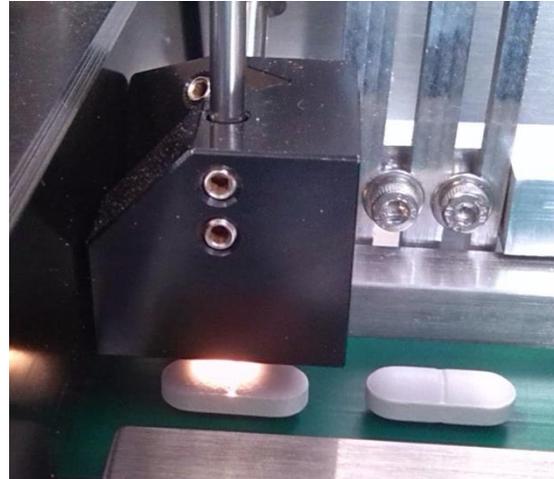
VisionNIR LS system on a PRODITEC bulk product inspection machine

#### Why optical inspection paired with a PAT technology?

Because looks can be deceiving; only NIR gives the peace of mind that the product not only 'looks' good but that from a content point of view it really is good. Qualifying a good product should not be based on appearance alone but by its content as well. Picture a pleasant smile with mouth closed then the person smiles with mouth open and seeing no teeth.

Today, when a batch does not pass routine in-process-control QA checks, manufacturers of bulk products are left with the decision to either destroy the entire batch or rework it via intensive manual inspection procedures.

A more efficient and more importantly qualify-able alternative is to use an automated inspection & sorting system: and combined with an established pharmaceutical PAT technology (NIR), not only 100% optically acceptable products but also 100% of the right products are released for downstream packaging - one important step to make the pharmaceutical supply chain safer.



Close-up of NIR measuring head scanning a tablet

#### A perfect combination: vision inspection and NIR

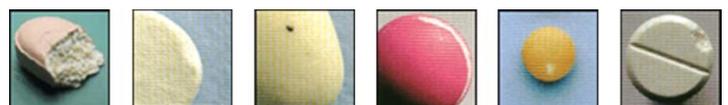
High resolution vision technology, covering the entire product surface area of a product, is inspecting each product for any cosmetic flaws. NIR is particularly interesting for spectral comparisons and, in analogy to criminal investigation it can be referred to as molecular "fingerprinting" or "forensic analysis". With both technologies built into one platform, it can support the manufacturing of bulk product and packaging operations to rule out any product issues ahead of time. The platform can also support rework activities.

#### Flexibility

VisionNIR LS can be implemented directly into any new or even existing inspection machines from PRODITEC. As a result of using diode array technology, the system is robust towards outside influences such as vibration.

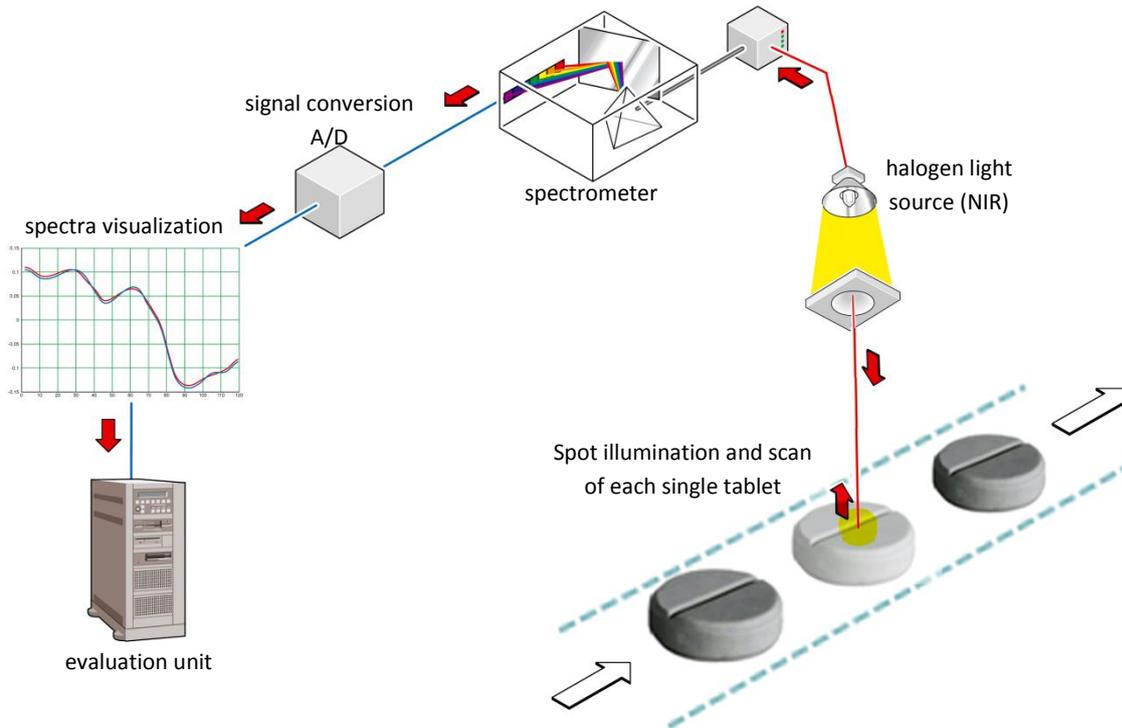
#### Knowledge and Competence

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.



Examples of typical optical defects of bulk products

### Functional Principle (NIR analysis)



### Highlights

The vision system takes multiple images of each product to cover the entire product surface area (360°) and performs its optical inspection (color, geometry, etc.) using high-res cameras and LED illumination.

The NIR system has a separate light source (halogen) which provides NIR radiation. This radiation is bundled and transported via an illumination fiber and targets each product with a light spot. On the same pathway back, the reflected NIR radiation with spectral information is then coupled into the collimation light fiber. The collimated NIR radiation is transported to the diode array NIR spectrometer and converted into a spectral chart. Evaluation is performed via software so the information of these spectral charts can be classified in order to distinguish tablets based on their physical-chemical characteristics resp. their "forensic fingerprint".

- Sophisticated in-line technique combining vision inspection and NIR technologies
- 100% inspection of individual products by state-of-the-art high-resolution vision system for cosmetic defects and with NIR for product chemical composition
- Integration time 0.1 ms – 100 ms (application dependent)
- Diode array technology with 256 pixel
- Wavelength range 850 – 1600 nm or 1100 – 2100 nm
- High-speed capable application to run up to 126,000 products/hour
- Retrofit-able into existing PRODITEC machines
- GMP design and 21 cfr part 11 capable