

A new standard in 100 % control

Greater reliability and productivity with NIR spectroscopy

Uhlmann VisioTec has been providing inspection systems based on NIR technology for several years. The latest developments in this area are the logical answer to PAT (Process Analytical Technologies) – tools initiated by the FDA to improve the quality and increase the productivity of pharmaceutical manufacturing processes.

VisioTec presented its VisioNIR liquid for the first time at theACHEMA 2003, installed on a labeller for ampoules. The task of this innovative system is 100 % control of the liquid directly prior to labelling.

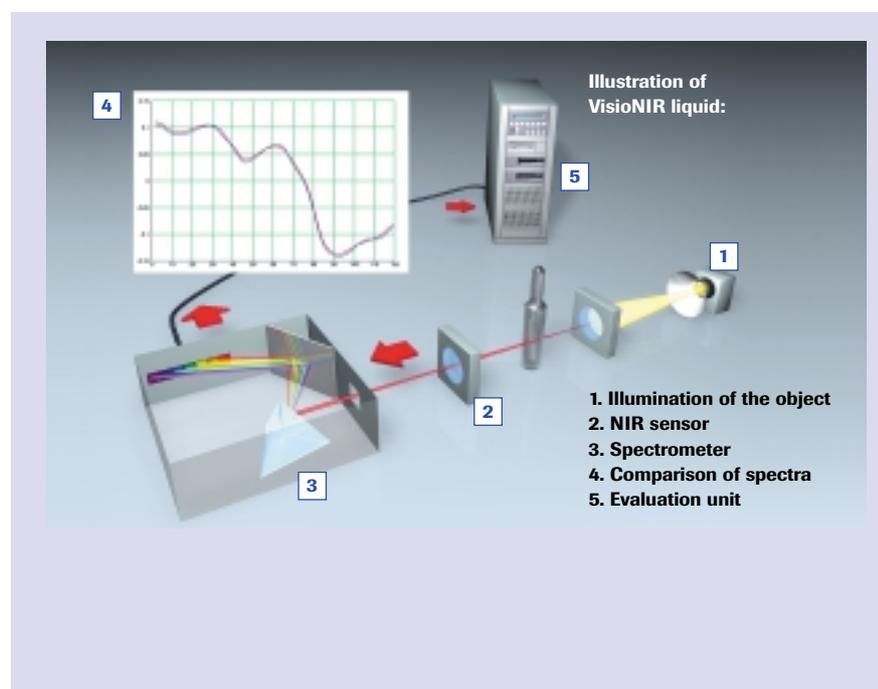
A significant milestone in the further development of NIR technology was the integration of VisioNIR liquid in a bottling line for suspensions. The task was to develop a method of “quantitative in-line control using NIR spectroscopy” in order to replace conventional high pressure liquid chromatography (HPLC) and gain benefit from all the advantages of NIR technology.

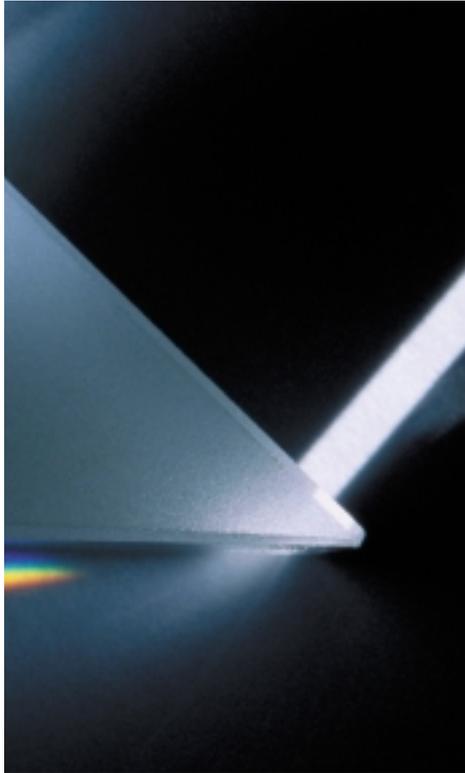
In the context of a feasibility study at the beginning of the project, extensive tests were carried out on a pilot machine at a customer’s manufacturing plant. Result: the newly developed NIR method can fully replace the HPLC analysis. It

actually provides the customer with additional information on parameters that were not quantifiable up to now, but can influence the process. For example, physical factors not previously taken into

account, such as temperature, pressure, growth of crystal particles and crystal modification, play a significant role during bottling. In contrast to the HPLC analysis, VisioNIR liquid recognizes these parameters. In this particular case, the VisioNIR sensor identified variations in temperature during the process. These could subsequently be eliminated.

The concentration of suspensions decreases towards the end of the bottling





limit. As soon as the measurement falls short of this limit production is stopped immediately. As a result, material costs

VisioNIR liquid replaces HPLC analysis

are saved by avoiding faulty production. In our case, the customer attained a return on investment in under 6 months.

In-line spectroscopy offers obvious advantages compared to conventional in-process control methods:

- **Production reliability – 100 % control of every product**
- **Indirect monitoring of the dosage**
- **Immediate production stop in the case of deviations and possibility of modifications**
- **Less faulty production so material costs are saved (e.g. cylindrical ampoules)**

process. VisioNIR liquid identifies this change much more quickly and reliably than the HPLC analysis. When using the HPLC analysis, products produced after the last good measurement are usually destroyed. VisioNIR liquid enables production up to the permissible tolerance

In-line NIR spectroscopy provides information on parameters that influence the process but were not previously quantifiable.

- **Lower infrastructure costs (e.g. for laboratory technology)**
- **Much less time involved**
- **Fast changeover to a different product**

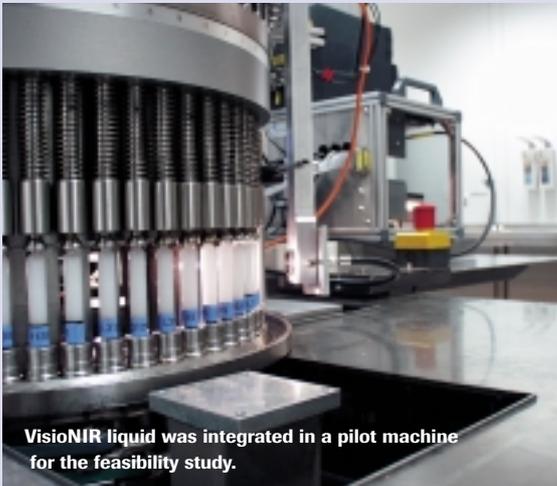
The advantages of in-line NIR spectroscopy in the areas of quality assurance and enhanced productivity speak for themselves. Consequently, VisioTec is planning to present the project to the FDA together with the customer.

VisioNIR liquid can be used on machines with intermittent or continuous modes of operation. The usual production

Presentation of the project to the FDA

speeds of 600 to 800 products per minute can easily be met. As the control measurements take just milliseconds, speeds of up to 3,000 products per minute are possible.

VisioNIR operates independently of the format and product. Product spectra can be read in, stored and called up as required. Practically all known lines and machines can be upgraded with the system. It can be validated and meets all pertinent guidelines governing pharmaceutical safety.



VisioNIR liquid was integrated in a pilot machine for the feasibility study.

