Built upon Viavi’s proprietary Linear Variable Filter Technology, the MicroNIR family of spectrometers are fully integrated, ultra-compact NIR sensors. We offer rugged field and industrial stainless steel manufacturing models. The MicroNIR family of NIR spectrometers was designed from the start as a fit-for-purpose sensor to meet the needs of these applications without unnecessary system features and complexity. When these small, robust and process ready sensors are implemented, virtually 100% of materials can be measured and monitored for critical quality attributes and processability, allowing for more efficient manufacturing, resulting in consistent product quality.

Because of the unique design of the MicroNIR sensor, several valuable benefits are realised for both field and manufacturing processes.

**Small Form Factor**
MicroNIR represents a major step forward in the performance to size ratio. This means the sensor systems can be placed in close proximity to the process in applications that were previously hard to implement with bulkier instruments.

**Robust Performance**
MicroNIR contains no moving parts and is therefore shock proof, allowing it to be implemented into harsh environments without the use of fibre optic cables. The systems behave like a sensor, but provide full spectrometer performance.

**Real-Time Results**
MicroNIR is based on diode array technology and can generate high quality spectra in less than one second. This speed makes it an ideal candidate for high speed applications, particularly in Continuous Manufacturing (CM).

**Connectivity**
With USB, Ethernet and WiFi communication protocols, MicroNIR can be used in remote locations and dynamic process monitoring, allowing multiple sensors to be easily distributed across your manufacturing operations.

**Simple Design**
The optical configuration is simple and compact, allowing the manufacture of MicroNIR to be highly repeatable. This provides a high degree of calibration transfer across multiple sensors.

**Qualification**
MicroNIR meets the specifications required by the USP and EP pharmacopoeias for operational and performance qualifica-
tion. Furthermore, all software solutions provide the necessary tools for enabling 21 CFR Part 11 compliance.

The MicroNIR family of NIR sensors is an ideal choice for a pharmaceutical manufacturer wanting to implement NIR for several applications in the complete end-to-end solid dose pharmaceutical production chain. All MicroNIR sensors operate on the same standard optical platform which allows for data collected on one sensor to be easily transferred to all other devices enabling easier and faster method development.

The MicroNIR OnSite is a handheld sensor for fast and easy raw material identification and product conformity analysis. The collected data and results are sent to a MicroNIR Database for storage and further use for process understanding in a QbD/PAT environment. The OnSite system can be installed in the warehouse on receipt or into the dispensary where true 100% material inspection is possible.

MicroNIR PAT-U is then utilised for monitoring the end-point of fluid bed drier (FBD) operations. The Loss on Drying (LOD) method is developed using MicroNIR Pro software and sent to MicroNIR Database for version control and integrity. The LOD method is then sent to MicroNIR Process client for the FBD operation where multivariate trending can be applied to data triggered manually or through the developed OPC triggering server. When the endpoint is reached for the process, the OPC write client will send a signal to the control system to shut the process down. All data are sent to MicroNIR database for retention and further investigation when required.

Next the MicroNIR PAT-W is utilised for blend uniformity analysis on a tumble blender. MicroNIR PAT software is used to develop the method and stored into the MicroNIR Database. The method is then deployed to MicroNIR Process Client for the blending operation where OPC triggering can be used to start the process and OPC write can be used to stop the process when the endpoint is reached. Data and reports are saved to the MicroNIR Database for retrieval and review through remote connection of the MicroNIR Process Client software.

MicroNIR PAT-U is utilised for monitoring of blend uniformity on the tablet press. Starting and stopping of the analysis is achieved through the use of OPC triggering and using trend charting. Statistical Process Control (SPC) charts can detect trends and alarm them before an issue occurs. This system will be monitored and controlled using the MicroNIR Process Client for the blending operation.

Finally, the MicroNIR PAT-U is again considered for tablet coating and can be adapted into the main spraying chamber for coating thickness monitoring. Data can be collected from a real process and stored in MicroNIR Database for retrieval into the MicroNIR Pro software and a model developed that is seamlessly transferred to the MicroNIR Process Client for coating operations. The system can be started by OPC triggers and stopped when the OPC write server sends a signal to the control system when the coating process has been completed.

A QA manager/delegate can remotely log into any client during the process and have a dashboard view of the complete factory. This will be able to be spread over multiple monitors to view all unit operations in real time. The overall enterprise solution will allow end users of the system to use a single platform for their NIR measurements and the results written to the MicroNIR Database can also be written to higher level PAT management systems such as synTQ from Optimal Automation allowing combination with other instrumentation and results thus allowing expansion into larger systems as a company’s needs grow. The above enterprise solution is provided in Figure 1.

The MicroNIR family of sensors are purpose built, real time PAT analysis tools that are highly applicable across the solid dose pharmaceutical manufacturing operations. This use of PAT enables QbD as it allows the complete monitoring of each batch throughout the entire process and not just relying on a single, non-representative measurement after the completion of each unit operation. This allows manufacturers to save time on waiting for time consuming laboratory results and improves Overall Equipment Efficiency (OEE).

Real time results can be displayed to operators that show when the unit operation has reached end point and/or uniformity, allowing manual intervention to stop the process or, the outputs can be sent to a third-party control system that stops the process when the endpoint has been reached.

MicroNIR provides a dedicated PAT solution for ensuring that the product meets all its quality and performance attributes in a manner that is aligned with the QbD initiative and checks the boxes with respect to the guidance by the various regulators.

Further information:
Viavi Solutions
www.viavisolutions.com/micronir

Figure 1: Possible enterprise solution for solid dose pharmaceutical manufacturing using MicroNIR hardware and software suite