



● **TANDEM** On-line Tablet Characterization PAT Tool

TANDEM is a fully automatic on-line PAT tool that allows the collection of process data and the control of the tablet compression process. The system provides information about physical and chemical characteristics of pharmaceutical tablets.

- Delivers data about physical tablet properties (weight, thickness, diameter, hardness)
- Content uniformity analysis; simultaneous quantification of multiple components, such as API(s) and moisture content
- Full validation with IQ/OQ/PQ documentation and USP/EP protocols

Improve your process understanding

The regulatory authorities require the accurate analysis of finished pharmaceutical goods to confirm the products' content uniformity and physical characteristics.

Traditionally, content uniformity analysis has been performed off-line by liquid chromatography. This time-consuming and operator-intensive process requires a manual collection of sample tablets at regular intervals during a batch and a consecutive laboratory analysis. Near-infrared transmission spectroscopy has proven to be a reliable, rapid and non-destructive alternative for routine tablet content uniformity testing along with moisture and excipient analysis.

TANDEM is an on-line pharmaceutical tablet characterization tool which incorporates the Sotax AT4 conventional tablet tester and Bruker's MATRIX FT-NIR spectrometer.



Automatic and accurate tablet positioning under the NIR transmission detector head for highest reproducibility.



The measurement sequence can be configured to optimize tablet handling time and quality of spectra.



After the non-destructive NIR analysis the tablets can be stored in a defined sequence for further evaluation.

Software

Bruker provides seamless integration of the TANDEM to the tablet press, utilizing the TabStatPro™ software along with Bruker's OPUS data collection and evaluation software. Measurement cycles can be pre-configured for certain tablet products. The setup parameters and analysis results are stored in a database. With an OPC interface, analysis parameters can be transferred real-time to other process software platforms, such as the Siemens SIPAT™.

Hassle-free maintenance

TANDEM is designed to be easily maintained by the user, e.g. exchange of NIR light source or tablet holders on product change. Permanent online diagnostics monitor the instrument and advise the user of a failing component. Instrument performance is validated at a click of a button using Bruker's Instrument Test Software in conjunction with the built-in Internal Validation Unit, assuring proper operation of the entire system. The instrument can be serviced quickly and will be back in operation with a minimal disruption of the manufacturing process.

Technologies used are protected by one or more of the following patents:
US 7034944; US 5923422; DE 19704598

Validation

Complete instrument and software validation including:

- Full 21 CFR Part 11 compliance
- Full GMP compliance
- Full IQ/OQ/PQ support

Bruker - the PAT Leader

Bruker offers the industry's most comprehensive range of solutions based on vibrational spectroscopy for the FDA Process Analytical Technologies (PAT) initiative:

- MPA At-line Method Development FT-NIR Spectrometer
- MATRIX Series Process FT-NIR and FT-IR spectrometers

Sotax Auto Test 4

The fully automatic tablet testing system sets a new standard for the measurement of weight, thickness, diameter and hardness. In contrast to other test equipment, the AT4 was designed specifically to meet the requirements of monitoring tablet quality during the production process.



The Model AT4 includes a unique separation unit and patented computer controlled tablet-transport positioning paddle. Product specific alignment and orientation is therefore possible for practically all tablet shapes. The mechanical construction of the AT4 is simple, allowing rapid and efficient cleaning. The component modules fitted on the machine can be dismantled easily. This facilitates thorough cleaning, for example when the product is changed or should the machine have to be decontaminated.

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