



A complete solution for pharmaceutical powder blending

SentroPAT blend uniformity

SentroPAT blend uniformity is a dedicated solution for non-invasive on-line monitoring of pharmaceutical powder blending. The NIR spectroscopy based turn-key solution provides valuable process insight from product development to operations. Due to its compact size and low weight the system can be easily mounted to the widest range of blenders and containers.

High Performance MEMS spectrometer

The heart of the instrument is a tunable laser based MEMS spectrometer. High analytical sensitivity is achieved by the combination of superior optical resolution and low noise. Outstanding system to system comparability simplifies method transfer between different blender types, processes and instruments.

Control the blending process

Besides determination of blending end point by statistical methods, quantitative analysis of API and other formulation ingredients applying chemometric calibrations is possible, too. Based on the gained process data it is possible to optimize blending time, avoid faulty batches and prevent blends from being segregated due to over-blending. There is no longer need for conventional thief sampling and laboratory analysis which retard manufacturing processes and therewith raise production costs. Fully implemented and applied the online monitoring of blend uniformity is a key element for real-time release.

Flexibility and easiest handling

A key focus of design and development from the very outset was ease of use and minimum maintenance effort:

- ▶ Mounting can be done by means of a simple 4" hygienic flange
- ▶ Mains adapter, internal and external charger and a hot swappable battery are providing a handling and possibilities as known from mobile PC or any other battery operated device
- ▶ The 3D orientation sensor allows software adjustable and reliable measurement synchronization to the blender rotation.
- ▶ The smooth cGMP-friendly unit can be easily cleaned, as it is required for use in GMP production facilities.

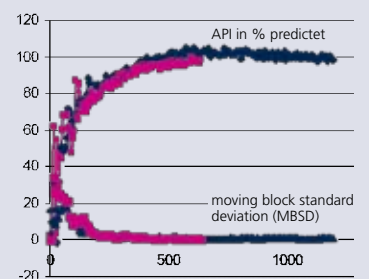
Highest data integrity

Highest data safety is guaranteed by the use of the internal PC running Windows XP, since all data are stored locally on the analyzer, before transmission through the wireless network. Standard PC periphery can be directly attached for service or IT administration. Wireless Ethernet connectivity and an OPC server are provided for the process environment.

A customizable solution

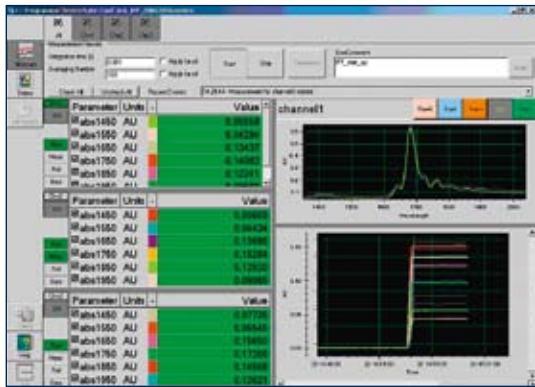
Sentronic enjoys a unique skill set, with many years' experience of spectrometer systems and probes, combined with in-depth knowledge of pharmaceutical production processes. With our engineering capabilities we are able to provide various system modifications if required, such as spot size modification or process window design.

Measured blend profile



NIR blend uniformity allows to optimize blending time (pink curve)





SentroSuite GmP

This user-friendly cGMP and 21 CFR part 11 compliant software package was developed within the scope of close cooperation with a number of customers in pharmaceuticals. The package is designed to maximize the benefits of Sentronic analyzers. Statistical functions for endpoint detection are directly accessible. Integrated interfaces to third-party chemometric applications, such as SIMCA and Unscrambler, allow you to use the modeling software of your choice for quantitative approaches. SentroSuite GmP includes an audit trail, comprehensive user management, file and data security, and other features suited to the needs of the pharmaceutical industry. Full IQ/OQ/PQ documentation can be provided in line with your specific needs.

Technical Parameters

Wavelength range	1350 – 1800 nm
Optical resolution (FWHM)	≥ 0.3 nm (configurable); specification at 2 nm
Wavelength accuracy	< 1 nm
Wavelength reproducibility	< 0.1 nm
Photometric linearity	Fulfilling USP<1119>
Noise - High Flux	< 0.3 x 10 ⁻³ AU
Noise - Low Flux	< 1 x 10 ⁻³ AU
Data acquisition time	400 msec
Sampling interface	Non contact, through sapphire window
Measurement spot size	25 mm, uniform beam shape for homogeneous sample illumination
Working distance	Depending on Sapphire window (27 mm at 8.5 mm Sapphire)
Power	Hot swappable battery with ≥ 3 hrs operation; External power supply for lab operation and recharging
Enclosure	IP65 / NEMA4, cGMP conform
Dimensions of complete system	230 x 210 x 150 (+50) ¹⁾ mm / 9 x 8.5 x 6 (+2) ¹⁾ inch ¹⁾ length of process flange
Weight	6.5 kg / 14.5 lb
Measurement trigger	Internal software controlled 3D position measurement
Communications	Wireless LAN (802.11b/g)
Software	SentroSuite GmP
Validation	Software integrated validation routines according OQ/PQ
Service port	Connections for CRT, keyboard, mouse, 2 x USB
Mounting	4" hygienic tri-clamp

Sentronic has been successfully developing and manufacturing optical sensors and analyzers, primarily for chemical parameters, since 1993. The company's core technologies comprise optical spectroscopy and optical chemical sensing. Our main product lines are innovative optical oxygen sensors and NIR process analyzers, including in-house-manufactured sampling interfaces and versatile analyzer manage-

ment software. Sentronic markets its technology and solutions to end-customers in the life sciences and chemical industry, and to OEM and private-label customers.

Partnership with Sentronic

Sentronic has implemented end-to-end, fully compliant documentation across the entire product life cycle for many customers, and for many projects. We are an

experienced, flexible partner. We understand that each customer has specific needs and imperatives, and we develop made-to-measure answers to the challenges of each PAT project. We are happy to play a supporting role within your existing organizational structures, providing vital input. You can be sure of effective communications, and quick, easy access to expert advice.

Sentronic GmbH

Gostritzer Strasse 63
D-01217 Dresden
Germany

Phone: + 49 (0) 351 / 8718653
Fax: + 49 (0) 351 / 8718465

e-mail: info@sentronic.eu
internet: www.sentronic.eu

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