SAM SPEC

SPATIALLY ADVANCED SPECTROSCOPY

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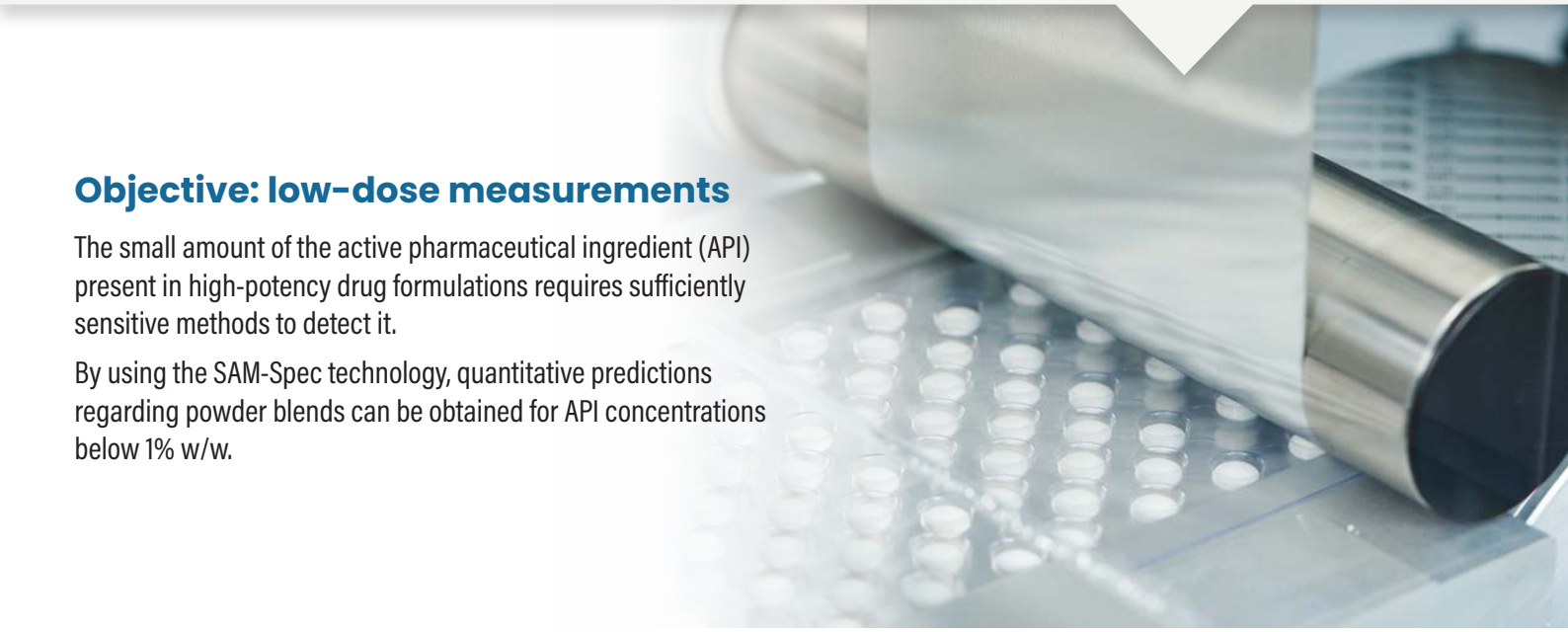
INDATECH

Pharma

Inspection of powder blends in a tablet press

Pharmaceutical tablet production is facing major new challenges such as more demanding FDA quality checks, continuous production or low dosage of active pharmaceutical ingredients.
Validation at all levels of the process is required in real time to ensure the quality of each drug batch and the stability of the continuous process over time.



Objective: low-dose measurements

The small amount of the active pharmaceutical ingredient (API) present in high-potency drug formulations requires sufficiently sensitive methods to detect it.

By using the SAM-Spec technology, quantitative predictions regarding powder blends can be obtained for API concentrations below 1% w/w.

SAM-Spec® : the solution for in-line monitoring of your critical process parameters

Indatech proposes a unique inspection solution capable of checking solids' physical and chemical characteristics simultaneously.
The patented SAM-Spec technology can be used for rapid, non-destructive, in-line analyses.
It is capable of:

- **Checking** up to 27 measuring points simultaneously, generating a sort of simplified hyperspectral snapshot of the product
- **Analyzing** up to 100 times greater volume than a traditional approach by measuring 3 times deeper than traditional spectroscopy

simultaneously acquiring the measuring points extremely quickly (< 10 ms)

Measurement in the tablet press: how?

In the study presented, our SAM-Spec solution was integrated in the feed frame of a rotary tablet press.

A Hy-Ternity acquisition unit was used to collect near-infrared spectra directly in-line.

Using optical fibers, the 12-point probe for data collection was incorporated into the feed frame.

Different powder blends were thus analyzed dynamically, using an integration time of just 3 ms for simultaneous acquisition of the 12 measuring points.

Exemple du contrôle d'une formulation à faible dose dans la presse à comprimés

The test setup is shown in Figure 1.

Nine blends were produced, with API (acetaminophen) concentrations varying between 0 and 3%.

This yielded 27 calibration data sets, as each formulation was measured with three different feed frame paddle rotation speeds: 15, 30 and 45 RPM.

A spectral filter was applied to eliminate the impact of paddle movement on the spectra.

A calibration model was then developed for each speed, correlating the near-infrared spectra to the API concentrations (Figure 2).

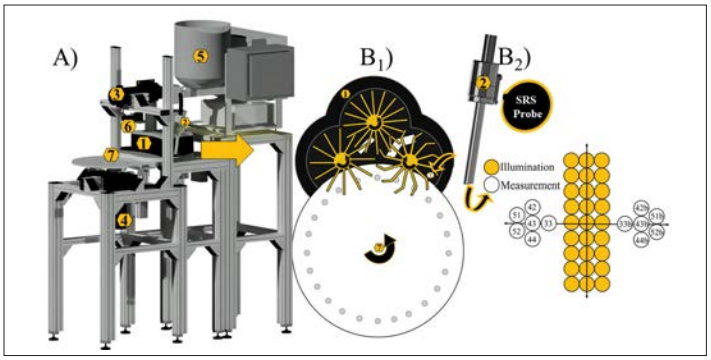


Figure 1: Feed frame table (A) with zoom on the feed frame paddles (B1) and the integrated SAM-Spec probe (B2) 1. Feed frame, 2. SRS probe, 3, 4. Motors, 5. Gravimetric feeder, 6. Encoder, 7. Die disk (turret).

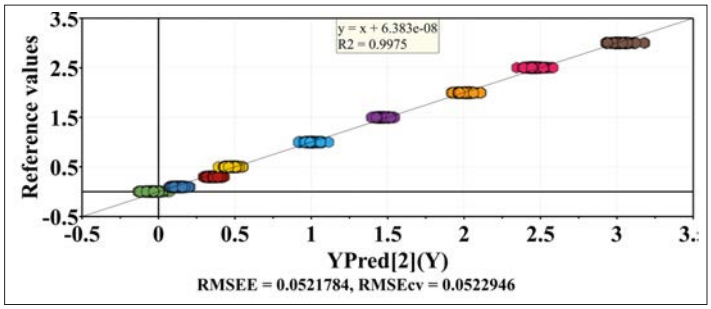


Figure 2: Correlation and error between the near-infrared spectra and the API concentration in the blends

Good-quality models were obtained to predict the API concentration, showing slight calibration and cross-validation errors, as well as excellent correlation (R^2). The model was applied at different paddle speeds without any real impact on prediction quality.

The short acquisition time and the multiple simultaneous spectral measurements by the SAM-Spec probe made it possible to quantify low-dose blends directly in-line in the tablet press.

Advantages of SAM-Spec®

The patented SAM-Spec technology offers a flexible solution for in-line testing of tablet production: :

- A set of tools for measuring powders directly in the feed frame, without modifying it,
- Near-infrared spectroscopy associated with chemometrics for precise quantification of the amount of API in low-dose blends (< 1%),
- A tool and a communication system enabling the application of established models for in-line monitoring.

For further information, please see the original research paper:

A.D. Román-Ospino et al., Sampling optimization for blend monitoring of a low dose formulation in a tablet press feed frame using spatially resolved near-infrared spectroscopy,

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