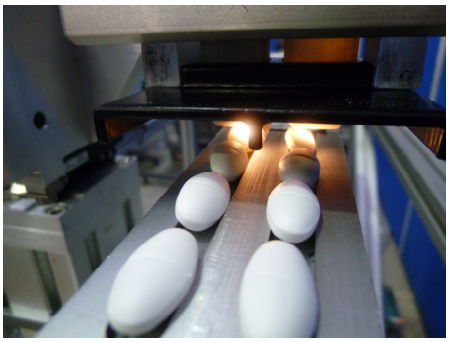
Case STUDY

Type } (produ š: E /^ZW d Z K ^ K W z
W Œ } µ š v u : ^ D r ^ W

Pharmaceutical Industry
Tablet Manufacturing



Keywords: API concentration, hardness, dissolution time, coating, cosmetic defect.

High-throughput inspection of all your tablets' critical parameters. Optimize your validation time to achieve real-time release!

For continuous production testing

The production of pharmaceutical tablets is facing new challenges such as more demanding FDA quality tests, continuous production and low or multi-product dosage of the active ingredients. To remain competitive and profitable while improving safety and quality, it is now essential to monitor all the critical quality features of large batches.

Goal

To meet these growing requirements for increasingly demanding validation, inspection machines capable of monitoring cosmetic defects are no longer sufficient on their own. More thorough validation in real time is needed, so that **the total quality of each batch of medicines can be checked in real time.**

NIR solution from CA INDATECH: penetrate inside your tablet in less than 2 ms

CA INDATECH proposes a unique inspection solution capable of testing both physical and chemical characteristics. The patented SAM-S NIR technology is ideal for quick, non-destructive analyses. This multipoint spectroscopic method can be used to accurately determine:

- the **content in active ingredient** of tablets
- the **hardness**, which may be linked to dissolution
- **the identification and thickness of the coating**
- **homogeneity/uniformity**

- **Example of application for tablet inspection on a high-speed sorting machine:**

Inspection of round-shaped tablets 8 mm in diameter with a red coating

Two SAM-S probes were used to analyze two tablet inspection lines simultaneously at a speed of 150,000 tablets/hour, giving a total of **300,000 tablets analyzed per hour**.
or each tablet, 8 acquisitions of 9 spectra were performed, providing **72 analytical points per tablet**.

CA INDATECH
4, rue Georges BESSE
34 830 CLAPIERS FRANCE
Tél. : +33 4 80 78 01 40
sales@indatech.eu
www.indatech.eu

Case STUDY

CHAUVIN ARNOUX INDATECH

Advantage of SAM-Spec inspection:

SAM-Spec proved capable of producing **an analysis of three important attributes**.
The active ingredient: it was possible to detect this and evaluate it between 0% and 18% as can be seen in figure.1. The same model was used for the tablets with and without a coating.
Compacting force: this was estimated very precisely on the basis of a simple SRS signal intensity relation, as shown in figure 2. This figure shows the direct correlation between the signal and kN (without a modelling phase). A relation was then established between the compacting force and the dissolution time.
Colored coating: this was analyzed and its thickness was predicted, as shown in figure 3. The coating signal did not overlap the API band, so it is possible to use the same mathematical model for products with and without coating.

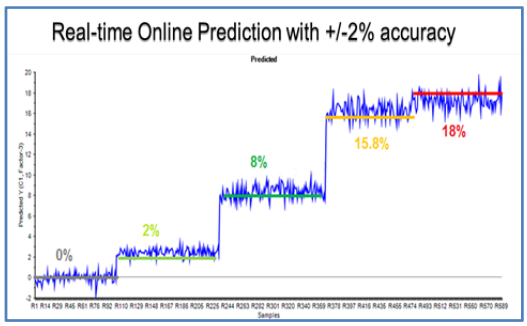


Figure 1: API concentration

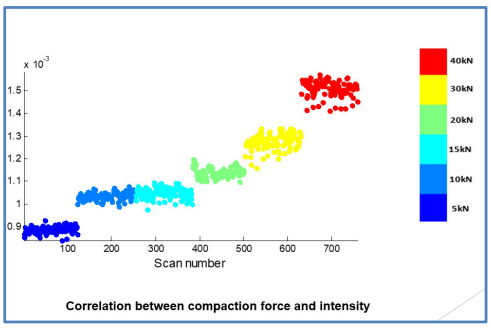


Figure 2: tablet hardness

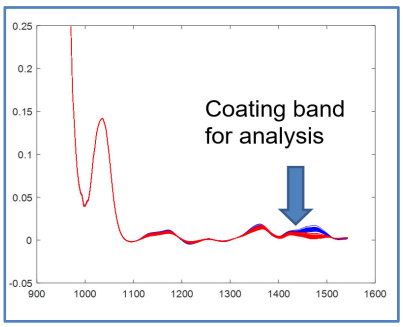


Figure 3: detection of coating signal

Advantages of SAM-SPEC

The **SAM-SPEC** system **helped to save tablet batches** worth more than €1 million which were blocked due a risk of cross-contamination with another tablet. In less than 3 hours, the SAM-SPEC system was able to identify the intruder with just one measurement campaign.

From the design phase, where control and traceability of the drug are particularly critical, through to its commercialization, to improve its effectiveness and safety after its market launch, the regulatory agencies require the drug to be tested in terms of its identity, dosage, quality, purity and stability before release. **The SAM-SPEC system considerably reduces the time needed to validate the tablets, while ensuring total quality and safety monitoring.**

SAM-SPEC Analyzer

Find out more

Our team will be pleased to hear from you

CA INDATECH

Tel.: + 33 4 80 78 01 40

CA INDATECH
4, rue Georges BESSE
34 830 CLAPIERS - FRANCE
Tél. : +33 4 80 78 01 40
sales@indatech.eu
www.indatech.eu

CHAUVIN ARNOUX GROUP