



Qualification of insulin in syringes

The qualification of insulin in the last phase of filling and conditioning of the syringes is essential to guarantee that the product is ready for administration to the patient.

The use of a spectrometer for this step is particularly advantageous because it allows quick, non-destructive analysis of the content of each cartridge. This innovative method ensures effective, reliable quality control while maintaining the syringes' integrity. In this way, manufacturers can guarantee patients' safety and improve the efficacy of their pharmaceutical products.

Goal: classification of insulin inside syringes

In the context of this study, we sought to classify several types of insulin products through the glass of the syringes by means of Raman spectroscopy. This classification is crucial to avoid mixing up the cartridges, thus guaranteeing the purity and integrity of each insulin batch.

Raman spectroscopy can be used for quick, non-destructive in-line analysis, which is particularly important in the last stage of filling and conditioning.

Viserion: the solution for in-line analysis of the critical parameters

Indatech offers a unique inspection solution capable of checking the chemical characteristics of liquid products. Viserion can be used to perform quick, non-destructive in-line analyses. It is capable of:

- Measuring up to 4 channels simultaneously
- Providing information on the chemical composition of complex liquids
- Performing very quick acquisitions (< 0.5 s)
- Analyzing finished products through plastic or glass packaging



How to measure syringes

For this study, the samples were measured in our «Vial Analyzer» (Figure 1), helping to ensure accurate measurements by keeping the syringes in a stable position, thus guaranteeing reliable, reproducible results.

The samples were analyzed using our Viserion Raman spectrometer connected to the «Vial Analyzer».

The spectral range extends from 400 to 2500 cm^{-1} . The acquisition parameters were configured with an integration time of 0.5 seconds and a single scan, allowing very quick measurement and offering the possibility of performing in-line classification at speeds of up to one syringe per second.

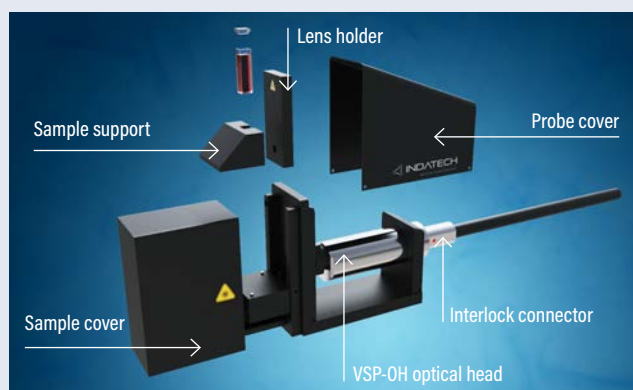


Figure 1: Vial Analyzer

Results and discussion

The data were analyzed using PLS_Toolbox 9.1, running on the MATLAB 2023b environment.

A PLS-DA (Partial Least Squares - Discriminant Analysis) model was developed to accurately classify the different products. Six insulin products (different monoclonal antibodies at various concentrations) were classified.

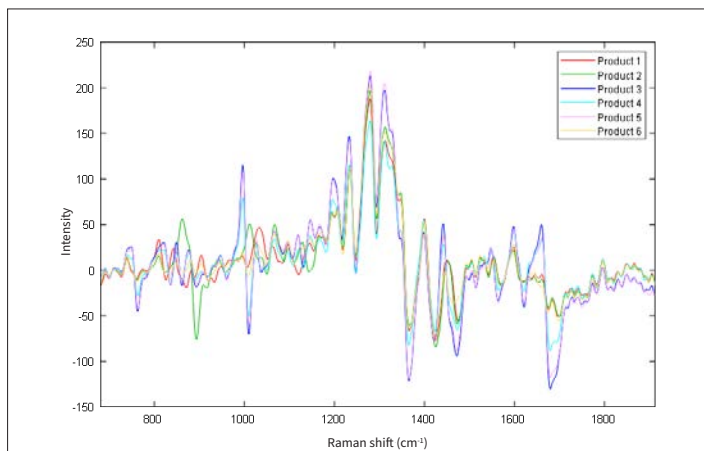


Figure 2: Mean preprocessed spectra of the samples

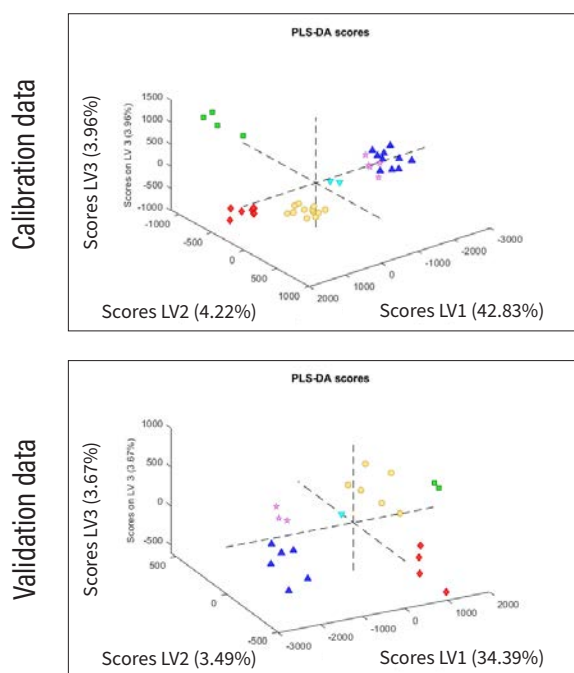


Figure 3: PLS-DA classification model

We obtained a high-performance PLS-DA classification model allowing precise identification of the products, which are chemically very similar.

Our Viserion Ready software includes chemometric models for making predictions in real time. It is not only possible to characterize the samples at-line via the Vial Analyzer, but also directly in-line using a probe.

In this way, each insulin product can be checked individually by means of a very quick measurement compatible with the speed of the syringes in the production process.

For full integration, information can be exchanged with a PLC via OPC-UA.

Advantages of the Viserion spectrometer

Raman technology offers a flexible solution for in-line inspection of insulin manufacturing processes:

- A quick measurement allowing insulin qualification through the glass of the syringes
- A set of probes, flow-cells and cuvette holders for reliable, reproducible measurements
- Raman spectroscopy combined with chemometrics for chemical characterization of the product of interest



Our teams at INDATECH will be delighted to answer your questions by telephone:
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