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U.S. Product Information & Quotations

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ASURYAN

CHAUVIN ARNOUX INDATECH

Biotech Pharma



Detection of leaks in syringes using UV-Vis spectroscopy

The safety and efficacy of pharmaceutical products are fundamental aspects.
One critical stage for guaranteeing the safety of liquid products stored in glass containers is the Container Closure Integrity (CCI) test.
This is an essential process to check the sealing and physical integrity of administration devices such as insulin syringes.

Goal: quantification of the methylene blue concentration in syringes

In the context of this study, we applied a probabilistic technique using methylene blue dye.

A number of syringes from the batch are sampled and filled with methylene blue. Once emtpied, the syringes are then filled with water and the remaining level of blue coloring is analyzed as it is an indicator of the possible presence of cracks or integrity failure.

The visual inspection currently used in quality control laboratories may lead to errors due to the limits of the human eye.

With our Asuryan solution, quantification of the coloring is automated and more accurate. This method thus offers precise, objective evaluation of container integrity by directly correlating the methylene blue concentration to the level of the cracking detected.



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

Indatech offers a unique inspection solution capable of checking the chemical and physical characteristics of liquids. Our Asuryan UV-Visible spectrometer can be used for quick, non-destructive in-line analysis.

It is capable of:

- Measuring up to 3 channels simultaneously
- Precisely analyzing the chemical composition of liquids
- Performing measurements with variable optical paths
- Characterizing the particle size by multi-angle measurement



How to analyze syringes

For this study, the samples were prepared by adding methylene blue to round glass syringes containing water.

To ensure accurate measurements, a specific support was designed to hold the syringes, thus guaranteeing reliable, reproducible results (Figure 1).

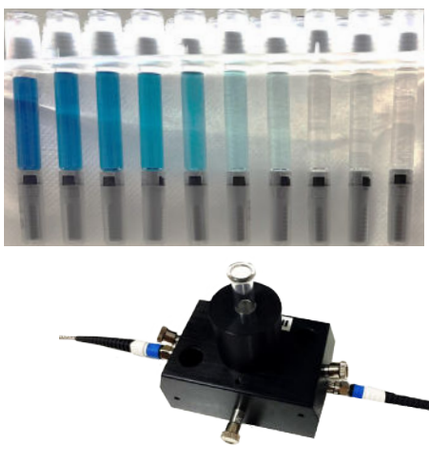

Figure 1: Syringes containing methylene blue solutions at different concentrations and the syringe-holder allowing repeatable measurements.

Results and discussion

The samples were analyzed in transmission mode using our Asuryan UV-Vis spectrometer connected to the syringe-holder. The acquisition parameters were configured with a 120 ms integration time and 10 scans automatically averaged by the Asuryan Ready software to improve the signal/noise ratio.

The data were analyzed using PLS_Toolbox 9.1, running on the MATLAB 2023b environment. A PLS (Partial Least Squares) model was developed to precisely quantify the methylene blue concentration. The concentration values and the results from the prediction model will not be disclosed for reasons linked to confidentiality and data protection.

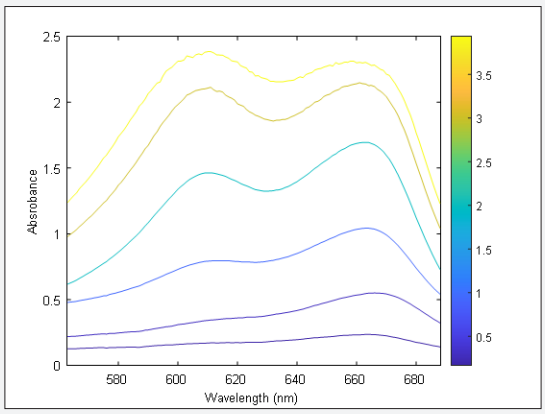

Figure 2: Absorbance spectra (560-685nm) of the syringes colored in function of the methylene blue concentration

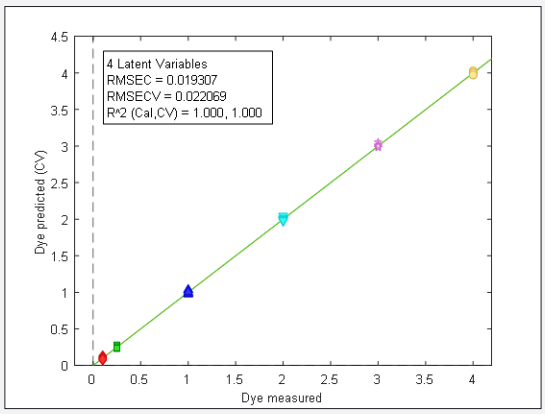

Figure 3: PLS quantification model

We obtained a high-performance PLS calibration model demonstrating good linearity and a low prediction error.

Thanks to the integration of these chemometric models in our Asuryan Ready software, it is now possible to precisely determine the quantity of coloring in new samples in real time, thus facilitating the assessment of cracks in the syringes.

It is possible to characterize the samples in the laboratory with a customized support or directly in-line using a probe or flow-cell.

This flexibility is extremely useful in various application contexts.

Advantages of the Asuryan spectrometer

UV-Vis technology offers a flexible solution for checking Container Closure Integrity (CCI) in-line or in the laboratory:

- Quick measurement allowing quantification of the dye concentration directly through the glass of the syringes
- A set of probes, flow-cells and cuvette holders enabling reliable, reproducible measurements
- Physico-chemical characterization of the products with different optical path lengths and scattering angles



The teams at INDATECH will be delighted to answer your questions by telephone: +33 4 80 78 01 40

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