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NIR Analysis of White Crystalline Powders and Nasal Solutions

Analytical Spectral Devices, Inc.

This experiment proposed utilizing NIR technology to assess the differences found in various white crystalline powders and four liquid solutions with different concentrations. The study's objective was proving the viability of using Analytical Spectral Devices' transportable QualitySpec® Pro Near Infrared Analyzer for qualifying the samples received.

Experiment

A series of spectra, covering the visible, and near-infrared range (350-2500 nm) were collected with the QualitySpec® Pro Near Infrared Analyzer in conjunction with a standard bifurcated reflectance probe. The baseline (reference standard) was derived by referencing to Spectralon®, a commercially available diffuse reflectance standard. The samples were placed in contact with the bifurcated reflectance probe and analyzed using Grams™ indiscriminate mode. For the liquid samples ASD's Multipurpose Fixture was used to measure the transmittance of the solutions.

Six different samples were obtained. The spectrum of each sample was collected using a two second measurement period.

The samples analyzed were:

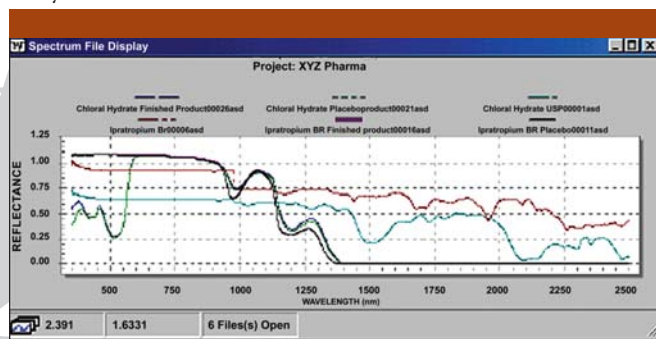
1. Chloral Hydrate RM
2. Chloral Hydrate Placebo Solution
3. Chloral Hydrate Syrup 500mg/5ml
4. Ipratropium Bromide RM
5. Ipratropium Bromide Nasal Solution 0.03%
6. Ipratropium Bromide Nasal Solution Placebo

The chemometric software Grams™ 32/AI was employed to compile all spectra and correlating data points. Using full cross-validation and limiting spectral regions, a sufficient calibration model was achieved.

For the white crystalline powders the spectral range was limited to 1000-2500 nm, whereas a spectral range of 350-1395 nm was used for the liquid samples.

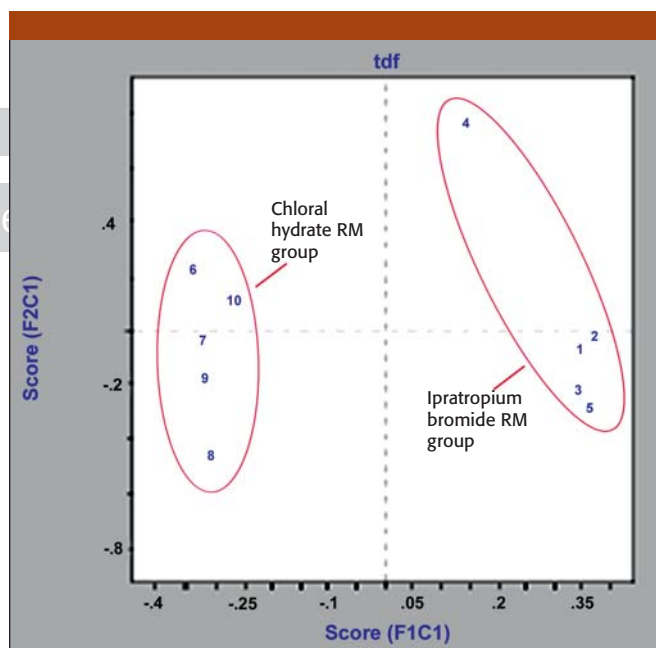
Results

The peaks in the NIR range are typically broad and overlapping due to the combinations and overtones of molecular vibrations from the many C-H as well as the N-H and O-H bonds in these large molecules. The results of the regression analysis are reflected in Graph 1, showing a representative spectrum of the samples analyzed.

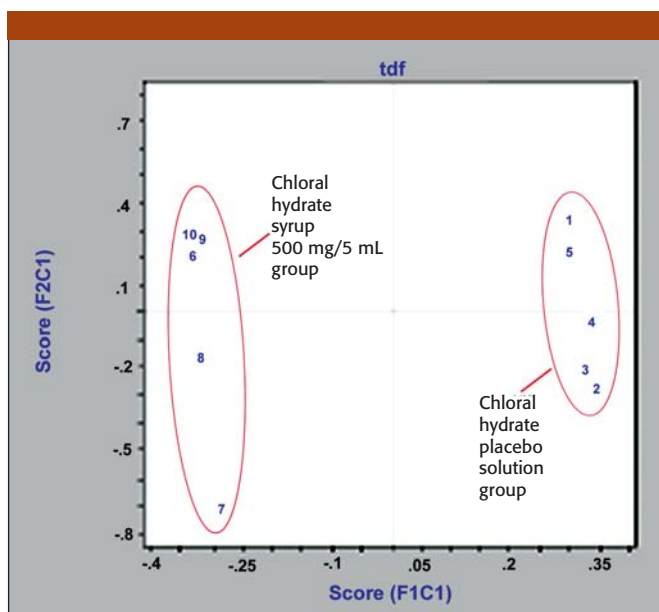


Graph 1.

Graph 2 shows the spectral grouping of the White Crystalline Powders (Chloral Hydrate RM and Ipratropium Bromide RM). Note there is a clear distinction between sample groups.



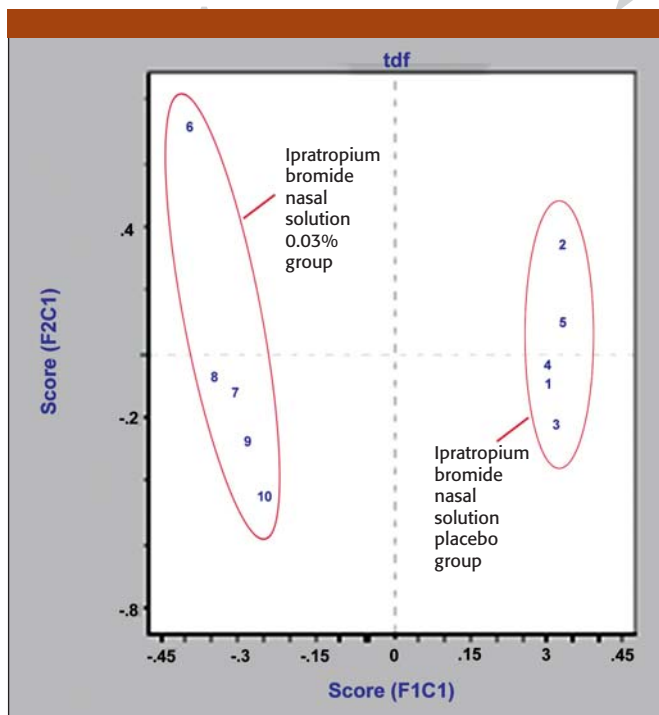
Graph 2.



Graph 3.

Graph 3 shows the spectral grouping of the Chloral Hydrate Placebo Solution and the Chloral hydrate syrup 500mg/5ml. Notice the separation between the placebo and the 500mg/5ml solution. The separation between these samples is about 8%.

Graph 4 shows the spectral grouping of the Ipratropium Bromide Nasal Solution 0.03% and the Ipratropium Bromide Nasal Solution Placebo. The separation between these two samples is about 1%.



Graph 4.

Conclusion

Preliminary data attest to the utility of the QualitySpec® Pro for the identification of Ipratropium Bromide RM, Ipratropium Bromide Nasal Solution 0.03%, Ipratropium Bromide Nasal Solution Placebo, Chloral Hydrate RM, Chloral Hydrate Placebo, and Chloral Hydrate Syrup 500mg/5ml. The spectral region of 350-1395 nm is recommended for the liquid solutions, and 1000-2500 nm for the powdered solutions. The Ipratropium Bromide Nasal Solution 0.03% and the Ipratropium nasal solution placebo are very close to the detection limit for NIR, so it would be advisable to have a larger data set to determine a true separation of the two solutions.

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