



High Throughput Analysis of Polymorphs Using the Avalon RamanStation

Avalon Instruments

Raman analysis of Polymorphs: From concept to product.

Raman spectroscopy is the most powerful technique for polymorph analysis and finds application in many areas of pharmaceutical development. The primary issue hindering the application of Raman in pharmaceutical environments is that, until recently, different instruments were required for different stages in the product development cycle. The advent of Hybrid Raman instrumentation, instruments with multi functional capability, is revolutionizing this area.

The Avalon RamanStation is the leading Hybrid Raman instrument having capabilities in all varieties of Raman including Raman Microscopy, high throughput Raman, fiber optic Raman, giant spot Raman analysis, and Raman chemical imaging.

Raman Microscopy

The Raman microscope is the standard Raman instrument format, offering the user the capability to acquire Raman spectra of microscopic samples with no sample preparation and by simply positioning the sample under the microscope objective. This analysis technique offers insightful and straightforward spectral collection.

Polymorph and Salt Screening Using High Throughput Raman

Salt screening is required to identify various polymorphic forms and hydrates, essential for maximizing product stability, efficacy, and patent protection.

The RamanStation can automatically map each well in a mul-

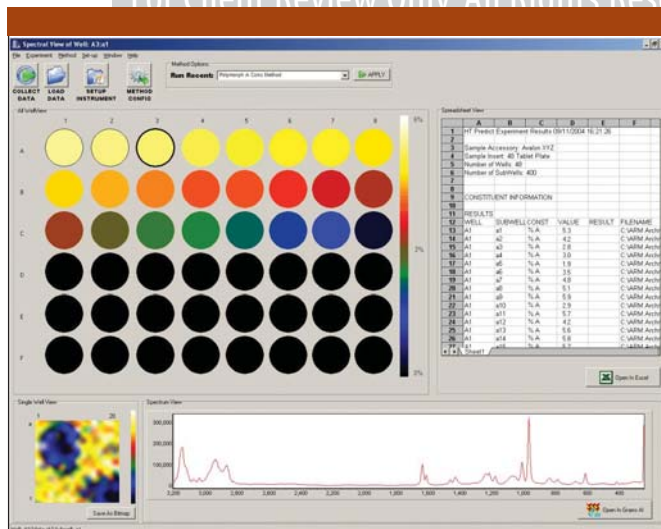
tiwell plate and use chemometric techniques to identify and quantify various polymorphic forms. In high throughput applications such as this, certain instrument characteristics are essential: rapid data acquisition, high spectral resolution, and a software interface that empowers the user, enabling them to understand and easily interpret the thousands of spectra acquired in each HTS run.

Dealing with Fluorescence

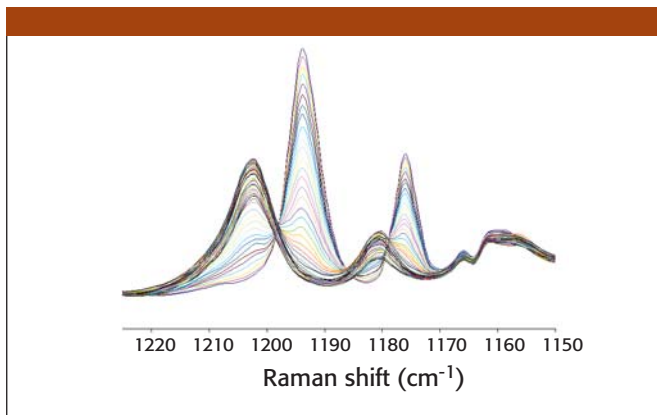
It is often the case that some polymorphic forms may be fluorescent. When using the RamanStation this fluorescence is seldom a problem. Firstly the RamanStation is typically equipped with a near infrared laser which minimizes fluorescence, secondly, Avalon's automated fluorescence quenching capabilities typically reduce any fluorescence to cosmetic levels, where the fluorescence can easily be handled by chemometric-based quantitative techniques. Automated baseline correction is also available for times that nicely processed data is required.

In Reactor Monitoring of Polymorph Transformation Using Fiber Optic Raman

In order to make stable or effective drug products, chemical or thermal treatment of polymorphs is sometimes required. The RamanStation's fiber optic probe can be fitted to reactors or ovens and allows for real time quantitative analysis and end point determination.

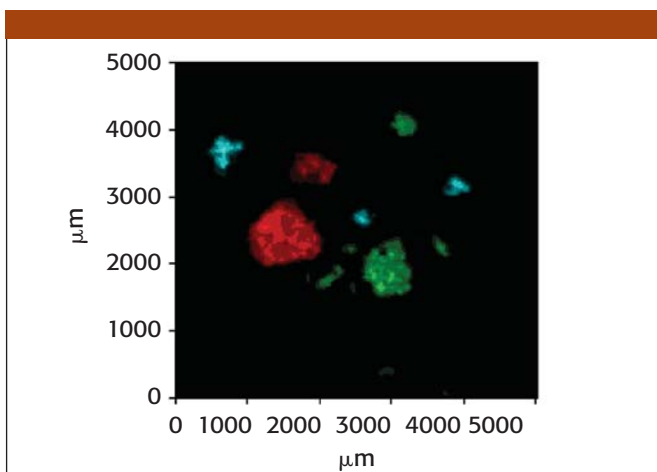


Drug development cycles include numerous steps and typically each step requires different instrumentation. The multifunctional nature of the RamanStation allows one instrument to be used for many of these steps.



Content Uniformity Studies Using High Throughput Chemical Imaging

Chemical imaging involves rapidly mapping a region and creating an image where it is possible to see the distribution of a particular chemical. Multiple images can be overlaid giving color images where the brightness of each color is related to the concentration of a particular component.

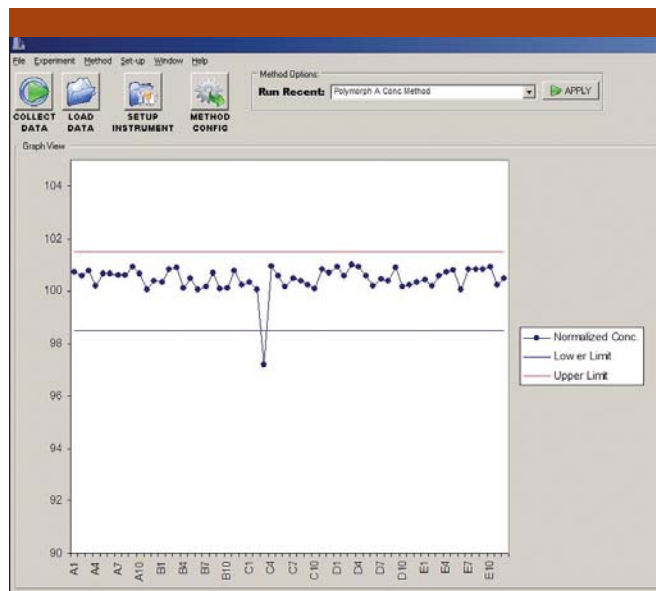


Color Chemical Image generated using Avalon's Insight software

Product Stability Study Using High Throughput Giant Spot Raman analysis

Giant spot analysis also known as super macro analysis allows for Raman spectral collection over the entire surface of a sample, this level of analysis is required precision quantitative analysis and analysis of low concentration components.

The RamanStation analysis spot size is variable which allows total coverage of samples of almost any size.



Conclusion

Spectroscopic study, development, and quality assurance of polymorphic materials requires a range of analytical approaches, high throughput screening, Raman microscopy, chemical imaging, and giant spot analysis. Now, for the first time all these modes of analysis are available in one instrument.

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