

Study the stability of pharmaceutical formulations with Raman spectroscopy

Chemical sciences

Many pharmaceutical materials are highly sensitive to changes in temperature and humidity which can affect their crystalline structure. Knowing the stability of these polymorphs and hydrates, in different conditions, is critical to ensure products are safe, efficient and can be patent protected.

The inVia confocal Raman microscope is the ideal system for testing pharmaceutical products. When used with a controlled sample environment chamber, the effect of changes in temperature and humidity can be monitored. The inVia provides a comprehensive and integrated solution for determining stability, whether you are focusing on drug discovery and development, formulation storage trials, or manufacture.

Investigate polymorph stability with temperature

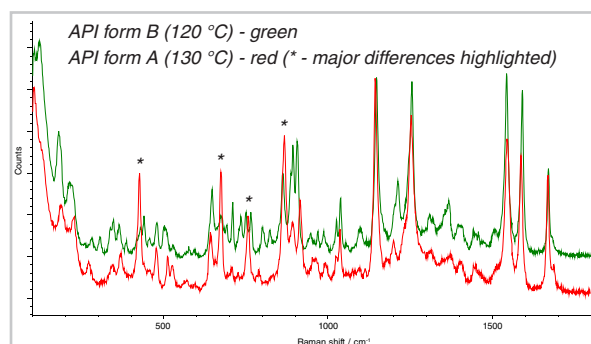
- Reveal and identify different polymorphic forms
- Non-destructive analysis ensures valuable samples are recoverable
- Adaptable control of sample temperature and data collection parameters as chemical changes are viewed live
- Integrated experimental temperature changes and data collection

Reveal hydration state changes

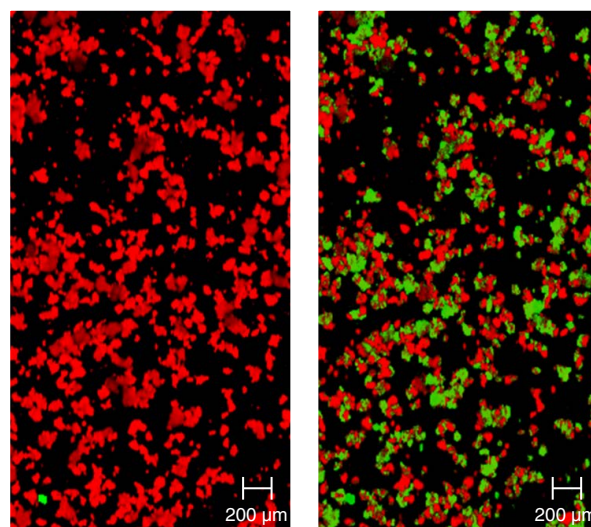
- Distinguish different anhydrous and hydrated states
- Establish the conditions at which specific changes occur
- Adaptable control of humidity

Monitor stability throughout the product development cycle

- Analysis of minute amounts through to entire tablets and formulations
- Ensure manufacturing and formulation processes maintain the desired forms
- Test stability of formulations to accelerated ageing
- Investigate different storage conditions
- Reveal regions where different species are co-localised
- Quantify particle size and distribution to micrometre resolution



Raman spectra revealing temperature induced polymorphic changes



Raman images showing the transformation of anhydrous lactose (red) to lactose monohydrate (green) during controlled hydration experiment

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Renishaw inVia: ideal for studying pharmaceutical materials

- Research grade confocal Raman microscope
- StreamLine™ imaging technology for high speed mapping without damage
- Integrated support for a large range of Linkam temperature cells (e.g. THMS600, and LTS350)
- Advanced temperature control (ATC) WiRE module for dedicated, integrated control of environmental cells
- Class 1 laser compatible
- Configure for Transmission Raman capability
- Designed for use within a 21 CFR pt11 environment
- Option to upgrade to particle statistics WiRE module



The Renishaw inVia confocal Raman microscope

Relevant reading:

- i. AN100 Raman spectroscopy of pharmaceuticals in a humidity and temperature controlled environment
Hedoux *et al*, 2012, International Journal of Pharmaceutics 417 (2011) 17– 31

A range of related Renishaw literature is available. Please ask your local Renishaw representative for more information.



Linkam THMS600 temperature cell

Renishaw. The Raman innovators

Renishaw manufactures a wide range of high performance optical spectroscopy products, including confocal Raman microscopes with high speed chemical imaging technology, compact process monitoring Raman spectrometers, structural and chemical analysers for scanning electron microscopes, solid state lasers for spectroscopy and state-of-the-art cooled CCD detectors, for both end-user and OEM applications.

Offering the highest levels of flexibility, sensitivity and reliability, across a diverse range of fields and applications, the instruments can be tailored to your needs, so you can tackle even the most challenging analytical problems with confidence.

A worldwide network of subsidiary companies and distributors provides exceptional service and support for its customers.

Please visit www.renishaw.com/pharma for more information.