INNOVATIVE SPECTROSCOPY SOLUTIONS FOR LABORATORY COMPLIANCE

PERFORMANCE, RELIABILITY AND COMPLIANCE

Agilent Cary 630 FTIR



The Agilent Cary 630 FT-IR spectrometer is perfectly suited for quality control, quality assurance, and method development applications in the pharmaceutical industry. The instrument's MicroLab software is 21 CFR Part 11 compliant, method guided and user friendly. With excellent wavelength accuracy, ruggedness, compact size, intuitive workflow, and pre-aligned sampling interfaces, the Cary 630 is an easy to use but powerful tool either in the lab or within manufacturing operations.

The Cary 630 FT-IR can answer questions that arise on a daily basis in the pharmaceutical workflow, such as:

What compound is it?

Simple spectrum-matching methods such as a library search can be used for positive identification of APIs, excipients and confirming final products.

Does the compound meet the specification criteria to either enter production for new product synthesis or to ship the finished product to the customer?

More rigorous classification method based on a multivariate chemometric algorithm such as PLS-DA can be used for qualification of similar types of compounds that are used in drug products.

What quantities of API or excipients are present?

Quantitative methods based on models developed using either simple Beer's law or multivariate PLS can be used for quantifying chemical components in the mixture.

Application Solutions

- Identify and qualify incoming raw ingredients (actives, excipients), in-process materials, and final products
- Ensure purity and authenticity for compounds at specific check points to prevent out of specification, contaminated, or incorrectly labeled ingredients from entering production or reaching consumers
- Screen packaging materials at all stages of the packaging process to confirm the quality
- Quickly and easily identify the base polymer in pharmaceutical packaging as required in the USP 661.1
- Determine if drug samples are counterfeit or adulterated by comparing spectra with reference standards
- Quantify a specific component in the chemical mixture (in solid and liquid states)



Cary 630 spectrometer advantages

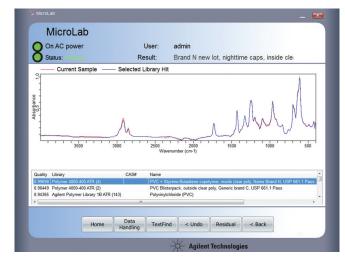
- Fully compliant with wavelength accuracy, spectral resolution, and other specification requirements as published by US, European, Japanese, Chinese, Indian, and International Pharmacopoeia
- GMP/GLP compliance features
- Any sampling accessory (ATR, diffuse reflectance, and transmission) specified in the USP and other pharmacopoeia is available to add additional functionality to the instrument
- Unique liquid sampling accessories (DialPath and TumblIR) for increased productivity and cost savings

- Sampling accessories mount in seconds with no alignment required due to automatic recognition of the inserted sampling accessory
- Requires minimal maintenance and occupies a small space (20 cm × 20 cm) on lab benches or inspection area and easily fits in a glove box or under a fume hood

MicroLab software benefits

- 21 CFR Part 11 Compliant meets the regulatory requirements and provides the data security and logging capabilities required by the pharmaceutical industry
- Has an automated installation qualification/ operational qualification (Auto IQ/OQ) capability to routinely verify instrument performance

- Method driven, highly visual, and intuitive, which allows even less experienced users to run the analysis workflow and interpret the color coded results
- Software available in regional languages



Quality inspection of packaging materials. The red spectrum of an unknown blister polymer is a match for the correct library material, PVC + SBR copolymer (blue spectrum), stored in a library of USP 661.1 approved polymers.



Cary 630 with Family of Accessories

For more information: Contact your local Agilent representative or visit: www.agilent.com

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Not for use in diagnostic procedures.
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