Media backgrounder

# Vaya, Raman Spectroscopy

The Agilent Vaya Raman instrument is the latest addition to Agilent's Raman Spectroscopy portfolio for rapid identification of raw materials, expanding existing capabilities, and speeding up the QA/QC workflow while supporting the most recent regulatory requirements of the pharmaceutical industry.

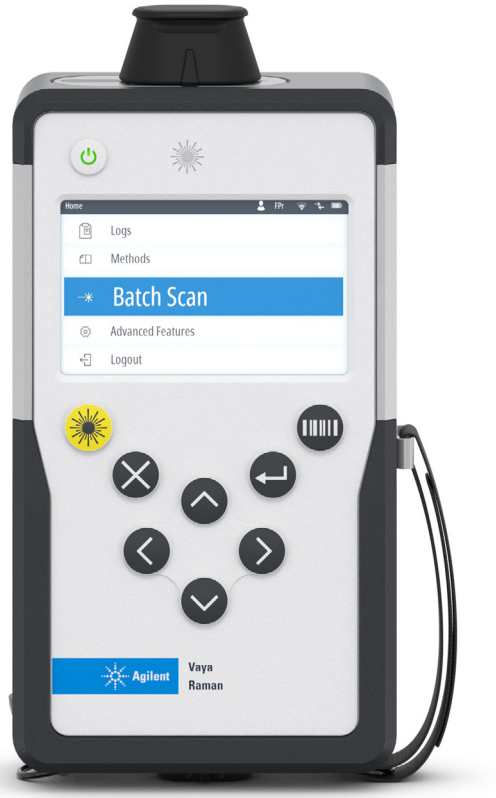
## Overview

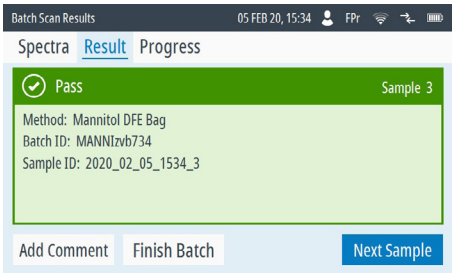
Raw material, used in the manufacturing of drug products, is purchased from a variety of suppliers, including from large chemical manufacturers with their own suppliers, to excipient brokers, to small specialized small molecule manufacturers worldwide. This variety can impact the quality of the raw materials. On a global scale, supplier qualification/vetting programs are difficult to implement through the entire supply chain and leave room for low purity, adulterated, counterfeited, or even harmful products entering the drug manufacturing supply chain

To ensure the quality of drug products, regulatory agencies around the world mandate that raw materials be verified for identity at receipt before being mixed with current stock used by production for manufacturing.

Using PIC/S (Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC scheme)) guidance, Quality control labs are only required to perform an identification test, provided a supplier evaluation program is in place. If not, full analysis is conducted.

Molecular spectroscopy-based solutions like Mid-IR, NIR or Raman are typically effective for verifying incoming raw materials because they are techniques which probe the vibrational mode of a material providing a structure specific spectrum, equivalent to a human fingerprint.

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## Key Uses of Vaya

- **A handheld SORS Spectrophotometer** for RMID verification of solid and liquid materials in pharmaceutical manufacturing.
- Agilent SORS technology enables **scanning through transparent and non-transparent containers** such as, polyethylene (PE) buckets, plastic liner bags, brown paper sacks, colored glass, FIBC big bags etc.
- Test incoming goods quickly in the warehouse on receipt, **reducing operator time, sample handling, and sample booth usage**.
- The Vaya system and software support **Good Manufacturing Practices (GMP)**[1]

## Key Features of Vaya

- Incorporated SORS technology for analysis through sealed opaque packaging including plastic tubs, paper sacks and FIBCs (big bags).
- 830 nm laser for fluorescence mitigation of containers and raw materials – enables compatibility with the broadest range of material and container combinations.
- Lightweight handheld instrument
- Barcode scanner for fast, error-free data entry.
- Data management/ System integration through Network (LIMS, backup, reporting).
- WiFi for wireless data sync.

Spatially offset Raman spectroscopy or SORS, a subset of Raman spectroscopy, is rapidly gaining popularity in this field. SORS presents significant advantages over other solutions available on the market. It can quickly verify materials through transparent and non-transparent containers alike enabling QC to check incoming raw materials directly in the quarantine area of the warehouse. This means no sampling (or sampling booth), no container opening, no exposure to hazardous materials, no consumables (vials, sampling room garbs), no cross contamination, no waiting for the QC lab, and limited logistical movements around the warehouse. It means that raw materials, once scanned and verified, can be made available within a few hours of being received.

The Agilent Vaya Raman system is the next generation of Raman spectroscopy solutions for raw material identification testing. Vaya is a handheld SORS based spectrometer used for Raw Material identity (RMID) verification in pharmaceutical warehouses. It can verify incoming solid and liquid raw materials through transparent and non-transparent containers.

Using a dedicated and intuitive RMID workflow, Vaya is designed to avoid time-consuming sampling steps without compromising on results. Delivering simple, user-friendly PASS/FAIL answers, Vaya requires minimal training, and, can be used by non-spectroscopists to verify raw materials in seconds.

Featuring system check for performance verification (PV), ID verification method development and validation workflow, Vaya meets all mandatory requirements for the pharmaceutical industry.

## Agilent Vaya

**Vaya Key Features Insights**


[1]GMP are standard guidelines for pharmaceutical manufacturing (and other manufacturing areas) recommended by regulatory agencies around the globe. These guidelines provide minimum requirements that a pharmaceutical manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use.

## Key Benefits for Laboratory Operators and Managers

**Data systems and software to resolve data integrity and quality control (QC) issues**

Developed for applications within the pharmaceutical industry, Agilent's Vaya system and software are set up to help users meet the stringent Good Manufacturing Practices (GMP) requirements. In particular, the Vaya features functionalities like user access control and data integrity logics for compliance with the FDA Title 21 Code of Federal Regulations Part 11 requirements (21 CFR Part 11).

The Vaya meets Raman Spectrometer specifications imposed by the United States Pharmacopeia (USP) (listed in general chapter USP<1120>) and European Pharmacopeia (EP) (listed in chapter EP 2.2.48) necessary for use in the pharmaceutical industry. Periodic performance verification of the Vaya using the system check test piece will enable the user to demonstrate compliance on an as needed basis. Method development and validation modules on the Vaya support scientists in developing identification methodologies meeting specificity and robustness requirements of USP chapter USP<1225>.

**Optimized through-barrier workflow**

SORS technology and Vaya optimize current raw material verification processes by eliminating sampling booth steps, therefore increasing testing efficiencies – from days to hours compared to conventional identification solutions. Vaya is the first and only handheld Raman system that works with a wide variety of opaque packaging, including colored plastics and paper sacks.

**Quicker measurements through transparent containers**

Whilst in operation, Vaya is designed to process raw materials at a faster rate than conventional handheld Raman instruments. An added benefit is its ability to obtain sample measurements inside more typically challenging containers, such as amber glass.

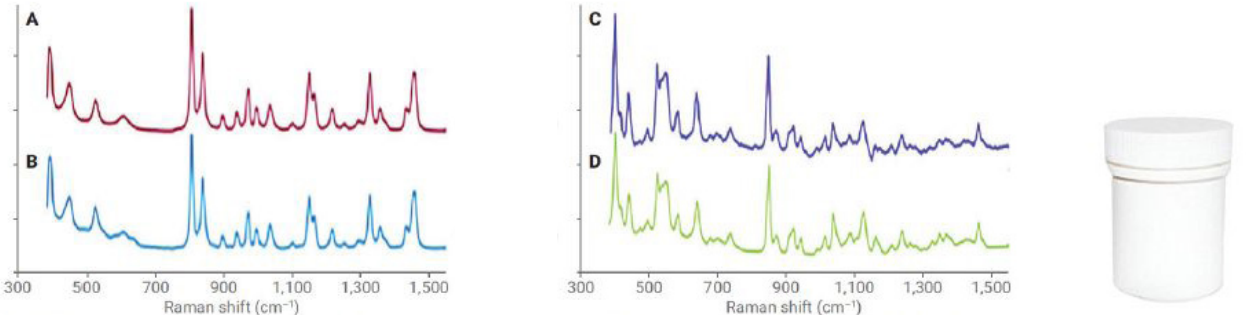
## What is Raman Spectroscopy?

Raman Spectroscopy is a non-destructive chemical analysis technique that provides rich information about molecular structure. Illuminating a sample with an incident laser generates scattered light. Raman scattering affects a very small number of the incident photons, which change wavelength due to the make-up of the sample's chemical structure.

Detecting these changes and plotting the result generates a spectrum of peaks akin to a chemical fingerprint. This can be used to identify a specific chemical or mixture of chemicals, using spectral libraries of many thousands of known chemicals to match against.

Raman spectra can also provide quantitative information, which can be used for applications such as checking the amount of active ingredient in tablets and capsules in pharmaceutical manufacturing. This is a key test required for quality control before batches of pharmaceuticals are released for sale.

Spatially offset Raman spectroscopy (SORS) is a derivative of Raman spectroscopy that enables high-quality Raman spectra of the contents of opaque packaging to be measured in seconds for an effective noninvasive material identification. Figure 1 shows the SORS measurement of sucrose through a 1.5 mm thick polypropylene (PP) tub. Non-transparency and fluorescence from packaging defeats conventional Raman instruments.




Polypropylene container

**Figure 1.** A) Conventional Raman spectrum through a white PP container without sucrose inside; B) with sucrose; C) SORS spectrum through the same white PP container, t = 8 s; D) reference sucrose spectrum.

## What is SORS technology?

SORS produces a high-quality spectrum through several millimeters of opaque plastic, multiple layers of paper, or many millimeters of colored glass, allowing positive identification where it would otherwise be impossible (see Figure 1A and B). The SORS spectrum in Figure 1C is a clear match for the sugar reference spectrum shown in Figure 1D.


### How SORS Works?

In a SORS measurement two spectra are automatically collected at differing laser excitation positions on the container (Figure 2).

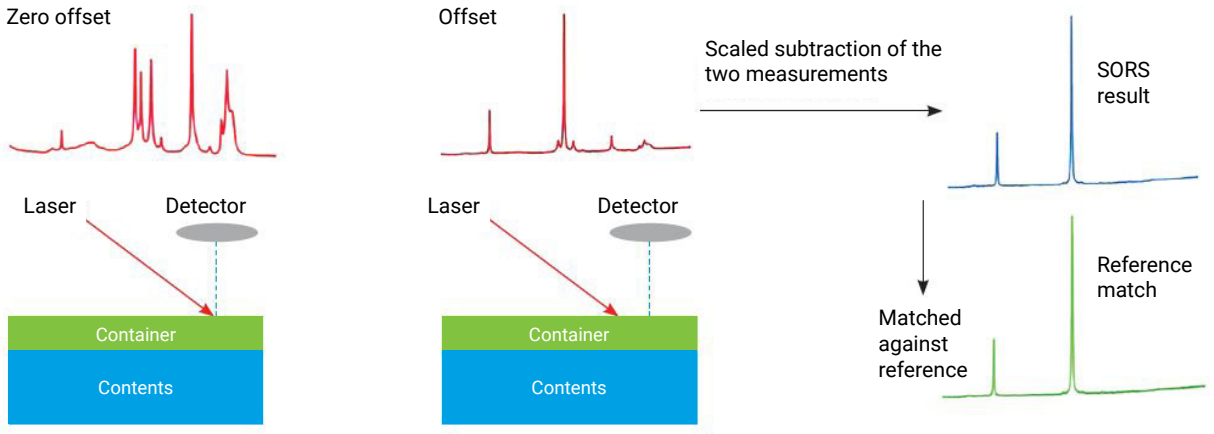



**Figure 2.** SORS measurements through a container. Zero offset geometry (left), with spatial offset (right). Scaled subtraction retrieves the contents spectrum only, which is matched with a reference for identification.

A surface or "Zero offset" container rich Raman spectrum is collected at the same place the material/container is illuminated, then a sub-surface or "Offset" content rich spectrum is collected after redirecting the laser some millimeters away. A scaled subtraction of the "Zero" spectrum from the "Offset" spectrum allows the container signal to be removed, leaving only the contents spectrum for analysis. The SORS spectrum, which is free from background or container spectrum, is then matched against a reference for identification verification.

For more details on SORS, visit our SORS technology webpage.

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