Agilent RapID Raman – Through-Barrier Raw Material Identity Verification

- 100% identity testing for all incoming containers
- Faster identity testing workflow
- Reduced operator time and sample-handling booth usage
- No contamination – better for quality and operator exposure
- Compatible with most containers, active pharmaceutical ingredients (APIs), and excipients

Lower costs and streamline your QC workflow

Raman is the most practical technique for raw material identity verification but it often requires a sampling step, which limits its ease and speed of use. Unique to Agilent, our proprietary spatially offset Raman spectroscopy (SORS) technology enables identification of most common materials through unopened opaque packaging, unlike conventional handheld Raman devices. The Agilent RapID Raman system is the fastest way to verify pharmaceutical raw materials and the most cost-effective means for high throughput or 100% testing.

ID verification with SORS – Raman without barriers

Conventional Raman works well for raw materials verification, but it needs line-of-sight of the contents. That means you must be able to see clearly through the container. With most packaging, conventional handheld Raman instruments don’t work. In contrast, SORS scans through containers such as paper sacks without opening and sampling in a booth.

The RapID system eliminates the logistical and handling steps of moving, opening and sampling each container and avoids quarantining, sampling booths, and clean-up. RapID fits into the quality control (QC) workflow of a busy warehouse and meets regulatory requirements. Compatible with most common excipients and containers, the RapID system’s 830 nm SORS technology avoids fluorescence from most containers and contents, making it ideal for use in oral solid dose, biopharmaceutical, and parenteral preparations manufacturing, and for testing through a wide variety of packaging.

Agilent RapID nose adapters

- 82 mm* cylindrical bottle
- 44 mm* cylindrical bottle
- Flat for general-purpose use
- Bar code scanner (1D and 2D) for material, batch, and container identification

*Other adaptors and sizes are available or custom-made

Magnetic adapters enable fast measurement of many container types.
Identify Raw Materials on Receipt

Most containers arriving in a pharmaceutical plant are nontransparent, for example, sacks, tubs, bottles, and barrels. These packaging materials are incompatible with conventional Raman and a sampling step is often required. The time and resource impact of the sampling step often reduces the benefit of the fast Raman identity measurement.

The RapID system avoids sampling, meaning that goods can be tested quickly in the warehouse on receipt, without quarantining, risk of exposure, or contamination.

Identify through the packaging
- Avoid sampling booths and quarantine delays
- Reduce QC lab turnaround times and expensive outsourced testing
- Maintain sterility, prevent cross-contamination
- Preserve shelf life of unopened products
- Avoid user exposure to high potency APIs
Comparison of Agilent's RapID Raman to a Conventional Raman ID Verification Workflow for 200 sacks

**Agilent RapID Raman**
- No opening or re-sealing containers
- One logistical movement to the warehouse
- Sample-to-warehouse averaging 1.2 minutes per sack - 200 sacks completed in <1 shift

**Sampling and Conventional Raman ID verification**
- Requires opening and re-sealing containers
- Multiple logistical movements to the warehouse
- Sample-to-warehouse averaging 5.25 minutes per sack - 200 sacks completed over 2-3 shifts

<table>
<thead>
<tr>
<th>4 hours for 200 sacks</th>
<th>17.5 hours for 200 sacks</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID verification of 200 sacks of lactose in 3 layers of paper</td>
<td></td>
</tr>
</tbody>
</table>

**Flowchart**

- QC test lab or outsourced testing
  - Receive samples
  - Test
  - Pass / Fail
  - Report

- Sampling booth
  - Open
  - Sample
  - Reseal
  - Clean / Sterilise

- Quarantine area
  - Waiting for sampling booth
  - Waiting for test results

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Sample and Container Compatibility

<table>
<thead>
<tr>
<th>Material/Container Combinations</th>
<th>Measurement Times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol three-layer paper sack</td>
<td>20–30 seconds</td>
</tr>
<tr>
<td>2.5 L amber glass bottle with acetic acid</td>
<td>5 seconds</td>
</tr>
<tr>
<td>Lactose in 1 ton supersack</td>
<td>10 seconds</td>
</tr>
<tr>
<td>Acetaminophen in plastic bottle</td>
<td>5 seconds</td>
</tr>
</tbody>
</table>

### Oral solid dose
- Sugars such as mannitol, lactose, dextrose, and glucose
- Microcrystalline cellulose (MCC), hydroxypropyl methylcellulose (HPMC), and croscarmellose sodium
- Magnesium stearate
- Active pharmaceutical ingredients (APIs)

### Parenteral preparations
- Sterile liquids such as phenol
- Salts such as MgCl₂·6H₂O, CaCl₂·2H₂O
- Amino acids

### Biopharmaceuticals
- Growth media
- Polysorbates 20–80
- Buffers such as tris(hydroxymethyl) aminomethane

### Extending the possibilities of Raman identification
The RapID system does everything conventional handheld Raman systems do but adds the capability to identify materials through colored glass, opaque plastics, flexible intermediate bulk containers (FIBCs), and multilayer paper sacks. RapID even works through some blue barrels.

### Agilent RapID Raman
The RapID system works with most containers, including multilayer paper sacks.

### Handheld Raman identification
Conventional Raman systems work with clear plastics and in some cases, can work with amber bottles. Most other containers need to be opened for direct access to the material.

*Successful ID verification depends on container/contents combination.*
The Agilent RapID Raman – Portable Through-Container Identification of Raw Materials

RapID software
The RapID system’s intuitive software is 21 CFR Part 11 compliant. The system can become part of your wired or wireless network with Windows-managed user logon credentials, shared folders and printers, data synchronization and automated backups, output for LIMS systems, and managing data security.

In routine use, the workflow is optimized for streamlined batch testing, optionally using bar codes for material identification, recording batch information and ensuring that all containers are measured with no accidental repeats. Adding new materials takes minutes, ensuring reliable performance for exceptional ID verification of a wide range of raw materials through most types of containers.

<table>
<thead>
<tr>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>Width 394 mm (15.5 inches)</td>
</tr>
<tr>
<td></td>
<td>Height 693 mm (27.3 inches)</td>
</tr>
<tr>
<td></td>
<td>Depth 630 mm (24.8 inches)</td>
</tr>
<tr>
<td>Laser</td>
<td>Class 3B</td>
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<tr>
<td></td>
<td>830 nm</td>
</tr>
<tr>
<td>Power</td>
<td>90–132/180–264 VAC, 47–63 Hz</td>
</tr>
<tr>
<td>Software</td>
<td>Includes RapID software</td>
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<tr>
<td></td>
<td>Windows 7 Pro operating system</td>
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<tr>
<td></td>
<td>21 CFR Part 11 compliant</td>
</tr>
<tr>
<td>Hardware</td>
<td>Touch-screen operated</td>
</tr>
<tr>
<td></td>
<td>Integral bar code scanner (1D and 2D)</td>
</tr>
<tr>
<td>Connectivity</td>
<td>Domain/network through RJ-45 or WiFi USB 2.0</td>
</tr>
</tbody>
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