GLOBAL COMPLIANCE: REDUCE RISK

All aspects of pharmaceutical manufacturing must comply with rigorous standards to ensure the consistent production of safe and effective drugs. As the pharmaceutical material supply chain continues to globalize, leading nations have imposed regulations that increase the amount of raw materials that require inspection.

Raman is an accepted spectroscopic technique by both the United States Pharmacopeia Convention (USP) and the European Pharmacopeia (EP). The widespread adoption of Raman technology combined with a spectrometer that is small in size, easy to use and produces high spectral quality,substantiates it as a sustainable materials validation method with trusted results.

SAFETY AND EFFICACY

Handheld Raman spectroscopy is a technique used widely as part of the pharmaceutical manufacturing process to ensure the safety and efficacy of medicine:

Raw Material Identification:

- Active pharmaceutical ingredients (API)
- Excipients
- Nutraceuticals
- Pre-formulated materials and packaging

Verification:

- Pre- and post-clinical trial materials
- Chemicals and solvents
- Cell culture media

Authentication:

- Finished products
- Anti-counterfeit/brand security

Progeny™

FEATURES AND ACCESSORIES

The evolution of handheld Raman analyzers continues. Beyond its revolutionary, ergonomic design and point-and-shoot functionality, Progeny adapts to pharmaceutical manufacturer's unqiue workflow processes and protocol by providing the following features and accessories:

Local control: benefit from flexible operation by manually using the touch screen and large buttons

Libraries: factory and customizable library spectra for easy method development, deployment and centralized management

Docking station: recharge for uninterrupted operation, auto-synchronize data with LIMS, or conveniently use with sampling accessories for benchtop use

Adjustable focus nose cone: optimize sensitivity and signal per application by adjusting the focal distance

Sampling accessories: obtain accurate results from a variety of packaging materials and sample shapes


Docking station


Bottle adapter


Adjustable focus vial adapter


Tablet adapter

COMPLIANCE AND SUPPORT

Progeny is backed by a global network of sales and service support partners of Rigaku, offering installation qualification, annual preventive maintenance and prompt service assistance, when necessary.
Visit www.rigakuanalytical.com to find your nearest distributor.

- 21 CFR Part 11 compliance, including electronic signature
- IQ/OQ/PQ support and protocols
- Preventive maintenance
- Extended warranty programs

Rigaku Analytical Devices is leading with innovation to pioneer a portfolio of handheld and portable spectroscopic analyzers for use in the protection of public health and safety, aid in the advancement of scientific and academic study, enable the recycle and reuse of metal alloys, and ensure quality of key metal alloy components in mission critical industries. Our core goal is to be recognized globally for quality, reliability and expertise in all aspects of our business through our commitment to exceed our customer's expectations by providing technologically advanced products.

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Progeny™

THE NEW GENERATION IN HANDHELD RAMAN

REVOLUTIONIZE YOUR MATERIAL IDENTIFICATION

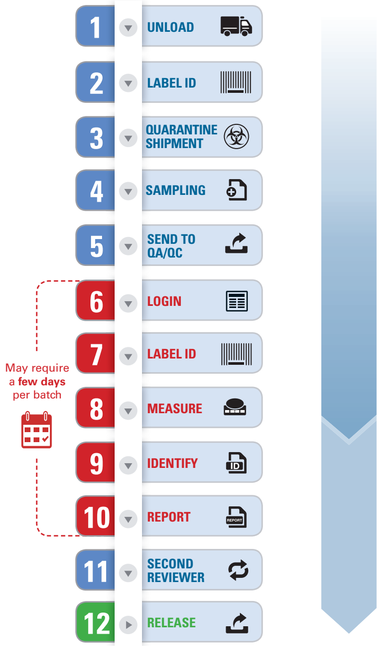
Rigaku Analytical Devices

PHARMACEUTICAL MATERIAL INSPECTION

With the push towards 100% inspection and lean manufacturing, pharmaceutical manufacturers are looking for efficient ways to reduce costs and risks associated with raw material identification (RMID), in-process analysis, finished product inspection and brand security, while complying with regulatory requirements. Traditional processes can include quality control (QC) lab analysis, a costly and time-consuming step especially when productivity must be optimized with fewer resources – and all without compromising quality. By implementing an identification method at the point of need with a tool that can be used by any employee, companies benefit from a process that is much more efficient and cost-effective. How can this be achieved?

Introducing **Progeny**™ – the first handheld Raman analyzer designed to be customizable for seamless integration into any work environment. Progeny delivers what truly matters in a customer's mind: error-free operation, repeatability, ease of use and the widest range of sampling capabilities – all in a handheld form. Progeny's open architecture software and data security features adapt to existing standard operating procedures (SOPs) or provide the flexibility in the creation of entirely new SOPs.

TRADITIONAL RMID WORKFLOW:



THE PROGENY RMID EXPERIENCE:

COLOR KEY
- WAREHOUSE PROCESS
- OFF-LINE LAB PROCESS

Progeny™

Smartphone inspired, touchscreen user interface using CompleteID™ software:
Fast learning curve for easy implementation into customized workflow

Sealed system (IP-68):
Rugged warehouse use while minimizing cross-contamination

Optional docking station:
Transfer data while instrument is safely docked for continuous charge*

*Via USB or WiFi

Adjustable focus nose cone:
Measure through thick polymer or dark glass

1064nm excitation laser:
Identify the most comprehensive range of materials in a handheld form

Integrated digital camera and 21 CFR Part 11 compliant electronic signature:
Error-free data entry tracking & compliance

Angled display with large-sized buttons:
Single hand operation for optimal usability

High-speed multi-function processor and on-board memory:
Flexible operation with on-board modern algorithms for accurate identification

MORE VALUABLE RAW MATERIALS CAN BE INSPECTED

Fluorescence interference prevents successful chemical identification and analysis of some materials. When using 785nm or 532nm visible range excitation lasers, colored materials or colored containers can be a challenge with Raman. Users can now minimize fluorescence and broaden their analysis range because Progeny uses a **1064nm** high power laser in the near infrared range with high efficiency optics.

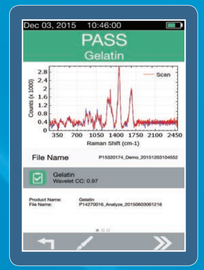
RAMAN-ACTIVE MATERIALS

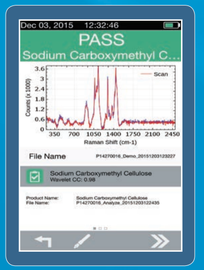
Problematic Materials Easily Detectable with Progeny (partial list)
- Sodium carboxymethyl cellulose
- Xanthan gum
- Alginic acid sodium salt
- Gelatin
- Indigo carmine
- Cell culture media
- Polysorbate 20
- Polysorbate 80
- Microcrystalline cellulose
- Lanolin
- Carnauba wax

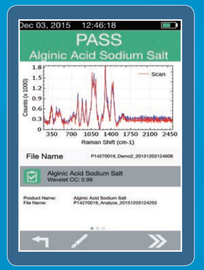
No Fluorescence Issues Fluorescence Issues

Many common materials can be measured and detected by handheld Raman instruments. Metals, salts, and some packaging materials still represent a challenge to any type of Raman technology. Talk to your representative about your list of materials.

EXCIPIENTS IDENTIFICATION IN PHARMACEUTICALS WITH PROGENY







Common excipients used in many pharmaceutical products do not fluoresce with 1064nm excitation laser, therefore are quickly and reliably identified with Progeny.