



Advanced Solutions for Pharmaceutical Raw Material & Packaging Identification

Ensure quality and safety with versatile,
portable, high-quality analyzers

Introduction

Raw material inspection is a critical step in any quality control process. It has a tremendous impact on customer safety, and a huge effect on the speed and cost of production. Global pharmaceutical manufacturers are seeking technology that will allow them to approach a 100% raw materials inspection goal without prohibitive financial or staffing investments.

In this ever-expanding and competitive market, material identification is critical to sustaining product quality while positively affecting throughput and production costs and, ultimately, helping to ensure consumer wellbeing. Whether the need is to verify the identity of raw materials at the point of receipt, ensure the purity of excipients during secondary manufacturing, or inspect finished products, having an efficient way to check the quality of materials throughout the manufacturing process is essential. The instruments and support information presented here are tailored to address these needs and provide solutions to the ongoing challenges inherent in pharmaceutical production.



Portable analytical instruments from Thermo Fisher Scientific

Thermo Scientific™ TruScan™ G3 & TruScan™ RM Analyzers

TruScan analyzers are designed to meet the specific needs of the pharmaceutical industry. They enable efficient identity testing of chemicals directly at the point of need, significantly reducing the time and costs associated with raw material inspection. The TruScan G3 analyzer represents the next generation of Raman-based spectrometers, featuring significant advancements in speed and ease of use, all within a more compact form factor.

Experience the future of chemical analysis with TruScan G3 & TruScan RM, designed to elevate efficiency and accuracy in the pharmaceutical industry.

Thermo Scientific™ TruScan™ G3 Analyzer

The TruScan G3 Handheld Raman Analyzer revolutionizes the identification of raw materials (ID) for pharmaceutical and biotechnology manufacturing quality control. Speed, ease, and efficiency are crucial to maintaining continuous manufacturing processes. Traditionally, samples are sent to a quality control lab for testing, which increases costs and reduces productivity. With the TruScan G3, non-technical operators can quickly perform raw material ID testing on-site, eliminating the need for a lab. This device delivers lab-quality performance and results in any setting, whether in a warehouse or at a loading dock.



Thermo Scientific™ TruScan™ RM Analyzer

The Thermo Scientific™ TruTools™ is embedded chemometric software that runs on the TruScan RM analyzer and allows users to build customized qualitative and quantitative methods for complex material analysis problems.

TruScan RM and TruTools methods can:

- Support quantification of up to 10 chemicals
- Discriminate between materials with similar chemical compounds such as magnesium stearate, zinc stearate, and calcium stearate
- Run qualitative and quantitative methods at line
- Expand TruScan RM's raw materials verification capabilities – allows for finer discrimination of materials



Thermo Scientific™ IonicX™ Portable XRF Analyzer

The IonicX portable XRF analyzer provides accurate ionic salt identification and high sample throughput to pharmaceutical and biopharmaceutical manufacturers. An innovative alternative to conventional benchtop analytical methods, the IonicX delivers instant analysis of ionic salts with minimal sample preparation at the point of need while complying with 21 CFR Part 11.



TruScan G3 Accessories

Extension probe:

Allows users to analyze samples in hard-to-access or confined spaces by extending the reach of the analyzer.



Vial holder:

Securely holds vials in place for accurate and stable analysis of liquids or powdered samples.



Nose cone:

Helps to precisely position the device against a sample, ensuring consistent contact and optimal analysis conditions.



Hot swap battery:

Allows users to replace the battery without turning off the device, enabling continuous operation and minimizing downtime during use.



Hand strap:

Provides users with a secure and comfortable grip, reducing the risk of dropping the device and improving ease of use.



Tablet holder

Designed to enhance the functionality of the analyzer, this device securely holds tablets of various sizes in place during the analysis process, ensuring accurate measurements.



Material identification solutions for Good Manufacturing Practice (GMP) environments

Use this helpful table to make a comparison of the optimal use cases and the different features of our portable analyzers to decide which model best meets your pharmaceutical analysis needs.

	TruScan G3	TruScan RM	IonicX
			
Technology	Raman Spectroscopy	Raman Spectroscopy	X-Ray Fluorescence
Uses	Raw material identification	Raw material identification	Ionic salt raw material identification
Key Features	<ul style="list-style-type: none"> ✓ Intuitive touchscreen interface ✓ Versatile connectivity options (Ethernet, USB-C, and Wi-Fi) ✓ User-friendly WebUI Interface ✓ Investigation Mode ✓ Backwards compatibility with existing TSRM methods ✓ 21 CFR Part 11 compliant 	<ul style="list-style-type: none"> ✓ Connectivity via ethernet ✓ Optional chemometric package add-on ✓ 21 CFR Part 11 compliant 	<ul style="list-style-type: none"> ✓ Minimal sample preparation ✓ Lightweight and portable ✓ Connectivity via Wi-Fi and USB ✓ 21 CFR Part 11 compliant
Accessories	<ul style="list-style-type: none"> • Extension probe • Vial holder • Universal tablet holder • Nose cone • Hot swap batteries 	<ul style="list-style-type: none"> • Vial holder • Nose cone • Universal tablet holder 	<ul style="list-style-type: none"> • Locking shielded carrying case • Safety lanyard • Portable test stand • Mini test stand

Product line overview

Thermo Fisher Scientific's advanced Raman and XRF analyzers can be applied in several ways to pharmaceutical manufacturing. The following are just a few of the ways these versatile, portable instruments can improve quality control and contribute to consumer safety.

Pharmaceutical raw material identification

Raw material testing and identity verification are critical steps in the quality control process, and they have a tremendous impact on customer safety, production speed, and cost. With increasing regulatory pressures and the drive toward lean manufacturing, implementing efficient ways to identify incoming raw materials accurately is now more critical than ever.

With analyzers like TruScan G3 and TruScan RM, which are based on Raman spectroscopy, and IonicX, based on X-ray fluorescence, pharmaceutical manufacturers can conduct rapid raw material identification at the point of receipt within seconds. Easily operated by non-technical staff, the analyzers perform non-destructive analysis and can operate through plastic or glass containers to enable the immediate release of raw materials into production. Each supports 21 CFR part 11 compliance and is consistent with USP and EP regulations.

Packaging raw material identification

Despite frequently going unnoticed by consumers, pharmaceutical packaging is carefully designed to protect drug tablets, pills, capsules, and other dosage forms. In addition to protecting against physical damage, chemical alteration through natural degradation, and environmental contamination, packaging is essential in offering evidence of temperature control in the supply chain and product sterility. According to the Code of Federal Regulations for pharmaceutical product packaging, components used to temporarily or permanently store drug products, such as blisters, films, plastic containers, or vials, must be identified before use by Quality Control (see 21 CFR Part 211.84). This is similar to the way raw materials are confirmed in the composition of the drug product.

Our handheld Raman analyzers can adequately identify the most common polymers used to produce finished product packaging in the pharmaceutical industry.

Anti-counterfeit screening

Counterfeit pharmaceuticals represent a deadly and growing worldwide problem. Efforts to combat counterfeit pharmaceuticals have focused on making the product packaging challenging to copy. However, in many places, drugs are not sold in their original packaging, and counterfeiters have become very adept at imitating even the most sophisticated packaging. One of the most promising approaches to removing counterfeit drugs from the market is authenticating the dosage form of the medication itself to confirm its origin.

Our handheld Raman spectrometers can help identify and eliminate dangerous counterfeit or substandard products to secure the supply chain and ensure patient safety.

Service and support

We provide service solutions that fit and match different customer needs and ensure the highest standards of reliability and productivity to support your business. Our fully documented quality procedures offer enhanced support and peace of mind in even the most demanding and highly regulated environments. From setup and training to extending instrument longevity, partner with the service team that have you covered!

Examples of service and support*



Installation qualification/operational qualification/performance qualification (IQ/OQ/PQ)

Save time with support to perform instrument qualification of processes.

IQ/OQ services include:

- Comprehensive documentation
- Compliance with pharmaceutical manufacturing requirements
- Application engineer support
- Onsite execution & user training
- Performance certification (remote option also available)



Depot support

With our depot repair services, you can trust that your instrument is cared for by a qualified service team who shares your goal to minimize downtime.

Included in depot support:

- Technical support
- Expert diagnostics
- Quality repairs with certified parts
- Equipment returned to factory specifications



Virtual analytical consultation

Rely on our consultants available to support you throughout your product's lifespan.

We assist with the following:

- Understanding the root cause of result issues
- Providing support solutions
- Partnering with you to innovate and focus on the future of your business



Technical support and remote diagnostics

In the unlikely case your instrument does experience a problem, our technical support team will:

- Provide remote technical support for immediate diagnosis
- Troubleshoot for a resolution to get you back up and running quickly

*Availability may vary based on service plan coverage status.



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