

World-Class Certified Reference Materials (CRMs)

10 CRITICAL STEPS

Whether it's a stock, off-the-shelf reference standard or a one-of-a-kind, custom-formulated solution, there are 10 critical steps that Restek takes to separate our certified reference materials (CRMs) from the competition. For every CRM produced in Restek's ISO-accredited labs, we always:

1 Review Customer & Method Requirements

To determine which organic reference standards we should develop as stock products, Restek experts closely monitor government regulations and methods from around the globe and also actively engage with our customers and distributors. Once a product is chosen based on regulatory changes, customer needs, and our 20+ years of experience, a veteran Restek chemist formulates a stable standard containing an ideal mix of compounds and concentrations. All formulations are then subjected to a thorough review of accuracy, compatibility, and solubility by a second chemist.

2 Verify Compatibility & Stability

All raw materials used in our reference standards are held to strict purity criteria, and compound compatibility is scrutinized during both formulation and review. We also conduct on-going, long-term stability and short-term shipping stability studies in accordance with ISO Guide 34 and ISO Guide 35 to ensure reliability and accurate shelf-life reporting.

3 Characterize Raw Materials Thoroughly

Restek's Quality Control (QC) lab confirms the chemical identity and purity of mixture components and solvents using one or more of the following techniques: GC-FID, HPLC, GC-ECD, GC-MS, LC-MS, refractive index, and melting point.

4 Calibrate Analytical Balances

All analytical balances are verified at seven mass levels daily using NIST* traceable weights and are also calibrated yearly by an ISO/IEC 17025:2005-accredited provider to guarantee accurate measurement.

5 Deactivate Glassware & Ampuls

Restek® reference standards are prepared using Class A volumetric flasks and/or Class A pipettes. Ampuls and vials used in preparation and packaging are deactivated to prevent the loss of target analytes.

6 Maintain ISO Accreditation

In 2011, the reference standard manufacturing and QC testing laboratories in Restek's state-of-the-art Bellefonte, PA, facility earned ISO Guide 34 and ISO/IEC 17025 accreditation. These accreditations—in addition to ISO 9001 registration, which we have maintained since 1994—serve as recognition that Restek and our labs meet the world-class quality standards established by the International Organization for Standardization (ISO). On-site manufacturing as well as raw material, qualitative, and quantitative analyses are completed in these ISO-accredited labs. Restek's ISO-accredited labs offer a full line of both stock and custom CRMs.

* National Institute of Standards and Technology



What are Certified Reference Materials (CRMs)?

A CRM from Restek is in an exclusive subset of reference standards that meets the following set of strict criteria defined under ISO Guide 34 and ISO/IEC 17025:

- Made of raw materials characterized via qualified methods on qualified instruments.
- Produced in an ISO-accredited lab under documented procedures.
- Falls under the manufacturer's scopes of accreditation.

To learn more about Restek's ISO quality credentials and to view our certificates (including scopes of accreditation), visit www.restek.com/iso

For more information, go to www.restek.com/crm

7 Offer a Variety of Documentation

Restek exclusively offers three levels of fully ISO-compliant documentation for our CRMs, and most stock CRMs come with quantitative-level documentation.

Gravimetric: Product supplied with the gravimetric records listing purity of each material used, calculated concentration, and a unique lot number.

Qualitative (Certificate of Composition): A sample withdrawn from the packaged units is tested by the appropriate technique to verify mixture composition. Product supplied with a certificate of composition showing a chromatogram of the standard with each peak identified, raw material purity, and gravimetric concentration.

Quantitative (Certificate of Analysis): A sample of the packaged unit is analyzed in triplicate and the peak areas are statistically compared to a previous lot (if available) or a second lot. A detailed data pack is available at www.restek.com/documentation containing gravimetric documentation, all quantitative assay raw data, exact amount of each raw material used, total volume prepared, and statistics. Test results for raw material purity and identification are available upon request.

Documentation for all of your stock and custom Restek® CRMs is a few clicks away at www.restek.com/documentation

8 Package Securely & Label Clearly

Every Restek® CRM is placed in durable, high-quality packaging for dock-to-door protection. Labeling provides critical storage, safety, and shelf life information in an easy-to-read format—and now features bar-coded GHS labeling for added safety and easier compliance.

9 Protect Product Quality After Opening

To help preserve the integrity of our CRMs after they are opened, we include a deactivated screw-top vial (cat.# 24640) with each stock reference standard <5 mL for worry-free transfer and reliable temporary storage.

10 Manage Warehouse Inventory

To ensure the inventory is available when it's needed, Restek continually analyzes and maintains inventory of more than 1,500 catalog standards as well as multiple lots of the most commonly requested calibration standards. We pull inventory months before its expiration date to eliminate inadvertent delivery of expired or nearly expired reference standards.



Consolidate Orders With Restek

Along with both primary- and secondary-source reference standards, you can order all of your GC and LC columns, sample prep supplies, accessories, and more from Restek!

Visit www.restek.com/solutions to request a custom quote!

For more information, go to www.restek.com/crm

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