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:

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.

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.

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.

Calibrate Analytical Balances

All analytical balances are verified at 7 mass levels daily using NIST* traceable weights and are also calibrated yearly by an ISO/IEC 17025:2005 accredited provider to guarantee accurate measurement.

Deactivate Glassware & Ampules

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

🗧 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 offers a full line of both stock and custom CRMs.*

* National Institute of Standards and Technology

For more information, go to www.restek.com/reference-standards



What are Certified Reference Materials (CRMs)?

A CRM is a reference standard that meets the following set of strict criteria defined under ISO Guide 34 and ISO/IEC 17025:

- All raw materials in the standard must be characterized via qualified methods on qualified instruments.
- The reference standard must be produced in an ISO-accredited lab under documented procedures.
- The reference standard must fall under at least one of the chemical classes for which the lab has been approved under its scope 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**

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Offer a Variety of Documentation

Our fully compliant certified reference materials (CRMs) are available with three levels of documentation:

Gravimetric: Product supplied with the gravimetric records detailing exact amount of each raw material used, purity of each material used, total volume prepared, calculated concentration, and a unique lot number.

Qualitative: A single 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: 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 independently prepared lot. Unless otherwise specified, the acceptance criteria are as follows: The coefficient of variation (CV) will not exceed 5% for the peak areas of the triplicate injections of the sample. The percent difference of the average peak areas of the sample compared to the previous or second lot will not exceed 10% (13% for gases). A detailed datapack is available at www.restek.com containing gravimetric documentation, all quantitative assay raw data, and statistics. All raw material purity and identification results are available upon request.

We also make your documentation available at www.restek.com/datapacks

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.

Protect Product Quality After Opening

To help preserve the integrity of our CRMs after they are opened, we include a deactivated screw-top vial with each reference standard for worry-free transfer and reliable temporary storage.

Manage Warehouse Inventory

To ensure the inventory is available when it's needed, Restek continually analyzes and maintains inventory of more than 1,100 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.

For more information, go to www.restek.com/reference-standards

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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!



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