

12 CRITICAL STEPS

in reference materials production that separate Restek from the rest!

1. Review Method Requirements

We carefully review the method to determine compound requirements and stock concentrations needed to produce working solutions. We confirm the required purity of raw materials and documentation needed to meet method compliance are important aspects of this review.

2. Verify Compatibility and Stability

We review chemical compatibility with a goal of long-term stability. We specify raw material purity and mixture composition, and test experimental batches.

3. Thoroughly Characterize Raw Materials

We perform chromatographic analyses on each solvent and mixture component to confirm identity and determine purity. For selected compounds, purity is confirmed by using nonchromatographic techniques to detect water, residual catalysts or surfactants, or inorganic contaminants not detected by chromatographic techniques.

4. Calibrate Balances

Calibration of all analytical balances is verified at seven mass levels each day, using NIST-traceable weights. Balances are serviced and certified by an outside organization, using NIST weights.

5. Deactivate Glassware and Ampuls

Weight/volume mixtures are prepared in ASTM Class A volumetric flasks, using Class A pipettes. Glassware, ampuls, and vials used in product preparation and packaging are deactivated for selected products to prevent loss of target analytes through adsorption to glass surfaces.

6. Prepare Two Independent Lots

Two independent preparers, using two independently calibrated analytical balances, prepare two lots of a mixture. Details of preparation are annotated on the certificate.

7. Assay to Assure Quality

Ampuls from each new lot are analyzed and data are compared to previous lots. Consistent relative response factors for difficult mixtures demonstrate that our production processes are accurate, consistent, reliable, and well controlled.

8. Assign Real-Time Expiration Dates

Expiration dates are assigned to a lot of material based on real-time expiration studies. We retain sample ampuls from each lot of material, and compare data from the earlier lots against data from the newest lot. For new formulations, we make these comparisons every 6 months for 2 years. We continue this study until we determine the shelf life of the product.

9. Use Customer-Friendly Product Packaging

Restek ampuls are packaged so you can see the contents. We include an ampul breaker, a deactivated screw-top vial to store unused solution, an extra product label to attach to the vial or your lab notebook, and a hazard card summarizing special precautions.

10. Prepare Documentation

Our data packs contain every record, from raw material identity verification and purity data through final testing. Free data packs for our catalog mixtures are available on our website at www.restek.com/datapacks. A certificate and an MSDS are included for all mixtures.

11. Comply with ISO 9001:2000 Registration

You can have complete confidence in our documented procedures, and in the accurate, reproducible reference materials we produce.

12. Offer a Custom Reference Materials Program

Contact us with your special requirements, and join the thousands of chromatographers worldwide who use Restek custom mixtures. A form for ordering custom materials is on page 427 of this catalog—or at www.restek.com/solutions.

