Residual Solvents & Elemental Impurities Testing for Pharma & BioPharma Products

Nelson Labs
A Sotera Health company

Nelson Labs is a global provider of microbiological testing, analytical chemistry, and advisory services, supporting pharma and biopharma companies. We have over 35 years of experience solving challenges that are not typically addressed in routine testing. We have the capabilities and expertise to support the CMC testing needs and lifecycle management of your drug products. We are US FDA registered, cGMP compliant, and ISO17025 accredited and have laboratories located throughout North America and Europe.

The following are some of the services Nelson Labs offers to support your pharma & biopharma products:

- **Residuals Solvents USP <467>, USP <1467>, ICH Q3C**
  - Headspace GC
  - Screening, Quantification, and Limit Tests
  - Water-Soluble and Water-Insoluble Articles
  - Method Development for Solvents Outside of Class 1, 2, or 3
  - Method Verification and Validation
- **Elemental Impurities USP <232> , USP <233>**
  - Elemental Impurities in Drug Substance, Excipients, and Drug Products
  - Method Development and Validation
  - Catalysts and Environmental Contaminants
  - Sample Preparation
  - Acid Extraction
  - Microwave Digestion
- **Impurities and Degradation Products**
  - Identification
  - Structure Elucidation
  - Method Development & Validation
  - Routine Analysis in Support of Release and Stability Studies
- **Instrumentation**
  - Our laboratories are equipped with Q-TOF, LC/MS/MS, GC/MS/MS, GC/MS, ICP/MS, and other analytical tools to support the identification, quantitation, and characterization of impurities/degradation products in API and drug products.

Note: Nelson Labs offers method feasibility, verification, and suitability for all compendial procedures.

Contact us today!

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US FDA registered and third-party accredited to ISO 17025 standards

