

When system setup and productivity tools combine with high-performance ICP-MS, the results are extraordinary

Metals analysis in pharmaceutical products and ingredients is changing. Existing colorimetric tests are being replaced with new instrumental methods to measure potentially toxic Elemental Impurities in drug products and ingredients. The new ICP-MS and ICP-OES methods require only a small amount of sample, provide quantitative results for individual impurities, and give accurate recoveries for all the elements included in the new ICH-Q3D Step 4 and USP<232> methods.

Implementing these methods could present a challenge for pharmaceutical laboratories, many of which are new to ICP techniques. The new Agilent 7800 ICP-MS helps you get ready for the latest methods. With hardware features that simplify sample preparation and analysis, software that automates many steps in method setup and optimization, and a standard operating procedure (SOP) to guide you through every step, ICP-MS has never been easier.



Elemental Impurity analysis with the Agilent 7800 ICP-MS

SOP includes:

- · Method summary and analytes
- Sample preparation details
- · Calibration and interferences
- · Pre-set Method parameters
- Method validation and USP<233> reports
- · Troubleshooting guide

For more, go to:

www.agilent.com/chem/7800icpms



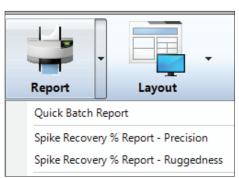
Accurate, reliable, quantitative results for Elemental Impurities

Some sample types measured in pharma labs can pose problems for ICP-MS. Samples can contain high levels of matrix, or be solubilized in organic solvents, which can overload the plasma. Furthermore, the analyte lists for ICH-Q3D and USP<232> include several critical toxic elements that can be difficult to measure at low levels. Some are poorly ionized (As, Cd, and Hg), meaning that they have relatively low sensitivity, and some suffer from polyatomic interferences (e.g., ArCl+ on As+ at mass 75).

The 7800 ICP-MS uses optimized hardware to address these issues. The robust plasma, with High Matrix Introduction (HMI) technology, tolerates high dissolved solids (up to 3%), and the solid state RF generator easily handles organic solvents. Standard helium (He) cell mode reduces all common polyatomic interferences, ensuring accuracy and removing the need for correction equations.

Simplify elemental impurity analysis workflow

- · Standard operating procedure
- · Auto-optimization tools
- Pre-set Method for USP<232> analyte list
- Pharma QC and sample analysis reports

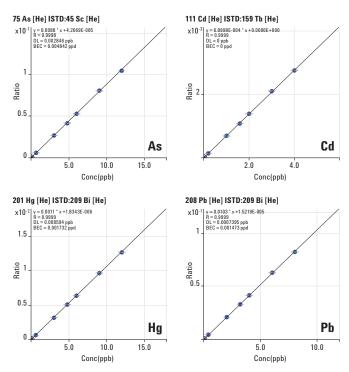


ICP-MS MassHunter's system suitability test reports for repeatability (within batch) and ruggedness (between batch)

System qualification and compliance

Agilent is a leading provider of compliance services, offering Installation and Operation Qualification (IQ/OQ) for ICP-MS hardware and ICP-MS MassHunter software.

Our compliance software packages suit any size and type of laboratory, from PC workstation-based solutions for labs with a single ICP-MS, to global enterprise-wide solutions with multiple sites and instruments.



Calibrations for the "Big Four" toxic trace elements

For more information, go to: www.agilent.com/chem/7800icpms

This information is subject to change without notice.

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