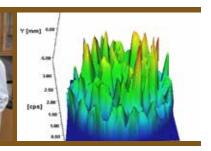


USP <232> and <233> Testing





The new USP general chapters <232> and <233> set forth limits and methods for elemental impurities determined by ICP-MS and ICP-OES. RTI International performs both limits and quantitative tests for elements included in <232>. We have validated instrumentation, trace metals preparation facilities, and cGMP quality assurance practices in place to meet all your USP testing requirements.

Your assays will be handled by highly trained, experienced scientists in RTI's state-of-the-art facilities. Our team's credentials and commitment to quality make RTI the laboratory of choice for USP metals testing.

- RTI has two validated ICP-MS instruments housed in facilities that are designed to facilitate high-throughput sample analysis.
- Uninterruptable power supplies on each ICP-MS system, a building back-up generator, and two bulk argon systems ensure instrument reliability and stability and minimize the potential for downtime.
- RTI has five qualified microwave digestion systems dedicated to metals sample digestion and clean preparation facilities to prevent potential environmental contamination.
- Our staff has more than 20 years of GxP experience and ICP-MS factory training.
- RTI's on-site quality assurance unit oversees process compliance. They perform inspections and audits in support of cGMP-regulated projects and provide regulatory training and consulting on compliance issues.

Alternative sample analysis methods such as wavelength dispersive X-ray fluorescence (WDXRF) and energy dispersive X-ray fluorescence (EDXRF), as described in USP <735>, are also available. RTI is experienced in method development for WDXRF analysis of pharmaceutical products

In addition to <232>/<233> testing, we are available to assist you with the following:

- Troubleshooting needs and any non-GxP analysis by WDXRF
- Thorough familiarity with other trace metal guidelines (e.g., ICH Q3D, EP)
- Metal testing using the following state-of-the-art instrumentation and methodologies:
 - Electron microscopy (SEM, TEM)
 - Optical microscopy
 - ICP-MS (quadrupole and sector-field)
 - X-ray fluorescence (EDXRF, WDXRF)
 - X-ray diffraction
 - TGA and DSC
 - Hyphenated techniques (UPLC/GC-ICP-MS)

USP <232> and <233> Testing

- ICP-OES
- CVAFS for ultra-trace Hg analysis
- LC-MS/MS
- Contamination identification in challenging matrices.

More Information

Keith Levine, PhD Frank Weber
Director Laboratory Manager
919.541.8886 919.541.8762
levine@rti.org fxw@rti.org



www.rti.org/page.cfm/Trace_Metals_Analysis

RTI International 3040 E. Cornwallis Road, PO Box 12194 Research Triangle Park, NC 27709-2194 USA

RTI 8260 R2 1014



RTI International is one of the world's leading research institutes, dedicated to improving the human condition by turning knowledge into practice. Our staff of more than 3,700 provides research and technical services to governments and businesses in more than 75 countries in the areas of health and pharmaceuticals, education and training, surveys and statistics, advanced technology, international development, economic and social policy, energy and the environment, and laboratory testing and chemical analysis. For more information, visit www.rti.org.