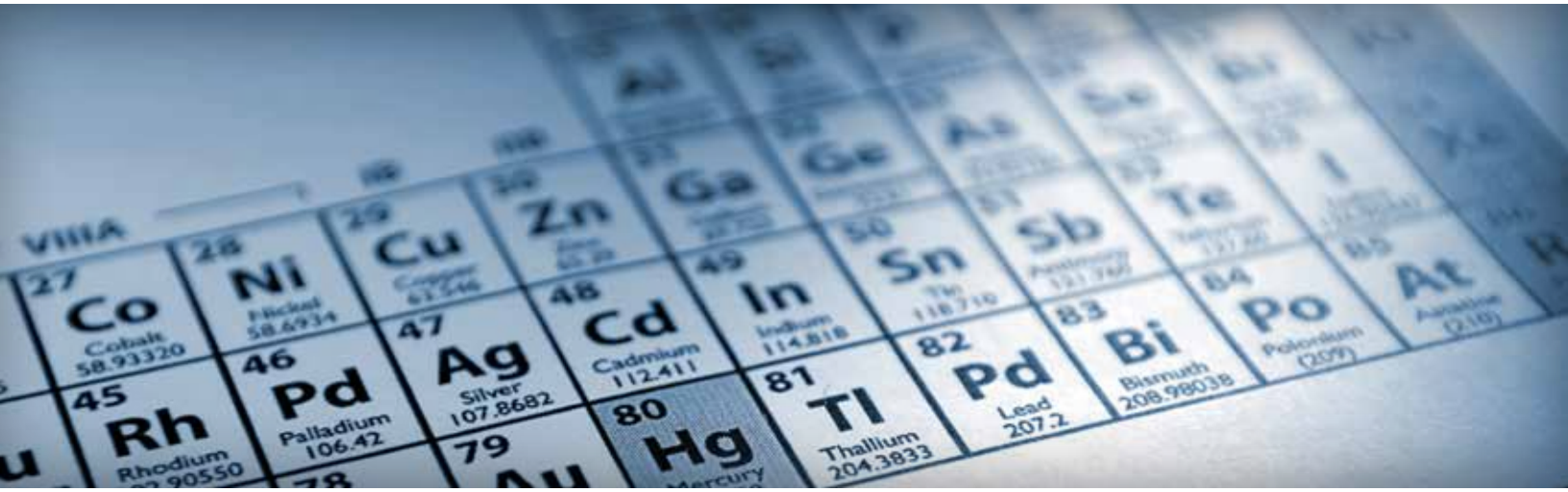
Nitto Avecia Pharma Services

elemental IMPURITIES



USP has announced the **new required methodology** proposed to replace General Chapter <231>, Heavy Metals.

In an effort to improve and modernize the USP General Chapter <231>, Heavy Metals, USP has proposed the addition of two new General Chapters and one Supplemental General Chapter.

- <233> Elemental Impurities – Procedures
- <232> Elemental Impurities – Limits
- <2232> Elemental Contaminants in Dietary Supplements

The updated USP methodologies (harmonized with ICH Q3D) utilize modern technologies to provide better precision, sensitivity, and accuracy. To comply with these changes, drug products will be required to fall within the proposed limits. The implementation date is proposed for January 1st, 2018.

WHO WILL BE REQUIRED TO COMPLY?

- Pharmaceutical
- Biopharmaceutical
- Excipient
- Medical Device
- Nutraceutical

UTILIZING MODERN, PRECISE INSTRUMENTATION

- ICP-MS
- ICP-OES

THE 2018 DEADLINE IS QUICKLY APPROACHING.
Contact an Avecia Pharma Subject Matter Expert today.

HOW CAN AVECIA PHARMA HELP YOU PREPARE?

Nitto Avecia Pharma Services has nearly 30 years of analytical experience with Heavy Metals analysis. Additionally, Avecia Pharma has actively participated in the industry since the early 2000s on this subject matter via technical posters, papers, presentations, and through collaborating with clients.

Avecia Pharma's experienced staff can help you:

- Develop/transfer, validate and test elements listed in <232> and beyond
- Perform a general screening for elements listed in <232> and beyond (for informational purposes only)

Contact us at 877-445-6554 or visit www.aveciapharma.com.
Learn more by downloading our Elemental Impurities Tool Kit.