

Featured Monthly Article

Inorganic Impurities USP's Heavy Metals Impurities Analysis for: Pharmaceuticals, Vitamins, Nutraceuticals, and Allied Industries

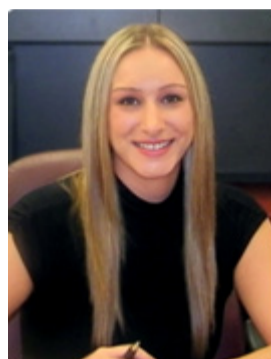
The US Pharmacopeia (USP) is in the process of finalizing the replacement of the general chapter <231> Heavy Metals. The proposed revisions are in the form of three new general chapters:

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

There have been many discussions, presentations and FAQs from the USP, those attempting to explain the changing requirements and those who eventually will need to comply with them. One has only to search "Elemental Analysis" on the USP home page in order to have the latest versions of these approaching new requirements. The USP expects to have the new elemental impurities standards finalized in 2010 and have them become official at a later date which is to be determined. Once official, general chapter <231> will have been replaced and we must comply with the new guidelines for drug substances, drug products, excipients and dietary supplements.

General Chapter <232> divides the elements of interest into two classes and only class 1 is of concern where we are looking at inherent content verses class 2 which is added content. Class 1 consists of Arsenic, Cadmium, Lead and Mercury and it would be expected to apply to most materials. General Chapter <233> gives information on the requirements for method validation requirements for either limit testing or quantitative testing and describes two referee procedures but also allows alternative procedures. General Chapter <2232> is concerned with the same class 1 elements from <232> except that it is concerned only with inorganic arsenic and looks at both Total Mercury and Mercury from Methylmercury. The same procedures in <233> can apply for <2232> and both the determined Arsenic content and the Total Mercury content will apply where Arsenic content is determined to be below the inorganic Arsenic specification and the Total Mercury content is determined to be below the Methylmercury specification.

QCL offering **fast, accurate**, Trace Element Detection, Identification and Quantification services at a **competitive rates**



Alison Monk
Business Development
Specialist

In response to our valued clients and to serve our industry even more effectively, QCL- Quality Compliance Laboratories is pleased to announce the expansion of its Elemental Analysis division. We have recently installed and qualified a new Varian 720-ES ICP-OES instrument which is one of the most advanced instruments recommended for <232>. In addition, we have a new Varian FS-240 AA equipped for

flame or graphite furnace and with a VGA-77 Cold Vapor Generator specific for mercury (Hg) and certain elemental hydrides. We are fully prepared and looking forward to the coming modifications to the USP where Heavy Metal determination will be specific to the element instead of the non-specific and generally outdated <231>.

When reviewing your outsourcing needs to comply with the latest guidelines, be sure to consider QCL Quality Compliance Laboratories where you'll find competence, quality and a good turnaround time at a very competitive price.

QCL trace elemental testing includes; identification and quantification of elements, elemental compounds and molecular species. Sample types and matrices tested for trace elements include organic and non-organic, aqueous and non-aqueous materials. Our labs provide elemental trace analysis detection ranging from parts per million (ppm), to parts per billion (ppb) levels, using proven and up-to-date techniques backed by strong technical expertise. Elemental trace analysis is available for a diverse range of samples and sample-matrices using various trace level analytical techniques.

Our Elemental Analysis testing capabilities include:

- Chemical Trace Analysis
- Trace Metals Analysis - AA & ICP Analysis
- Raw Material Screening and Testing
- Method Development & Validation
- Quality Control
- Assay and Purity Analysis
- Contamination Analysis
- Inorganic Analysis
- Troubleshooting
- Identification of Unknowns

For further information about our Heavy Metal Elemental analysis and other laboratory services please visit www.QCtest.com or call us directly at 905 305-0998. We will be happy to assist you with your analytical requirements.

All Rights Reserved.

Copyright 2010 Quality Compliance Laboratories

Lab Services - Consultancy - Training Events - Careers - Contact Us