GEO Analytical, Inc.

HEAVY METALS TESTING

The proposed 2013 toxicological limits on elemental impurities are targeted to replace the existing methods outlined in USP <231> Heavy Metals. The new regulations include USP methods:

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

These methods incorporate the use of modern instrumentation, enabling the qualitative and quantitative analysis of various pharmaceutical drug products, excipients and dietary supplements.

GEO Analytical is focused on streamlining the analysis of a wide range of pharmaceutical products with the latest in ICP-MS technology. Our ICP-MS features high temperature plasma for low oxide production, high matrix interface (HMI) and the latest collision/reaction cell technology along with a new ion lens design. These features combine to assure the sensitivity, robustness and analytical range required to easily meet the requirements of the new procedures. API's, raw materials and excipients can be analyzed efficiently and accurately to demonstrate compliance with the proposed limits. Higher instrument sensitivity allows for smaller required sample sizes for analysis. Semi-Quantitative analysis can also be performed for investigations of unknown constituents producing reliable data using primary and secondary isotopic verification across nearly the entire periodic table.

GEO ANALYTICAL OFFERS:

- cGMP compliance
- Knowledgeable staff with extensive experience in pharmaceutical testing.
- Modern instrumentation that provides low detection limits and small sample sizes.
- Compliance with the proposed Heavy Metals Limits and Procedures
- Method Development
- Method Transfers
- Method Validation
  - Accuracy
  - Precision
  - Limit of Detection
  - Limit of Quantitation
  - Range & Linearity
  - Robustness
  - Ruggedness
  - Specificity
  - System Suitability
- Semi-Quantitative analysis

GEO Analytical recommends the use of ICP-MS to meet the requirements of the proposed Elemental Impurities methods due for implementation in 2013. Taking a proactive approach will assure compliance for all pharmaceutical products and dietary supplements. The benefits of the new technology in ICP-MS greatly enhance the quality of data and provide more accurate and reliable product information.

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