

Metrics Contract Services offers a complete elemental impurities program designed to comply with the USP 232 and USP 233 Elemental Impurities proposed chapters which become official on December 1, 2015.

Our veteran trace metals group has more than 18 years of experience with development and validation of ICP-OES and ICP-MS methods. Our depth of experience allows Metrics to ease the path of compliance to the new USP 232 and USP 233 chapters.

Our program consists of three steps:

STEP 1: Non-GMP Screening for Elemental Impurities

Metrics performs semi-quantitative screening of multiple lots/batches of API, excipients and/or drug products to assess the elemental profile of the material. Screening can include all of the current USP and ICH elements or simply the Big Four — arsenic, cadmium, lead and mercury — as well as any specific elements of possible concern, such as residual catalysts and organometallic reagents.

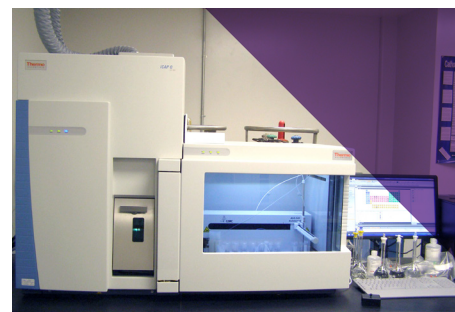
Once the initial screening is completed, the data is used to assess which elements will require monitoring and validation per the USP 233 chapter. Multiple materials can be screened simultaneously, allowing clients to build elemental impurities profiles for their APIs and drug products.

STEP 2: Method Development and Optimization

Using the screening data obtained in Step 1, Metrics uses the client's specifications to develop and optimize either a limit test or quantitative method incorporating all of the elements of interest. This step focuses on the sample preparation and analytical procedure to achieve the specified limits for each element to be validated in Step 3. ICP-OES or ICP-MS is selected based on the specifications, method accuracy and precision is assessed, and a final analytical procedure is documented.

STEP 3: Method Validation

The USP 233 chapter provides the specific validation requirements for both a limit and a quantitative procedure. Metrics will draft and execute a validation protocol specific to the material and client's limit specifications. Upon completion of the validation, the client can submit samples for routine analysis per USP 232.



Trace Metals Instrumentation

includes:

- Inductively Coupled Plasma with both Mass Spectrometry (MS) and Optical Emission Spectroscopy (OES)
- Milestone UltraWAVE Single Reaction Chamber (SRC)