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Elemental Analysis by ICP-OES and ICP-MS

Products on the market have the potential to contain harmful contaminants or residuals of elements that may be harmful to the consumer, even in small quantities. It is the responsibility of the manufacturer and distributor to ensure that any hazardous chemicals including heavy metal or elemental impurities meet the current regulatory guidelines for finished products. BioScreen offers Inductively Coupled Argon Plasma - Optical Emission Spectroscopy (ICP-OES) and Indutively Coupled Argon Plasma - Mass Spectrometry (ICP-MS) analysis for fast, low-level detection of such elemental impurities.

It is a mandatory practice to incorporate an assay for heavy metals or other elemental impurities into testing regimens for bulk drug release, due to their potential toxicity. In most cases, specific metals employed as catalysts or reagents in the synthetic route must be shown to be less than conventionally acceptable thresholds. While this limit varies depending on the metal or element, in general the limits for a specific metal or element span from the low ppm to low ppb range.

Historically, heavy metals content has been established pursuant to USP methodology (USP<231>). This fraught with problems:

- The assay is a colormetric method – and borderline results are subjectively decided
- The assay is non-specific. It affords a pass/fail without providing valuable information as to the exact amounts of specific metals.
- The assay is, in general, dated. There is significant discussion of substituting more advanced technology for the colormetric method.

The state-of-the-art methodology for quantitating heavy metal and other elemental content in raw material or API is Inductively Coupled Plasma (ICP) spectroscopy. This technique may be employed in two modes: A scanning, semi-quantitative mode to identify which metals are present (up to 60 different metals per assay), and a direct, quantitative mode which determines the concentration of specific elements in a sample matrix. ICP is a proven, reliable, and fast method to determine whether an API lot is acceptable for animal or clinical use. In addition, the technique provides valuable information that process chemists may use to modify reaction, reagent, or workup procedures.

Samples chosen for heavy metal or elemental impurity analysis can be prepared directly or by digestion using a hotplate or microwave procedure. ICP-OES or ICP-MS analysis may then be selected for analysis based on the sample matrix, digestion solutions used, elements requested for analysis, or the required detection limits for the specified elements. Typically, ICP-MS provides the lowest detection limits for the majority of elements the may be analyzed by the ICP technique.

Bioscreen offers a full range of ICP services aimed at the pharmaceutical industry. Whether it is analysis of process research sample to support route-scouting and optimization efforts, or testing of raw materials or API for release to clinical use, Bioscreen has a program that will help you reach your raw material or API manufacturing goals.

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