

METAL IMPURITIES



Background

Metals Analysis at Maxxam

Total Metal Analysis

Metal Speciation: As, Hg, Cr, Se

Maxxam Analytics offers contract analytical services in support of pharmaceutical product manufacturing and quality control.

Maxxam's experienced team of scientists and analysts act as a seamless extension of your Analytical R&D group. Maxxam offers heavy and other trace metals analysis in pharmaceutical drug products and dietary supplements of various types such as:

- Proteins
- Cytotoxics
- Peptides
- Oligomers

Our heavy metals analysis service falls fully in line with the new USP Heavy Metals general chapters as well as established regulations such as California's Proposition 65.

Utilizing ICP-MS and ICP-OES technology and microwave digestion sample preparation techniques, we are able to meet the requirements set out in the new USP general chapters:

- USP <232> - Limits
- USP <233> - Procedure
- USP <2232> - Dietary Supplements

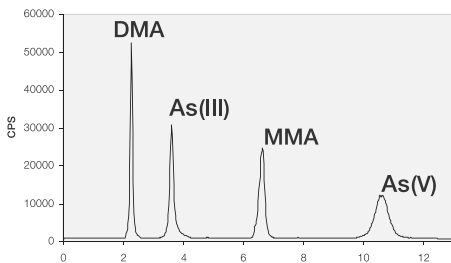
Background

The traditional method for determining heavy metals in test articles is the classic colorimetric method outlined in USP <231>. This wet chemical technique involves the precipitation of metal sulfides from an aqueous solution, then visually comparing the colour of the test sample with that of a standard lead solution. Unfortunately, USP <231> method suffers from several drawbacks because it is:

- Nonspecific
- Insensitive
- Inaccurate
- Labour intensive



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Maxxam provides clients with Heavy Metals, Metal Catalysts and other Trace Elements testing in full compliance with GMP regulations:

- 21 CFR Parts 210 and 211
- EMEA
- USP
- ICH

In addition to the “Big Four” elements of Hg, Pb, As and Cd, ICP-MS also allows for analysis of 60+ other elements found in the periodic table including transition metals, precious metals and metalloids.

USP <232> categorizes the Big Four elements as Class 1 requiring mandatory tests owing to their higher degree of toxicity. Class 2 elements such as Cr, Cu, Ni, Pd, Pt and Ir have less toxicity but do need to be tested if they are part of the manufacturing process.

- Class 1 elements: Hg, As, Pb and Cd
- Class 2 elements: Cr, Cu, Mn, Mo, Ni, Pd, Pt, V, Os, Rh, Ru, Ir

Total Metal Analysis

Combining chromatographic techniques such as LC or GC with ICP-MS, speciation of elements such as mercury and arsenic, a key feature of the proposed USP<232> chapter, is possible. Our technical team has been providing such speciation services for almost a decade.

Metal Speciation: As, Hg, Cr, Se

- Arsenic: As(III), As(V), Methyl- As, Dimethyl-As
- Chromium: Cr(III), Cr(VI)
- Mercury: Methyl-Hg, Hg(II)
- Selenium: Se(IV), Se(VI)

Maxxam is the Canadian market leader in analytical services and solutions to the energy, environmental, food and DNA industries and a member of the Bureau Veritas Group of companies – a world leader in testing, inspection and certification services. We support critical decisions made by our customers through the application of rigorous science and the knowledge and expertise of our over 2500 employees.

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