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Water Testing for Heavy Metals by ICP-MS

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An Informative Overview of Analytical Procedures and Considerations



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Introduction
Purified water may not always receive the attention it warrants in pharmaceutical manufacturing; however, it is a major component in plant and throughout production processes. Ensuring its purity is as crucial as any other raw material, and one of the key quality requirements is the absence of heavy metals. Heavy metals can be introduced from a variety of sources including equipment, facilities, or as an indicator of poor purification filters. Inductively Coupled Plasma Mass Spectrometry (ICP-MS) has become the method of choice for detecting trace levels of heavy metals in purified water due to its sensitivity, precision, and ability to analyse multiple elements simultaneously. ICP-MS is already in use for the detection of elemental impurities in raw materials, API's, and final products of pharmaceuticals.

What Is Purified Water?
Purified water is produced by distillation or reverse osmosis and must meet stringent requirements for pharmaceutical use. It is used in pharmaceutical applications such as API production or Water for Injection (WFI) and must comply with pharmacopeial standards regarding microbial contamination, endotoxins, and chemical purity, including heavy metals.

Why Test for Heavy Metals?
Heavy metals such as lead, mercury, cadmium, and arsenic are toxic even at low concentrations.

Their presence in purified water can result in adverse health effects for patients, including organ toxicity, neurological disorders, and carcinogenicity. Regulatory agencies, including the European Pharmacopoeia and the US Pharmacopeia, mandate strict limits on these metals in WFI. Current European pharmacopeia testing requirements detail testing for heavy metals using methodology that has been confirmed as non-selective and interference-susceptible to interference. This visual testing approach is now considered outdated, and ICP-MS provides a more robust selective solution to these issues.

ICP-MS: Principles and Advantages
ICP-MS is a highly sensitive analytical technique used to detect and quantify trace elements in liquid samples. The sample is introduced into an inductively coupled plasma, where it is ionised. The resulting ions are then separated and detected based on their mass-to-charge ratio.

ICP-MS offers several advantages for heavy metal testing in water:

- Detection limits in the parts-per-trillion (ppt) range

- Ability to analyse multiple elements simultaneously
- Rapid analysis time
- Wide dynamic range
- Minimal sample preparation

Regulatory Compliance to the Heavy Metals limits

According to the European Pharmacopeia, the maximum allowable concentration of heavy metals is 0.1 ppm. Since the current EP method is non-selective and sets a threshold for total heavy metals, Almac Sciences applies the approach that the combined quantity of individual metals must remain below 0.1 ppm. Utilising ICP-MS enables us to detect trace amounts of each metal, making this strategy both practical and insightful by providing comprehensive data on the composition of your water samples.

Purified Water testing at Almac Sciences

Testing Purified water for heavy metals with ICP-MS is a critical element of pharmaceutical quality control. The instrument's sensitivity and accuracy help ensure patient safety and regulatory compliance and enhance the detection and quantification of trace contaminants, thereby aiding the production of safe and effective pharmaceuticals. Here at Almac Sciences, we work closely with each customer to determine their full requirements. We can provide technical expertise and knowledge to support adherence to testing requirements. We can provide quantified results with ultra-low limit of quantification compared with alternative techniques alongside a qualitative assessment of the material to allow customers a full overview of what is present in their water.

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