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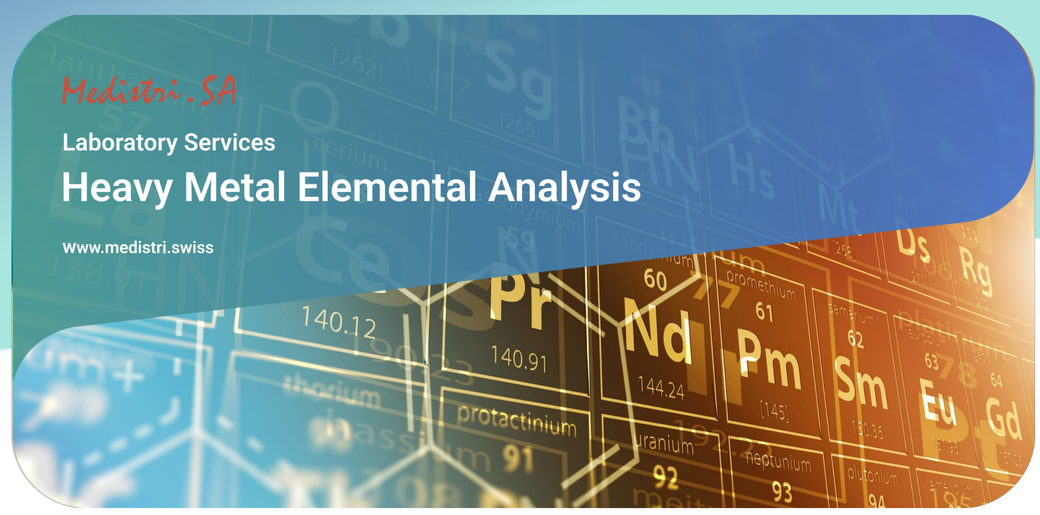

Heavy Metal Elemental Analysis - Medistri

🚀 Heavy Metal Elemental Analysis

Heavy metals are largely found in nature as minerals and ores. They get into the environment as a result of being extracted, from erosion or from volcanic activity. Heavy metals are used in a number of technical applications and processes and can get into the environment or into products unintentionally.

The term "heavy metal" is not scientifically well-defined. Different elements may be classified depending on the classification criteria (density, number of periods, etc.). Technically, any metal with a density greater than 5 g/cm3 is considered a heavy metal. "Heavy metals" usually means toxic elements, however, this is only partially true, as the small amounts of elements essential to human life also fall into this category.

Heavy Metal Elemental Analysis can be carried out in accordance to Pharmacopoeia USP 232, Ph. Eur. 2.4.8, USP <231> or to specific customer requirements.

Heavy metal elemental analysis is the process of measuring the concentration and composition of metals in biological samples. Heavy metals can be toxic and essential for living organisms, depending on their dose and bioavailability. Therefore, it is important to monitor their levels in the environment.

Heavy metal elemental analysis is important for several reasons:

- Heavy metals can have adverse effects on human health and the environment. Some heavy metals, such as mercury, lead, arsenic, and cadmium, are known to be toxic and carcinogenic, even at low doses. They can cause damage to the nervous system, blood, organs, and tissues, and increase the risk of various diseases. Therefore, it is important to monitor their levels in food, water, soil, air, and biological samples to ensure they do not exceed the safe limits set by regulations and standards.

- Heavy metals can also have beneficial effects on human health and the environment. Some heavy metals, such as iron, zinc, copper, and selenium, are essential for living organisms in trace amounts. They play important roles in various biological processes, such as enzyme activity, oxygen transport, immune function, and antioxidant defense. Therefore, it is important to measure their levels in food, supplements, and biological samples to ensure they are adequate and balanced for optimal health.

Heavy metal elemental analysis can be done by different methods, depending on sample type, the required sensivity, the number of elements to be measured, and the available equipment.

At Medistri, ICP-MS is used in the chemical characterization of medical devices. ICP-MS stands for Inductively Coupled Plasma Mass Spectrometry. It is a type of mass spectrometry that uses an inductively coupled plasma to ionize the sample and a mass spectrometer to detect the ions.It can detect a wide range of elements at very low concentrations (as low as parts per trillion) and distinguish different isotopes of the same element.

👉 ICP-MS is a powerful and versatile technique for chemical characterization, and one of the most important spectroscopic techniques for elemental analysis. It has a very high sensitivity and a wide linear dynamic range, which allows the simultaneous analysis of major components and ultra-trace elements.

Chemical characterization is the process of determining the chemical properties and structure of a material, which may include its elemental and isotopic composition, as well as its molecular, crystalline, or morphological structure. Chemical characterization can be used for various purposes, such as identifying the components of a material, detecting the presence of impurities or degradants, evaluating the quality or performance of a material, or assessing the biological safety of a material.

Heavy metal elemental analysis standards are defined by different pharmacopoeias, such as the United States Pharmacopeia (USP) and the European Pharmacopoeia (Ph. Eur.). These standards specify the limits and procedures for measuring elemental impurities in drug products and ingredients. Some of the common standards are:

- **USP <232> Elemental Impurities – Limits:** This chapter specifies the maximum permissible daily exposure (PDE) of 15 elemental impurities in drug products, based on their toxicity and route of administration. The PDE values are expressed in micrograms per day (µg/day) and are derived from the ICH Q3D guideline. The 15 elemental impurities are arsenic, cadmium, lead, mercury, cobalt, copper, molybdenum, nickel, vanadium, chromium, manganese, selenium, silver, gold, and palladium.

- **USP <233> Elemental Impurities – Procedures:** This chapter specifies the analytical procedures for measuring elemental impurities in drug products and ingredients, using inductively coupled plasma optical emission spectrometry (ICP-OES) or inductively coupled plasma mass spectrometry (ICP-MS). The chapter also defines the performance criteria and validation requirements for these methods. The chapter recommends the use of closed vessel microwave digestion for solid samples to ensure complete recovery of volatile elements.

- **Ph. Eur. 2.4.8 Heavy metals:** This chapter specifies a colorimetric test for measuring heavy metals in substances for pharmaceutical use, using sulfide precipitation and comparison with a lead standard solution. The chapter defines the limit as not more than 20 ppm of heavy metals, unless otherwise specified in the individual monograph. The chapter also provides a list of substances that are exempt from this test because they interfere with the color reaction or have inherent color.

- **ISO 10993-18:** ISO 10993-18 is a standard for chemical characterization of medical device materials within a risk management process. The relation between them is that ICP-MS is one of the common testing modalities used in chemical characterization studies, as recommended by ISO 10993-183. These studies are designed to identify the types and amounts of chemical entities, known as extractables and leachables, that may impart a biological risk to patients when used in a clinical setting.

USP <231> Heavy Metals was a general chapter in the United States Pharmacopeia (USP) that specified a colorimetric test for measuring heavy metals in substances for pharmaceutical use, using sulfide precipitation and comparison with a lead standard solution. The chapter defined the limit as not more than 20 ppm of heavy metals, unless otherwise specified in the individual monograph.

However, USP <231> Heavy Metals was deleted from the USP in April 2015 and replaced by USP <232> Elemental Impurities – Limits and USP <233> Elemental Impurities – Procedures. These chapters specify the limits and procedures for measuring elemental impurities in drug products and ingredients, using inductively coupled plasma optical emission spectrometry (ICP-OES) or inductively coupled plasma mass spectrometry (ICP-MS). These methods provide specific, quantitative determination of individual elemental impurities, based on their toxicity and route of administration.

🎯 To learn more about Heavy Metal Elemental Analysis, visit on our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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