Elemental Impurities Analysis

The elemental impurities in drugs are trace metals that can be found in final products, which may be harmful and must be controlled in the production process. The limits of drug elemental impurities are determined by the regulatory agencies of the corresponding countries/regions, such as the USP, ICH, Ph. Eur., ChP and JP. The sources of elemental impurities include raw materials, production process, packaging and container sealing system (CCS). They can interfere with the efficacy of drugs or have a direct toxic effect on patients. Therefore, the elemental impurities analysis of drugs is very important for drug quality control.

CD Formulation laboratory is cGMP-compliant and equipped with state of the art analytical instruments. We have experienced analysis experts who can work with our formulation and manufacturing team to provide you with drug elemental impurities analysis services. Our elemental impurities analysis is performed in accordance with pharmacopeia methods to give you reliable, independent data, which can help you to make an appropriate risk assessment for your final drug products. In addition, we are also able to develop and validate tailored methods of elemental impurities analysis that will meet your specific needs.

Permitted Daily Exposures (PDE) for Elemental Impurities

A total of twenty-four elemental impurities are listed in the ICH Q3D guideline. The PDE limits are shown in the table below:

Element	Cd	Pb	As	Hg	Co	V	Ni	Tl	Au	Pd	Ir	Os
Class	1	1	1	1	2A	2A	2A	2B	2B	2B	2B	2B
Oral PDE (µg/day)	5	5	15	30	50	100	200	8	100	100	100	100
Parenteral PDE (µg/day)	2	5	15	3	5	10	20	8	100	10	10	10
Inhalation PDE (µg/day)	2	5	2	1	3	1	5	8	1	1	1	1

Our Methods of Elemental Impurities Analysis

- Inductively Coupled Plasma – Mass Spectrometry (ICP-MS)
- Inductively Coupled Plasma – Optical Emission Spectroscopy (ICP-OES)
- Ion Chromatography (IC)
- Flame Atomic Absorption Spectroscopy (FLAA)
- X-ray Fluorescence (XRF)
- Atomic Absorption Spectrometry (AAS)
- Atomic Emission Spectrometry (AES)

Deliverable

- Data analysis
- Provide full study report

References

1. Fischer L, Zipfel B, Koellensperger G, *et al.* Flow Injection Combined with ICP-MS for Accurate High Throughput Analysis of Elemental Impurities in Pharmaceutical Products According to USP< 232>/< 233[J]. *Journal of Pharmaceutical and Biomedical Analysis*, 2014, 95: 121-129.
2. Balaram V. Recent Advances in the Determination of Elemental Impurities in Pharmaceuticals-Status, Challenges and Moving Frontiers[J]. *Trac Trends in Analytical Chemistry*, 2016, 80: 83-95.