Elemental Impurities

Ultra-trace quantification of elemental impurities with ICP-MS

The careful monitoring and quantification of elemental impurities in finished drug substance is essential to avoid interference with drug metabolic activity and unwanted toxicological effects, both of which directly affect the patient.

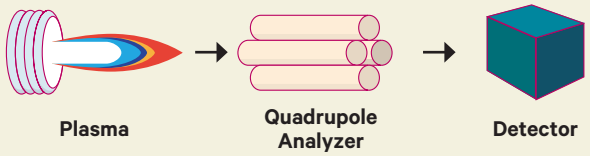
Sai Life Sciences delivers excellence in quantifying elemental impurities at parts per billion (PPB) levels using the highly sensitive ICP-MS technique. Nearly 40 elemental impurities can be assessed by this analysis.

Highlights

- Analytical proficiency spanning over 300 compounds
- Evaluation using highly sensitive Inductively Coupled Plasma Mass Spectrometry (ICP-MS) technique
- Quantification down to parts per billion
- Over 50 developed methods are validated and implemented successfully during routine release operations
- Capacity to assess almost 40 elemental impurities (as against 24 recommended by ICH Q3D (R1) list for risk assessment)
- Risk assessment carried out for several orally administered compounds
- Dedicated and well-trained scientific team

State-of-the-art equipment to enhance quantification capabilities

Inductively Coupled Plasma Mass Spectrometry (ICP-MS)



- Detection of trace elemental impurities (Class-1, 2A, 2B & 3) down to PPB
- ICP-MS from Agilent (Model 7700)
- Software support for ICP-MS – Mass Hunter v 4.5 with 21 CFR part 11 compliance
- Microwave digester (CEM Model Mars 6) that provides clean, fast and efficient sample preparation
- Octopole Reaction System (ORS) that reduces polyatomic interference
- Accurate and reproducible results of elements concentration

Illustrative examples of overcoming technical challenges

- Thiourea was added to an Osmium (Os)-containing sample to prevent oxidation and allow accurate assessment of osmium concentration
- The stability of Mercury (Hg) in a solution was enhanced by the addition of Gold, thereby preventing its underestimation
- For an accurate estimation of Arsenic (As), Hydrochloric acid (HCl) was avoided during sample preparation to reduce the formation of the Argon-HCl complex, reducing interference during assessment

For more information contact: **contact@sailife.com**