Elemental Impurities

Our dedicated elemental impurities team offer targeted, bespoke screening and quantitative analysis of elemental impurities in final products, excipients, APIs, raw materials and packaging materials.

We perform reliable and accurate analysis in accordance with ICH Q3D and USP <232><233> guidelines using a combination of ICP-MS and ICP-OES as appropriate.

This combination enables us to measure down to ppt levels as required for impurity quantification in high dose materials, as well as up to ppm or wt% levels where an assay is required. Our team also has extensive experience in the preparation of samples in complex matrices including the unique challenges of topical products.

We deliver these cGMP compliant services from our purpose built, dedicated elemental analysis laboratory to minimise contamination, achieve low backgrounds and increase sensitivity.

Applications

» ICH Q3D and USP <232><233> elemental impurity screening
» Method development and validation
» Targeted metals analysis
» Extractable and leachables testing
» Pharmacopeia testing
» Active/Drug substance testing
» Finished product testing
» Raw materials testing
» QC, stability and batch release testing
» Metal speciation
» Contamination identification

Sample preparation

» Microwave digestion or extraction
» Wet chemical digestion
» HF capability
» Solvent extraction

Techniques

» Inductively Coupled Plasma with Mass Spectrometry (ICP-MS) - Agilent 7700x and Agilent 7900
» Inductively Coupled Plasma with Optical Emission Spectrometry (ICP-OES) - Thermo iCAP7600 Duo

We have in-depth technical knowledge and extensive experience in the quantitation of elemental impurities in pharmaceutical materials by ICP-OES/ICP-MS.

The requirement for simultaneous multi-element determination, often in complex matrices, across a wide concentration range can lead to significant analytical challenges. Our scientists are experienced in the development and validation of both limit and quantitative test methods for a wide range of sample matrices.

www.resolian.com

Learn more about our services