

Your Partner to Fast-Track Trace Metals Analysis



Proven track record in trace metal detection and estimation in diverse matrices - APIs, drug products and packaging materials



Experienced team of analysts with extensive understanding of regulatory requirements



Established accuracy and integrity of analysis



Data successfully submitted to/approved by global regulatory agencies

Our Capabilities

Development and Validation studies designed as per ICH Q3D and USP <232>/<233> for Active Pharmaceutical Ingredients (API), Intermediates and Drug Products

Determination of Class 1, 2A, 2B, 3 and other elements like Aluminium (Al), Boron (B), Calcium (Ca), Iron (Fe), Potassium (K), Magnesium (Mg), Manganese (Mn), Tungsten (W) and Zinc (Zn)

Provide solutions for analysing the critical elements like Zirconium (Zr), Silicon (Si) and Sodium (Na) in drug product & Excipients

Ability to develop single ICP-MS method for 24 elements

Detailed risk assessment report for drug product which suits to regulatory filings like ANDA, NDA etc.

Why GVK BIO

Expertise on wide element coverage (72 elements)

Executed 200 method developments and validations on ICP-MS

Rapid multi-element quantitative analysis

Low detection limits with high sensitivity

Quick turnaround time

Dedicated team of 30 Analytical Scientists for Analytical Development, Analytical Method Validation and Routine Analysis

Project Management support to ensure seamless execution

Leading Small Molecule CRDO



Large Molecule Discovery Partner



To know more, contact us at:

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