aragen

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

Established accuracy and integrity of analysis

Experienced team of analysts with extensive understanding of regulatory requirements

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, 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 Aragen

- 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

Let's begin the Conversation

E: bd@aragen.com
W: aragen.com
in /company/aragen-life-sciences
f /AragenLifeSciences

aragen

India • USA • UK • Netherlands • Japan • Italy