



RAPID RESPONSE

FOR BESPOKE INVESTIGATORY ANALYSIS OF PHARMACEUTICAL PRODUCTS



OVERVIEW

Element Analytical Services offers a flexible approach with turnaround times to meet your needs. From our state-of-the-art Manchester laboratory, we support all areas of analytical method development and validation. Our mass spectrometry expertise and extensive problem-solving capability covers all aspects of pharmaceutical and consumer healthcare product testing including:

- Active pharmaceutical ingredients (API) & drug products
- Delivery devices & packaging
- Biopharmaceutical single use systems (SUS)

CHARACTERISATION OF PHARMACEUTICAL PRODUCT IMPURITIES

- API related
- Production process related
- Degradation products
- Residual solvents - USP<467>
- Extractables and leachables
- Extrinsic contamination
- Elemental impurities - ICH Q3D

INVESTIGATIONAL / PROBLEM-SOLVING

- Extraction feasibility / solvent compatibility
- Peak identification
- Structural elucidation
- Product deformation
- Root cause analysis

DEVELOPMENT AND ICH Q2 VALIDATION OF CUSTOMISED METHODS

- Target leachable assay
- Drug assay and related substances
- Residual solvents
- Elemental impurities

KEY INSTRUMENTATION

- Agilent GC-MS (headspace & direct injection)
- Waters Xevo QTOF-MS
- Agilent LC-MS/MS
- Agilent ICP-MS

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