element

SANTA FE SPRINGS

OVERCOME TESTING BARRIERS AND ACCELERATE YOUR PATH TO MARKET

Regulatory complexity, analytical bottlenecks, and quality control issues can derail even the most promising pharmaceutical programs. When precision matters and deadlines are non-negotiable, you need a scientific partner who transforms analytical obstacles into strategic advantages. Element's experts work alongside your team, delivering reliable results that ensure regulatory compliance while flexibly scaling with your pharmaceutical development requirements. Partner with our Santa Fe Springs team to focus on your innovative therapies while we provide the precise analytical testing that helps bring critical treatments to patients faster.

TURN ANALYTICAL OBSTACLES INTO STRATEGIC ADVANTAGES

Partner with Element Santa Fe Springs to:

- Overcome raw material and excipient testing challenges that threaten manufacturing quality and continuity
- Meet rigorous compendial testing standards with accurate, quality methods
- Obtain API and impurity characterization data that supports your regulatory submissions
- Maintain product quality with reliable NMR-based structural analysis
- Convert complex analytical data into actionable insights for process decisions

GMP-COMPLIANT, ISO 17025 ACCREDITED TESTING THROUGHOUT THE PRODUCT LIFECYCLE

Ensure your pharmaceutical products meet the highest quality standards with comprehensive testing services that adapt to your most challenging requirements. Our specialized analytical capabilities cover critical requirements across the product development journey:

- Raw Material & Excipient Testing
- API & Impurity Characterization
- Method Development & Validation
- NMR Spectroscopy Analysis

EARLY DEVELOPMENT

- Accelerate early-phase research with efficient analytical support
- Make data-driven decisions
- Characterize critical quality attributes

CLINICAL & REGULATORY

- Generate data for regulatory submissions
- Meet compendial testing requirements
- Meet strict regulatory timelines

COMMERCIAL

- Ensure consistent product quality
- Support continuous process improvements
- Maintain ongoing compliance

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COMPREHENSIVE ANALYTICAL SOLUTIONS

Our Santa Fe Springs laboratory is US FDA registered and inspected, ISO 17025 accredited, and DEA licensed (I-V), providing specialized testing services:

RAW MATERIAL, COMPENDIAL, EXCIPIENT, AND RELEASE TESTING

- Compendial testing
  - USP <232> <233> ICP-OES, ICP-MS, ICP-QQQ
- Harmonized compendial testing
- Trace metals testing
  - USP/NF, EP, JP, BP, ACS, FCC, etc.
- Physico-chemical properties
- Potency, purity, identification
- Quantitative NMR
  - USP-NF assays
  - Impurity testing
  - Reference standard impurity assay
- Residual solvents – USP <467>
- Contaminants and impurities testing
- Container closure integrity testing (CCIT)
- Qualitative NMR including identification of small molecules
- 500 MHz NMR Brucker

API, DRUG PRODUCT, AND IMPURITY CHARACTERIZATION

- cGMP NMR testing
- Peptide analysis by NMR
- Quantitative NMR
  - USP-NF assays
  - Impurity testing
  - Reference standard impurity assay
- Qualitative NMR including identification of small molecules
- 500 MHz NMR Brucker

KEY INSTRUMENTATION

- Amino Acid Analyzer
- Autotitration
- Conductivity
- FTIR
- GC / GCMS / GCFID / HSGC
- IC / LC-PAD / UV
- LC-QQQ
- ICP-OES / MS / QQQ
- Loss on Drying (LOD) / Gravimetric Analyses
- Nuclear Magnetic Resonance (NMR)
- Polarimeter
- Residue on Ignition (ROI)
- Thin Layer Chromatography (TLC)
- UV Spectroscopy
- Viscosity
- Water Determination - Karl Fischer (Volumetric and Coulometric)
- Nitrogen content by Kjehldahl

READY TO OVERCOME YOUR TESTING BOTTLENECKS?

Discover how Element Santa Fe Springs can help bring your therapies to patients faster. Our team of experienced scientists is ready to discuss your specific program needs and develop a customized solution.

Click or scan the QR code to learn more.

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