element

TORONTO

OVERCOME ANALYTICAL CHALLENGES AND ACCELERATE YOUR PATH TO MARKET

Regulatory complexities, material characterization hurdles, and quality control challenges can delay even the most promising pharmaceutical programs. When material quality is critical and regulatory expectations are increasingly rigorous, you need a scientific partner who transforms analytical obstacles into strategic advantages. Element's experts deliver reliable testing data that provides the evidence needed for regulatory compliance while flexibly scaling with your pharmaceutical development needs. Partner with our Toronto team to focus on your innovative therapies while we provide the precise analytical testing that helps bring life-changing treatments to patients faster.

TURN TESTING BOTTLENECKS INTO DEVELOPMENT ADVANTAGES

PARTNER WITH ELEMENT TORONTO TO:

- Overcome raw material and excipient testing challenges that threaten manufacturing quality and continuity
- Transform extractables and leachables concerns into comprehensive safety data
- Ensure product stability with comprehensive ICH-compliant storage and testing
- Meet rigorous compendial requirements with comprehensive material characterization
- Maintain consistent product quality with reliable analytical methods
- Address regulatory expectations with precise, well-documented testing services

GMP-COMPLIANT AND HEALTH CANADA CERTIFIED TESTING THROUGHOUT YOUR PRODUCT LIFECYCLE

Navigate the complex journey of pharmaceutical development with specialized testing services that adapt to your most challenging analytical requirements. Our comprehensive testing capabilities cover critical aspects across the development pathway:

- Raw Material & Excipient Testing
- Materials Characterization
- Extractables & Leachables
- Method Development & Validation
- ICH Stability Storage & Testing

EARLY DEVELOPMENT

- Accelerate research with efficient analytical support
- Make data-driven formulation 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 Toronto laboratory is cGMP compliant, FDA registered and inspected, Health Canada certified, ISO 17025 and SCC accredited, providing specialized testing services:

RAW MATERIAL, EXCIPIENTS, AND RELEASE TESTING

- **Raw Materials – API and Excipients -** Comprehensive characterization for manufacturing confidence
- **ICH Stability Studies -** Long-term and accelerated stability storage and assessment
- **Elemental Impurities – ICPMS, ICPOES, AA -** Precise quantification of elemental contaminants
- **Container Closure Systems -** Critical packaging component evaluation
- **Trace Metal Analysis -** Sensitive detection of elemental impurities
- **Physico-chemical Properties -** Essential material attribute characterization
- **Potency, Purity, Identification -** Core quality attribute testing
- **Residual Solvents -** Complete solvent profile analysis
- **Contaminants and Impurities -** Identification and quantification of undesired compounds

MATERIALS CHARACTERIZATION

- **Solid State Characterization -** Comprehensive physical form analysis
- **X-ray Diffraction and Polymorphism -** Crystalline structure determination
- **Particle Size and Morphology -** Critical physical attribute assessment
- **Microstructural Analysis by SEM EDS -** Detailed surface characterization
- **Contaminant Analysis -** Identification of foreign materials
- **Glass Delamination Studies -** Container integrity evaluation
- **Mechanical Testing -** Physical property determination
- **Surface Area Analysis -** Material interface quantification
- **Particulate Matter Analysis -** Foreign particle identification and quantification

EXTRACTABLES & LEACHABLES

- **Pharmaceutical Packaging -** Container closure compatibility assessment
- **Transdermal and Single Use Systems (SUS) -** Delivery system qualification
- **Processing Equipment -** Manufacturing component evaluation
- **Medical Devices -** Device material compatibility testing
- **Customized Protocols -** Study designs for unique challenges
- **Low AET's Regularly Below 10 ppb -** Sensitive detection capabilities
- **Experience with Diverse Container Closure Systems -** Broad packaging expertise

METHOD DEVELOPMENT AND VALIDATION

- **Supporting All Phases of Small Molecule Drug Development and Characterization -** Comprehensive analytical support
- **Assays, Degradants, Impurities, SIA Assays -** Specialized method development

STABILITY STORAGE AND TESTING

- **ICH-Compliant Stability Studies -** Long-term, intermediate, and accelerated conditions
- **Temperature and Humidity Controlled Environments -** Precisely maintained storage conditions
- **Stability-Indicating Methods -** Sensitive detection of degradation products

READY TO OVERCOME YOUR ANALYTICAL TESTING CHALLENGES?

Discover how Element Toronto 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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