KEYSTONE LABS

Testing Services

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Keystone Labs, a trusted leader in analytical testing, is a Health Canada accredited GMP facility located in Edmonton, Alberta, Canada. Since 2005, we have been delivering precise, reliable, and high-quality testing solutions using validated methods and cutting-edge equipment. Our unwavering commitment to excellence ensures that pharmaceutical, biotechnology, and medical device companies worldwide receive accurate and compliant results they can trust. Partner with Keystone Labs – where science meets integrity.

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Overview

Keystone Labs is a trusted leader in analytical testing, proudly holding a Drug Establishment Licence with Health Canada since it was founded in 2005. Located in Edmonton, Alberta our team is dedicated to delivering precise, high-quality results using validated methods and state-of-the-art equipment. As a full-service testing lab, we partner with global pharmaceutical, biotechnology, and medical device companies to ensure compliance and quality at every step. At Keystone Labs, we don't just test – we empower companies with confidence and reliability.

The Keystone team delivers a powerful combination of experience, quality, reliability, and technical expertise to meet your unique needs. Our microbiological testing services include sterility testing, microbial enumeration, bioburden analysis, genus/species identification, and more – all performed in compliance with the latest U.S Pharmacopeia standards. In addition, our analytical capabilities encompass HPLC, GC, method development and validation, controlled environments, utilities, and quality systems. With extensive experience in developing customized testing protocols, we provide precise, reliable results tailored to your specific product and process.

Explore our extensive expertise and capabilities designed to meet your unique needs:

MICROBIOLOGY ANALYSIS

We offer a wide range of microbiological testing

- Microbial Enumeration (Total Aerobic Counts and Total Yeast and Mold) (USP<61>, USP<2021>)
- Absence of Specified Microorganisms (USP<62>, USP<2022>)
- Bacterial Endotoxin Testing (USP<85>)
- Antimicrobial Effectiveness Testing (USP<51>)
- Identification of Microorganisms
- Disinfectant Testing

- Sterility Testing: (USP<71>)
  - Membrane Filtration
  - Direct Transfer
- USP product verification
- Cell Banking:
  - Preparation of cell banks
  - Purity and viability testing

ANALYTICAL TESTING

We offer a wide range of analytical laboratory testing services

- Gas Chromatography Analysis
- High Performance Liquid Chromatography Analysis
- USP Raw Material Testing
- Total Protein Assays
- Enzyme-Linked Immunosorbent Assays (ELISAs)
- Total Organic Carbon analysis – low level of detection
- Conductivity and pH analysis
- Loss on Drying
- Identity, purity and quality of raw materials using compendia or client supplied methods

METHOD DEVELOPMENT AND VALIDATION

At Keystone Labs, our method development and validation services are designed to deliver precision, reliability, and compliance. We ensure every project is:

- Conducted by expert professionals with the necessary skills, experience, and state-of-the-art equipment.
- Tailored to your specific needs, achieving the accuracy and range required for your applications.
- Structured using a collaborative approach, following a clear, agreed-upon protocol to ensure alignment with your goals.

- Communicated efficiently and with transparency, keeping you informed every step of the way.
- Finalized with a comprehensive report, that has been reviewed and approved by both Keystone Labs and the client.

With Keystone Labs, you gain more than just testing – you gain confidence in results that meet the highest standards.

CONTROLLED ENVIRONMENT AND UTILITIES MONITORING

Cleanrooms and controlled environments are utilized to reduce contaminants entering pharmaceutical and medical device production facilities. The objective of an environmental monitoring program is to quantify the microbial and particulate content of room air and on surfaces. An effective environmental monitoring program can alert you when conditions are changing due to ineffective cleaning, sanitation or other personnel/equipment issues. Keystone Labs can provide you with the service you need to ensure your manufacturing environment complies with regulatory requirements, including:

- Total Particulate Monitoring
- Viable Particulate Monitoring (surface and air)
- Full monograph testing of pharmaceutical waters (USP and EP)
- Sampling Plan Establishment

Keystone Labs has experience performing cleaning validations for your controlled environment. We can prepare validation protocols and final reports to establish sampling plans with appropriate sample sites and determine appropriate alert or action levels for your controlled environment rooms, clean steam and water systems.

Keystone Labs tests process water samples to monitor compliance with Pharmacopeia specifications, including:

- Total Organic Carbon (USP<643>)
- Conductivity (USP<645>)
- Bacterial Endotoxin (USP<85>)

STABILITY STUDIES

Stability studies are essential to ensuring the safety, efficacy, and longevity of regulated consumer products. A well-designed stability study rigorously tests how external factors such as temperature, humidity and time impact the product activity over time. By simulating real-world conditions, stability testing provides criticial data to determine accurate shelf-life and optimal storage requirements, safeguarding both product quality and consumer safety. Conducted in full compliance with Health Canada's regulatory guidelines, our stability studies give you the confidence to bring relialble, high-quality products to market.

Keystone Labs has multiple stability chambers to conduct studies at the following conditions:

- **Real-Time Stability testing**: (25±2°C / 60±5% RH) is normally performed for a longer duration to check for significant product degradation under recommended storage conditions.
- **Accelerated Stability testing**: (40±2°C / 75±5% RH) provide a means of comparing alternative formulas, packaging materials, and/or manufacturing processes within a shorter test period.
- **Client Specific Stability Conditions**: Designed to meet the client's storage and production degradation conditions.

WHY US?

Your decision on your lab and testing facility is an important one. You deserve more than just an in-and-out service. You need to know and trust your testing partner. That's where Keystone comes in. We want to be a part of your team. Keystone performs a wide range of analytical and microbiological testing. We can also monitor your manufacturing facility or environment and help you improve internal processes. Regulatory requirements are often changing and can seem overwhelming. We'll prepare you for what you need to do today, and ensure you're prepared for the future.