



KEYSTONE LABS

Testing Services

December 2022 V.2

Keystone Labs is a Health Canada accredited GMP regulated facility located in Edmonton, Alberta, Canada and was incorporated in 2005. Keystone is a full-service testing lab, utilizing validated methods and equipment to deliver results with intrinsic quality. At Keystone Labs, we are committed to providing superior quality testing solutions to regulated industries. Our clients are global pharmaceutical, biotechnology, medical device, food manufacturers and nutraceutical companies.

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Overview

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The Keystone team brings a unique combination of experience, quality, reliability, and technical diversity to meet the client's needs. Our extensive experience in microbiological analyses includes sterility testing, procedures for absence of specified microorganisms, growth promotion and inhibitory properties, bioburden, microbial enumeration and genus / species identification. Keystone's microbial procedures follow the current U.S. Pharmacopeia. Also, Keystone Labs has expertise in Analytical capabilities, include HPLC, GC, method development and Validation, Controlled Environment, Utilities and quality systems. We have extensive expertise in developing specific testing protocols for unique processes, providing you with results tailored to your needs.

Below is a detailed list of our expertise and capabilities;

MICROBIOLOGY ANALYSIS

We offer a wide range of microbiological testing

- Total Microbial Counts
- Microbial Limit Testing
- Bacterial Endotoxin Testing
- Antimicrobial Effectiveness Testing
- Identification of Microorganisms
- Aflatoxin Testing
- Presence/Absence of Objectionable Microorganisms
- Total Aerobic Counts and Total Yeast and Mold
- Disinfectant Testing
- Sterility Testing:
 - 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
- 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
- Melting Point/Boiling Point
- Identity, purity and quality of raw materials using compendia or client supplied methods

METHOD DEVELOPMENT AND VALIDATION

All Method Development and validation services will be:

- Carried out by qualified personnel equipped with adequate resources.
- Designed to obtain the range and accuracy relevant to client's needs.
- Handled by utilizing a protocol or plan agreed upon by both the client and by Keystone Labs.
- Communicated effectively and efficiently between Keystone Labs and Clients.
- Summarized in a final report that will be signed off by both the client and Keystone Labs.

CONTROLLED ENVIRONMENT AND UTILITIES MONITORING

Cleanrooms and controlled environments are utilized to control the levels of non-viable and viable particulates that medical devices and pharmaceutical products are exposed to during the manufacturing process. The objective of an environmental monitoring program is to estimate the microbial and particulate content of room air and surfaces. An effective environmental monitoring program can alert you when conditions contributing to excessive microbial levels arise due to ineffective cleaning, sanitation or other personnel/equipment issues. Keystone Labs can provide you with the appropriate level of service that 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/EP/JP)
- 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
- Conductivity
- Bacterial Endotoxin