KEYSTONE LABS

Stability Study Document

June 2022 V.2

A stability study is the recorded data of how the quality of a substance, active ingredient or finished product varies when different environmental factors such as temperature and humidity are introduced. The stability program assesses whether any physical, chemical, or microbiological changes affect the efficacy and/or integrity of the final product, thereby ensuring the regulated product is safe and effective, irrespective of where in the world it will be supplied. Stability testing is conducted to establish a shelf-life for the product and recommended storage conditions.

A good stability study program is required for the registration of any regulated consumer product. It gives both regulators and consumers confidence that the product will perform as expected from the date of manufacture through to the end of the product's shelf life.

Key Contacts:

VP of Business Development
Rod Szarka
p: 780-784-8925 x. 102
e: rszarka@keystonelabs.ca

President
Jodi McDonald
p: 587-458-8411 x. 101
e: jmcdonald@keystonelabs.ca

ABOUT US

Keystone is a GMP accredited lab that delivers analytical and microbiological testing services for pharmaceutical, cannabis and related industries. We have almost 20 years of experience in providing regulated services to the innovative pharmaceutical industry, we go farther than other labs or testing facilities. Our key to success is understanding the integral relationship a contract lab has with its clients, we work as your lab partner and an active member of your team. Keystone helps you better understand, interpret and apply the data generated by our testing. Our testing helps you improve your products and processes, meet your regulatory requirements, and add to your bottom line. We know good science is good business.

The keys to success for Keystone include:

- Reputation for quality and integrity
- Superior Customer Service
- Teamwork

INTRODUCTION

Stability studies are a key component of the life sciences, chemical, food and cosmetic development processes. The focus is to evaluate the effects of external factors such as light, heat, humidity, temperature, and stress on the product. These environmental conditions will assist with determining the product shelf life and storage requirements for consumer safety. There are two common types of stability studies; Real-time and Accelerated.

Stability studies are conducted according to the local regulatory guidelines. In Canada, Health Canada outlines real-time stability study requirements are 25°C / 65% Relative Humidity (RH). The minimum requirements for testing the product are at 3, 6, 9 and 12 months for the first year, twice a year in the second year, and once for each year thereafter until the products fails to meet specifications and safety standards.

Accelerated stability studies are designed to add stress to the product to predict the timeline of product failure. For Canada, the recommended conditions are 40°C / 75% RH. By performing accelerated studies, the degradation can be determined and the potential product expiry date can be extrapolated.

DETAILS

To test the stability of a regulated product, samples need to be stored in environmentally controlled chambers as part of a stability study program.

Samples are then removed from the stability chambers at specified time points and tested for physical, chemical or microbiological changes that would impact product quality, safety and efficacy.

The following information is critical in order to design a good stability study:

- What are the stability zones and stability conditions?
- What is the desired length of the stability studies?
- When do you require test samples be removed from the chamber(s) for analysis during the stability study timeline?
- What testing should be conducted on the test samples to meet your requirements?
- What are the specifications for the product?

The shelf life of a regulated product is commonly estimated using real-time and accelerated stability testing:

- **Real-Time testing**: 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 testing**: Accelerated stability tests (40±2°C / 75±5% RH) provide a means of comparing alternative formulas, packaging materials, and/or manufacturing processes within a shorter test period.

STABILITY CHAMBERS

The chambers used for the stability testing at Keystone Labs are validated Forma Scientific Environmental Chambers. We maintain the equipment to ensure optimal operation, which means that studies are completed with minimal disruption.

Each chamber is monitored through an alarm notification system which assures that appropriate personnel are notified if a chamber is outside of the operating range.

PRICING

Stability Study Conditions	Chamber Rental (Price / Month)	Sample Pull (Price / Pull)	Analytical Testing
Real-Time	$250	$40	To be determined by client
Accelerated	$250	$40	To be determined by client
Custom	$650	$40	To be determined by client

NOTE: All units have been validated and mapped at the appropriate temperatures and RH. Temperature and humidity are monitored using a calibrated chart recorder. The stability chamber is part of the Facility Monitoring System.

GUIDANCE DOCUMENTS

To assist with designing and implementing stability studies which comply with regulations, Keystone Labs follows the ICH Q1A guidelines. These documents define the stability data package for a new substance or product that is required for a registration application within the three regions of the European Union, Japan and the United States. Health Canada endorses the principles and practises described within the Guidance for Industry - Stability Testing of New Drugs Substances and Products (ICH Topic Q1A(R2)) by adopting the ICH guidance.

1. Health Canada: Guidance for Industry - Stability Testing of New Drugs Substances and Products (ICH Topic Q1A(R2)) https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/quality/stability-testing-new-drug-substances-products-topic.html

2. World Health Organization (WHO): Guidelines for Stability Testing of Pharmaceutical Products Containing Well Established Drug Substances in Conventional Dosage Forms https://apps.who.int/iris/handle/10665/62169

REQUEST A QUOTE

Reserve your space in Keystone Labs stability chambers.

Provide our account managers with answers to questions in the “Detail” section of this document and we will provide a quote within 48 hrs.