KEYSTONE LABS

Stability Study Document

June 2021 V.1

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, humidity, and light are introduced. The stability program also includes whether any physical, chemical or microbiological changes affect the efficiency and 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:

Accounts Manager
Stephanie Ostrander
p: 780-540-7717 x. 105
e: sostrander@keystonelabs.ca

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

KEYSTONE LABS

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 pulled at specified time points and tested to see whether there are any physical, chemical or microbiological changes that are likely to impact drug or product quality, safety and efficacy.

The following Information is required to design a good Stability study:

- What are the Stability zones and Stability conditions?
- How long are the Stability Studies?
- When will test samples be pulled from the Environmental Chamber(s) for analysis during the stability study timeline?
- What testing will be conducted on the test samples to meet the client's requirements?

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 of the test period to allow 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 in short-term experiments.

Pricing

Stability Study Conditions	Chamber Rental (Price / Month)	Sample Pull (Price / Pull)	Analytical Testing
Real-Time	Contact Keystone for Pricing		To be determined by client
Accelerated			To be determined by client
Custom			To be determined by client

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

Guidance Documents

Keystone Labs uses the following Regulatory board Guidance documents to assist with designing and implementing stability studies which comply with the policies and governing statutes and regulations. These documents are revised versions of the ICH Q1A guidance documents and define the stability data package for a new substance or product that is sufficient for a registration application with the three regions of the European Union, Japan and the United States. In adopting the ICH guidance, 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)).

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.