Stability Testing Guidance - Supplements

Stability studies are useful tools to help you understand the stability of your supplements over its given shelf life and to determine whether or not the product remains within specification under the labelled storage condition.

Here at ICNE Ltd., we can help manage all of your stability testing requirements. This document provides guidance on planning and organising of stability protocols for supplements.

Stability Study Process:

The diagram below gives you a brief overview of the process flow during a stability study. Each point is discussed in more detail below and we have indicated (underlined) who would be responsible for the management of each point.

Stability Protocols:

There is not one specific stability protocol that every company should follow. Therefore it is the responsibility of the individual companies to set their own parameters and to determine that the stability protocol meets their local product regulations.

We would need the customer to confirm storage conditions, time points to pull samples from storage, and the specific analysis required. Further guidance on all these aspects are detailed below. When we have details of the all the parameters we would be able to help set up a protocol and provide you with accurate quotes.

Storage Conditions:

Stability testing is performed in regulated storage conditions, usually in real time (with parameters of 25°C, 60% humidity), and/or accelerated conditions, (with parameters of 40°C, 75% humidity). Real time is the preferred option, as sometimes with the accelerated conditions, the packaging or product can ruin with higher temperatures and humidity.

Also, spoilage microorganisms behave differently at higher temperatures, therefore microbiological results obtained from samples stored in accelerated conditions may not be representative of those seen in samples kept in real time storage. Stability studies using accelerated storage conditions is usually only recommended in certain circumstances, for example: to assess the viability of active ingredients.

It is generally accepted that accelerated storage conditions means that it cuts storage times approximately by a third (i.e.1 month in real time equals approximately 3 months in accelerated time). These are approximations only. Real time stability testing is always recommended in order to achieve accurate and representative results. For other storage conditions, please contact us directly.

Time Points:

We would need to know at what time points you need your sample pulled from storage and tested. Recommended time points for a product with a 3 year shelf life, in real time storage conditions are 0, 3, 6, 9, 12, 18, 24 and 36 months. Recommended time points with accelerated storage conditions would be 1, 2, 3, 6, 9 and 12 months.

The listed time points are recommendations only, and it is the responsibility of the customer to confirm which time points they would like the analysis performed at.

Analysis of Samples:

We would need to know which particular tests are required at each time point. It is recommended to perform active ingredients analysis (where possible), and possibly microbiology and physical testing, but this can be tailored to meet the customer's needs.

It is also recommended to validate the required analysis in your product prior to commencement of a stability study. This is to ensure the tests methods are compatible with the product.

Further Information:

All samples for the whole stability programme need to be submitted in one go. Samples would need to be in the packaging that you intend to sell the product, which can be monitored at the customer's request. We would manage the whole process for you by organising the storage, sample pull and testing. We would send you a report at each time point, and trending data if numeric results are given and required by the customer.

The minimum size storage unit is 100 litres which incurs a monthly charge (per condition) as well as a sample pull charge.

This document is intended to be a guide only and it is the customer's responsibility to ensure that the entire programme complies with product specific and local regulatory requirements. Please be aware that this document is not guidance for stability testing on licensed medical products. For stability testing on licensed medicinal products please refer to the ICH guidelines Q1a – Q1c.

If you have any further questions or would like us help with your stability testing requirements on supplements, please contact us.