

QUALTECH GROUPE

QUALTECH
AGROBIO
ABIOC
ADN ID
CEVA SECURITE ALIMENTAIRE

STABILITY STUDIES ACCORDING TO ICH NORM

The stability tests provide evidence on how the quality of a product varies according to time and under the effect of various environmental factors (temperature and humidity), while allowing to establish the conditions and the duration of storage.

STUDIES	STORAGE CONDITIONS	SAMPLE FREQUENCIES (general case)
Long term	25°C / 60% HR	T0, T3, T6, T9, T12, T18, T24 et T36 months
Intermediate condition	30°C / 65% HR	T0, T3, T6, T9 et T12 months
Accelerated conditions	40°C / 75% HR	T0, T3 et T6 months

Stability studies must be conducted on all sizes and types of packaging provided for the placing on the market of the product.

They are made with temperature-controlled sterilizer, under controlled humidity and under defined conditions according to ICH standards.

(International Conference of Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use).

Long term conditions allow to define the expiration date of the product, time interval in which the product remains in compliance with its specifications.

Accelerated degradation is a study designed to increase the chemical degradation rate or physical alteration of an active substance, while remaining compatible with the mechanisms involved in normal conservation.

When a significant change occurs during the 6 months of accelerated study, a additional study in intermediate condition must be set up.

It is recognized that an aging study accelerated of 6 months is representative of a study in normal conditions of 24 months.

These various tests allow to appreciate the consequences of a formulation change or process on the preservation of a product, or even the effects of stabiliser.

We propose you several physical, chemical, biological and microbiological tests in various times to determine the conformity of the product (according to the pharmacopoeia or your specifications) during all the duration of the storage:

- description : size, color, shape, appearance
- identification and active ingredients
- dissolution, disintegration, hardness and friability tests
- uniformity of mass
- microbioly analysis

Example of putting in stability on a food complement in capsules (AGROBIO results) :

