Stability Testing

The stability of a product's primary packaging, along with that of its active substances, is a basic quality characteristic that must be evaluated after product has been stored under different environmental conditions

Eurofins offers customers a sample storage service in climatic chambers that simulate different environmental situations, as well as control of the product's critical post-storage parameters.

The laboratories are equipped with climatic chambers with different temperature and humidity conditions and a number of incubators, refrigerators, and freezers that allow performing stability studies according to specific regulations for each type of product (ICH, ISO, CIPAC, etc.)

Storage conditions monitoring includes continuous recording of temperature and humidity using validated software to manage data obtained from the measuring probes. The climatic chambers are subject to qualification at least once a year.

Eurofins provides:

- Advisory on the design of studies under both accelerated and shelf-life conditions
- Storage of the samples under controlled conditions
- Development and validation of methods for products' critical parameters
- Analytical research for the identification of unknown degradation products
- Analytical control of critical stability parameters
- Preparation of preliminary reports for each period of stability
- Preparation of a final report on the stability study plus evaluation of the results obtained.

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Available storage conditions*:

- 25℃ ± 2℃ / 60% ± 5% R.H
- 25℃ ± 2℃ / 40% ± 5% R.H
- 30℃ ± 2℃ / 75% ± 5% R.H
- 30℃ ± 2℃ / 65% ± 5% R.H
- 30℃ ± 2℃ / 35% ± 5% R.H
- 40℃ ± 2℃ / 75% ± 5% R.H
- 40℃ ± 2℃ / 30% ± 5% R.H
- 40℃ ± 2℃ / <25% ± 5% R.H
- 54℃ ± 2℃
- 45℃ ± 2℃
- 5℃ ± 3℃
- -20℃ ± 5℃
- -80℃ ± 5℃

(*) Other conditions can be established depending on the availability of the climatic chambers.

Additionally a cyclic chamber is available with the capability for temperature cycles from -20℃ to +50℃ and humidity from 10 to 90% R.H.

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