

Enlarged services for stability studies

The stability of a product's primary packaging, its active substances and the properties of the drug formulation is basic qualities and characteristics that must be evaluated. This is done after the 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.

You get access to considerable expertise in conducting stability studies. Eurofins has during the last three years performed around 700 studies.

Our laboratories are equipped with climatic chambers under different temperature, humidity and light 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.



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Eurofins provide:

- Advice 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 and final reports for each period of stability

Available storage conditions*:

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

Very large volume chambers are available to suit almost any client need for stability studies.

(*) 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°C to +50°C and humidity from 10 to 90% R.H.

With kind regards,
Eurofins Pharma A/S

Planned Eurofins newsletters

- Eurofins introduces pre-clinical and clinical services from 4 European sites
- Cleaning validation of production lines
- REACH
- New opportunities for microbiological identifications with Eurofins (Microseq)