NAMSA

ICH Stability Studies

Due to the integration of active pharmaceutical ingredients (API) and antimicrobial agents, more medical devices are being considered combination products than ever before. While the stability of these ingredients is often known, it must be tested in conjunction with the device. ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) provides guidelines in a joint effort of regulators and researchers from Japan, Europe and the U.S. to help ensure the safety of these combination products and outline the testing requirements. These testing requirements include specific temperature, humidity and duration specifications as well as tolerances of the chambers used for the storage conditions. After subjecting the combination product to the condition, certain stability-indicating tests would need to be performed to assure potency, functionality and sterility for the intended shelf-life of the product. Continuously monitored chambers for customized long-term or short-term (accelerated) services for your stability programs give you access to NAMSA's analytical, microbiological and toxicological labs throughout your entire design process.

Accelerated studies are designed to increase the rate of chemical degradation or physical change of a substance or product by using exaggerated storage conditions as part of the formal stability study. Data from the studies, in addition to long-term stability studies, can be used to assess longer term chemical effects of non-accelerated conditions and to evaluate the effect of short-term excursions outside the label storage conditions.

Intermediate studies conducted at 30°C/65% Relative Humidity (RH) are designed to moderately increase the rate of chemical degradation or physical changes for a substance or product intended to be stored long term at 25°C. Long-term studies designed to represent real time use as required by the FDA are also available under the recommended storage conditions for the shelf life proposed (or approved) label claim.

The following stability conditions are available for your use:

25°C ± 2°C/ 60% RH ± 5% RH
30°C ± 2°C / 65% RH ± 5% RH
40°C ± 2°C / 75% RH ± 5% RH
5°C ± 3°C
-20°C ± 5°C

NAMSA also continues to offer a variety of additional chambers for your shelf life and package testing needs. These chambers are available in a wider range of temperatures (from 45-60°C) and humidity conditions (from ≤20% - 70% relative humidity) and provide options for aging up to the equivalent of five (5) years real time. For more information regarding this and other testing inquiries, contact a NAMSA Account Executive.

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