intertek
Total Quality. Assured.

GMP & CMC LABORATORY SERVICES

ICH STABILITY STORAGE & cGMP STABILITY STUDIES

Pharmaceuticals & Biopharmaceuticals

CASE STUDY

Supporting our client's novel device development

An innovative developer of inhalation medicines wanted to ensure that their new inhaler design was suitable for registration.

Our Solution

Intertek characterised the parameters that define performance and function (critical quality attributes). The effects of long term storage (stability study) and simulated patient use / misuse were studied.

Benefit Delivered to our Client

Our experts confirmed that the device displayed consistent performance across 60 days in use and the medicine was stable for three years under recommended storage guidelines. We were able to verify that the design was suitable for our clients to proceed with their market release, which was successful.

Stability Storage and Stability Testing

Stability programs are a fundamental component of pharmaceutical product development, playing an essential role across the lifecycle of pharmaceutical products and in particular, during development of Investigational New Drug (IND) and New Drug Application (NDA) submissions. The influence of environmental factors such as temperature, humidity and light enables storage conditions, retest intervals and shelf lives to be established.

Pharmaceutical stability studies are complex and present many challenges. They demand considerable time and scientific expertise. It is important to select an experienced outsourcing partner who offers efficient study management, flexible storage conditions and testing capabilities which satisfy all regulatory criteria for your real-time, accelerated or forced-degradation studies. Stability testing can also present significant analytical hurdles that require knowledgable experts to develop and validate stability indicating methods.

With a network of ICH stability facilities in the UK, US and Australia, we offer extensive storage capacity and a range of conditions including climatic walk-in chambers, cabinets and refrigeration, as well as freezer storage which is fully controlled and monitored with back-up chambers at each site. All sites have 24-hour alarm systems with dedicated on-call teams to react to any excursions from storage conditions. Our teams provide professionally managed Good Manufacturing Practice (cGMP) stability programs for even the most complex of dosage forms, APIs or product types, including orally inhaled and nasal drug products (OINDP), biopharmaceuticals, consumer healthcare, medical devices and vaccines. We also offer a responsive and bespoke stability contingency and disaster recovery service to help you mitigate the risks associated with costly stability trials.

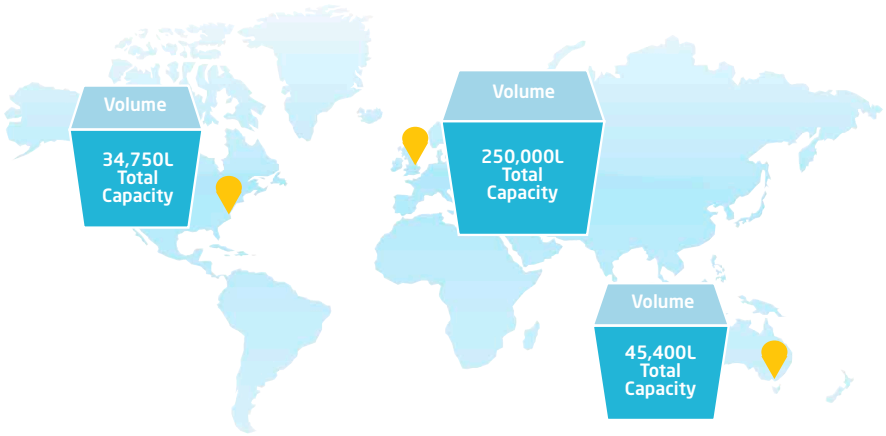
Over 20 years of experience in stability studies

- Pharmaceuticals
- Biologics, Vaccines
- Orally Inhaled and Nasal Drug Products
- Consumer healthcare & Personal care products
- Solid, Liquid, Gels, Suspension Dosage Forms
- Innovative Drug Delivery
- Injectables

GMP stability services

- cGMP Registration Stability Programs
- Storage at all ICH Conditions
- Protocol Design and Program Management
- Stability Testing for APIs, Clinical Trial Materials, Formulated Products
- Support for Accelerated Stability Assessment Programs (ASAP)
- Development & Validation of Stability Indicating Methods
- Photostability (ICH Q1B Options 1 & 2)
- Bespoke or Specialised Conditions
- Temperature Cycling, Freeze-Thaw and Shipping Studies
- Stability Contingency and Disaster Recovery Storage
- Tailored Reporting (Timepoint and Final Reports)
- Forced Degradation Testing with Degradation Product Identification & Quantification
- Real-Time Stability Testing
- Accelerated Stability Testing
- Formulation Stability Testing
- Biologics Stability Studies
- Specialist Expertise for OINDP Stability Programs
- Extractables / Leachables

Stability Storage Global Network



Intertek offers current cGMP compliant stability studies for the pharmaceutical, biopharmaceutical and consumer healthcare market. We have an extensive range of ICH stability conditions available to our customers across the Intertek network:

- 21°C / 45% RH
- 25°C / 40% RH
- 25°C / 60% RH
- 30°C / 25% RH
- 30°C / 35% RH
- 30°C / 65% RH
- 30°C / 75% RH
- 40°C / 75% RH
- Cabinets 50 °C, 57 °C, 60 °C
- Storage at 2-8°C, -20°C, -40°C, -80°C
- Photostability (ICH Options 1 & 2)
- Specialised Conditions
- Freeze / Thaw Cycle Tests

Analytical testing for stability programs

Our analytical laboratory network provides development and validation of stability indicating methods through state-of-the-art technology such as UPLC-MS, LC-MSMS, GC-MS, HPLC, GPC, UV-VIS, GC to identify and quantify degradation products. Routine time point testing includes tests such as assay and impurities, excipient degradation, dissolution, water content, hardness, friability, disintegration and more. Intertek's scientists have specialist knowledge for OINDP stability testing including measurement of particle or droplet size, providing data critical to understanding the size distribution of the delivered formulation and the delivery of the drug from the device.

With unrivalled know-how in extractables and leachables studies, we can ensure that the complete product and packaging system demonstrates sufficient stability and protection over the relevant lifecycle of your product.

Biopharmaceutical stability expertise

Changes in biopharmaceutical stability due to aggregation, degradation, chemical or physical instability can alter protein folding and the 3-dimensional protein structure, potentially affecting the quality, safety, biologic activity, and efficacy of the drug.

Our scientists are adept at conducting biopharmaceutical forced degradation, accelerated stability studies, short and long-term stability studies for proteins, biosimilars, antibodies or other biologics. Our expertise in establishing stability-indicating profiles addresses potential degradation pathways for your specific biologic through stress testing and forced degradation. By applying expert method development skills, we provide assurance that any changes in physicochemical properties, structure, aggregation, biological activity, visual appearance, impurities, excipient degradation, and container/closure interactions will be detected. We employ a host of traditional and complex analytical methodologies to determine stability including RP-HPLC, IEX, SEC (MALLS), DLS or electrophoresis. We also conduct bioassay / potency testing.

Our experience

With over 25 years of experience in conducting stability programs, we apply our comprehensive understanding of the latest regulatory and technology developments to offer a truly flexible stability outsourcing partnership with an integrated storage and testing capability which allows you to focus on your core business objectives. As a key service from our GMP & CMC laboratory teams, we apply strategic approaches to your stability programs that mitigate risk, optimise efficiencies and help you meet your next milestone.

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