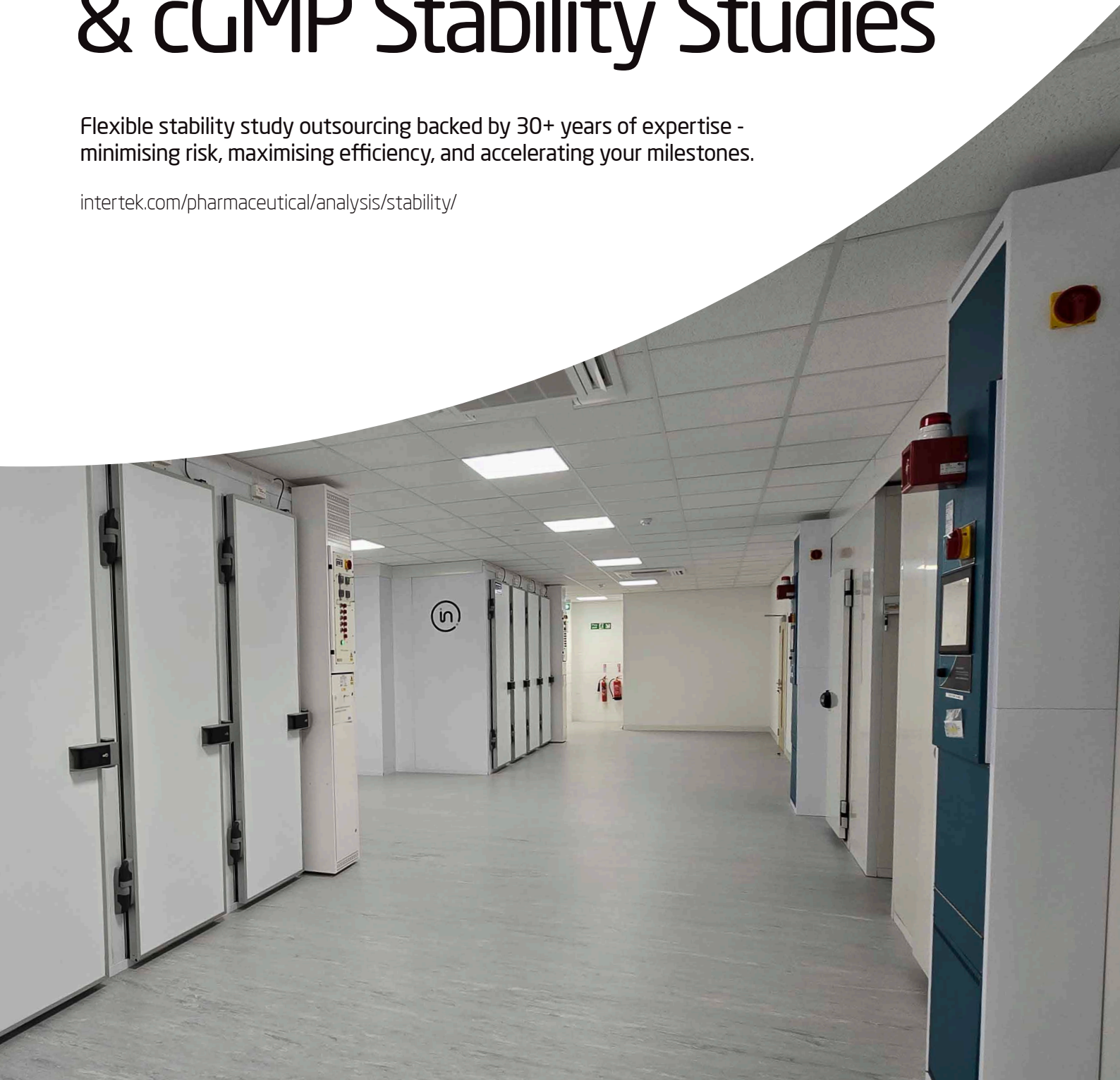


GMP & CMC Laboratory Services

ICH Stability Storage & cGMP Stability Studies

Flexible stability study outsourcing backed by 30+ years of expertise -
minimising risk, maximising efficiency, and accelerating your milestones.

[intertek.com/pharmaceutical/analysis/stability/](https://www.intertek.com/pharmaceutical/analysis/stability/)





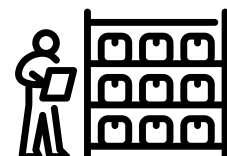
Over 30 years' expertise delivering flexible, integrated stability solutions that reduce risk and keep your programmes on track.

Stability studies are a key part of pharmaceutical development, helping to show how factors like temperature, humidity and light affect a product's quality, storage, and shelf life. They are complex and time-intensive, requiring specialist expertise and reliable testing methods to ensure studies meet regulatory expectations.

With over 30 years of experience and a global network of ICH-compliant facilities across the UK, US, and Australia, we provide flexible storage, comprehensive testing, and fully managed cGMP stability programs. Our expertise spans pharmaceuticals, biologics, OINDPs, and consumer healthcare products. We offer a wide range of storage conditions, including climatic walk-in chambers, cabinets, refrigeration, and freezer storage, all supported by advanced facilities, 24/7 monitoring, backup chambers, and dedicated on-call teams to safeguard your studies.

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
- Ultra-Low Temperature Storage (-80 and -150oC)
- Temperature Cycling, Freeze-Thaw and Shipping Studies
- Tailored Reporting (Timepoint and Final Reports)
- Forced Degradation Testing with Degradation Product ID & Quantification
- Real-Time Stability Testing
- Accelerated Stability Testing
- Formulation Stability Testing
- Specialist Expertise for OINDP Stability Programs
- Extractables / Leachables

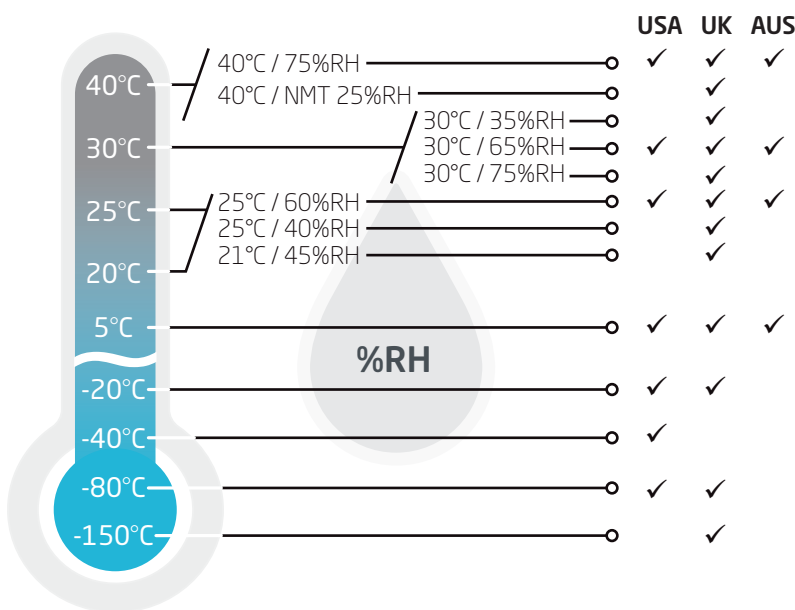


Seamless stability and analytics, from development to delivery

GLOBAL CAPACITY



Wide range of conditions available



- All ICH Climatic Stability Zones (I to IVb)
- Extensive range of bespoke storage
- Temperature cycling
- Photostability studies
- Ultra low temperature storage
- Additional stability storage capacity supporting E&L in China, India and Switzerland

'With over 30 years of experience in designing and managing pharmaceutical and biopharmaceutical stability studies, we offer a truly flexible stability outsourcing partnership'

Integrated Stability & Analytical Development

Our integrated stability and analytical capabilities combine advanced method development, validation, and routine testing to support the full product lifecycle. Using state-of-the-art technologies, we identify and quantify degradation products, assess critical quality attributes, and deliver stability-indicating methods for a wide range of pharmaceutical and biopharmaceutical products. Also providing specialist expertise in OINDP testing as well as extractables and leachables (E&L) studies.

From small molecules to complex biologics, our scientists design and execute forced degradation, accelerated, and long-term stability studies to characterise degradation pathways and ensure product integrity. Supported by a global network of cGMP and ICH compliant facilities offering extensive storage conditions, we provide a seamless, end-to-end solution to safeguard product quality, performance, and regulatory compliance.






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