Reference Standard Storage and Analytical Testing

Reference standards are important materials for the analysis of stability timepoint samples and to assist you in completing your development projects. Cambrex offers long term storage and analysis of these materials to ensure a consistent, high-quality supply for your needs.

Cambrex and Q1 Scientific's stability storage and sample management capabilities serve the Pharmaceutical, Medical Device and Life Sciences industries, with locations across North America and Europe.

The Analytical Services laboratory at our Edinburgh facility can perform the analysis necessary for initial characterization of your reference standard and routine re-analysis for generation of certificates of analysis to allow release and use of existing reference standards.

Reference Standard Storage

At Q1 Scientific, our expert team and state-of-the-art cGMP facilities set us apart. With extensive validation and quality systems we provide the following secure, transparent, and trusted storage services for long-term storage of reference standards.

- ICH stability storage
- Ultra-low freezer storage
- Reference/retain storage
- Sample management
- Disaster recovery

Monitoring and Backup

- **24/7 Notifications:** 24/7 alarm system connected to each storage chamber to alert of any deviations in control parameters recorded by the monitoring system.
- **Network Support:** All networks are UPS supported and connected to an external notification center to alert if there is any connection failure. Data is backed up off-site daily.
- **CCTV Monitoring:** CCTV throughout the building. Approved for storage of controlled drugs.
- **Generator Backup:** External generator to provide power to the entire building in the event of a power failure.

About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 40 years of experience and a growing team of over 2,400 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.

About Q1 Scientific

With a decade's worth of expertise, Q1 Scientific is transforming the way companies store their products, enabling faster drug launches to market, and saving companies the expense of building and monitoring their own storage chambers.

Learn more about our stability storage and testing services. Contact us today. Visit www.cambrex.com/contact.

Controlled Shipping

Shipping for all materials and products between Q1 Scientific and Cambrex Edinburgh are conducted by established 24hr specialist bio-medical courier services with recorded and verified temperature monitoring

Analytical Testing for Reference Standards

For routine re-analysis and supply of Certificates of Analysis

- Appearance
- Confirmation of Identity
- Assay by HPLC
- Purity by HPLC
- Water Content by coulometric Karl Fischer.

Additional analysis required for initial characterization of primary or secondary reference standards.

- GC by Flame Ionisation and Electron Capture for residual solvent determination for both halogenated and non-halogenated solvents determination.
- Thermal analysis by Differential Scanning Calorimetry (DSC) and Thermogravimetric Analysis (TGA).
- NMR
- FT-IR
- Residue on Ignition
- Crystallinity by X-Ray Powder Diffraction.

Maximizing Opportunities, Minimizing Risk

People

- Solution-driven.
- Sample management and testing experts.

Technology

- Bespoke sample management system.
- Innovative web-based study visibility.

Process

- Operating to cGMP standards.
- Purpose-built, state-of-the-art facilities.

Why work with us?

- **Expertise:** Secure storage and experienced testing of your samples.
- **Maximize space:** Free up valuable space and resources in your factory to work on your core operations.
- **Transform CAPEX to OPEX:** With a reduction in your capital investment for stability storage, testing facilities and infrastructure.
- **Flexible capacity:** Scale up or down your stability storage and analytical testing with no minimum contract.
- **Manage risk and compliance:** Stability storage and testing at cGMP facilities with extensive validation, quality systems, 365/24/7 security monitoring, backup power and systems.
- **Complete visibility:** Access your storage data 24/7 through the secure Q1 Scientific documentation portal.

Facilities Overview

Waterford, Ireland	Liege, Belgium	Edinburgh, Scotland
30,000 sq ft facility	20,000 sq ft facility	15,000 sq ft facility
39 walk-in stability storage chambers	6 walk-in stability storage chambers	9 UHPLC Systems with UV/DAD/CAD
22 ultra-low freezers	1 reach-in stability storage unit	2 KF Coulometers with Vaporiser
6 reach-in stability storage units	2 ultra-low freezers	2 GC-HS with FID and ECD
3 reach-in freezers	2 -20˚C freezers	pH analysis
1 photostability unit		PSD by Wet & Dry Dispersion
1 thermal cycling unit		Thermal Analysis by DSC/TGA
		Crystallinity by XRPD
		Physical Testing
		Potent Handling Capability to 10 ng/m^3
		Method Development & Validation