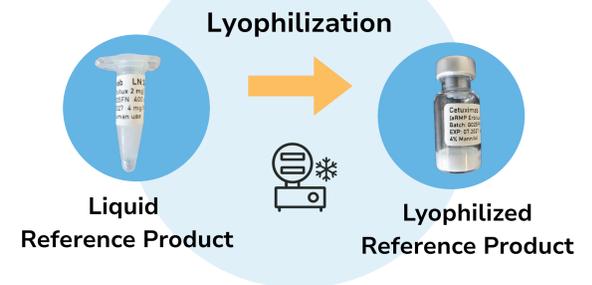


Choose Your Format: Clinical Antibodies Without Cold Storage

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Background

Reference products are the same molecules as those given to patients, providing biologically relevant controls in bioassays. High-quality reference products are essential for reliable biotherapeutic characterization. We provide clinical-grade reference products, in frozen liquid and lyophilized format, offering researchers flexible solutions for their analytical needs. While liquid formats provide benchmark reliability and proven performance, lyophilized formats deliver additionally extended stability, simplified logistics, and enhanced global accessibility.

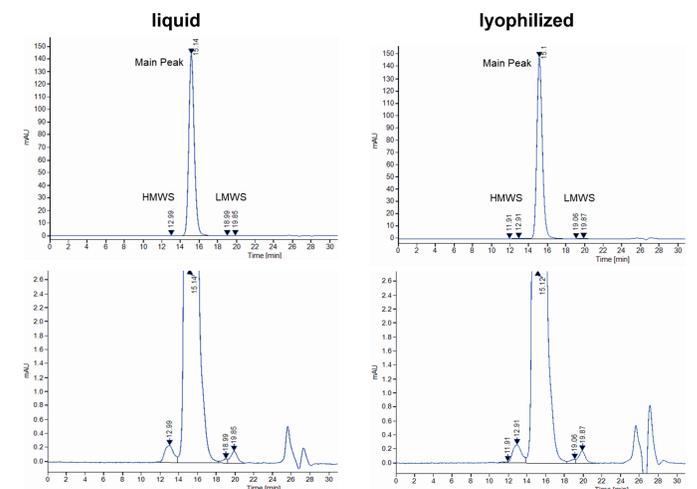


Results

This study represents the **first availability** of clinical-grade Cetuximab in **lyophilized format** for research applications, expanding beyond the traditionally available **liquid format**.

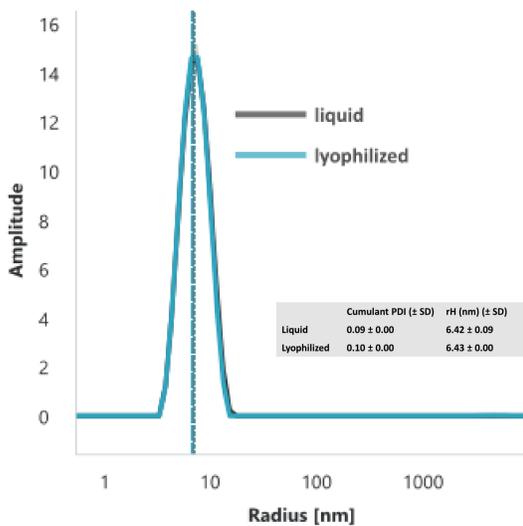
- Both **liquid** and **lyophilized formats** demonstrated **exceptional analytical robustness** and retained **full bioactivity** profiles throughout testing.
- **SEC analysis** and **scattering techniques (DLS)** confirmed preserved **monomer integrity** and **size homogeneity** across both formats.
- **NanoDSF** revealed that **lyophilized Cetuximab** maintained **conformational stability** equivalent to liquid counterparts.
- **Sucrose-spiking** even **enhanced thermal stability** by shifting thermal unfolding to higher temperatures.
- Comprehensive **ADCC bioassay** showed **identical functional performance** with normal assay-level variability observed between formats, **confirming the viability** of this **innovative dual-format approach**.

Fragmentation /Aggregation – Size Exclusion Chromatography



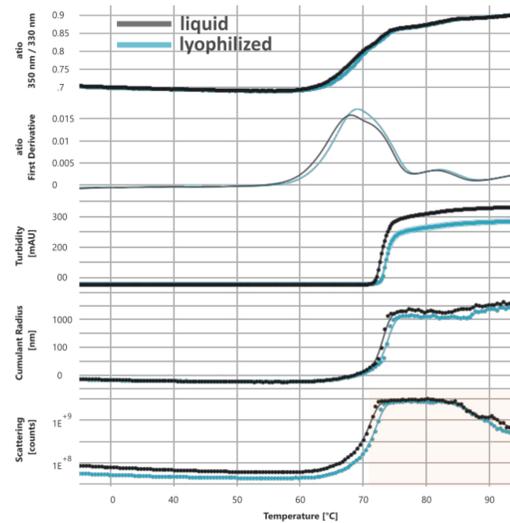
Analysis of fragmentation and aggregation of liquid (left panel) and lyophilized reference product (right panel) Cetuximab by SEC-UV. The chromatograms display high molecular weight species (HMWS), the main peak, and low molecular weight species (LMWS). In both cases, the main peak accounts for 99.5 %.

Fragmentation/ Aggregation – Scattering Techniques



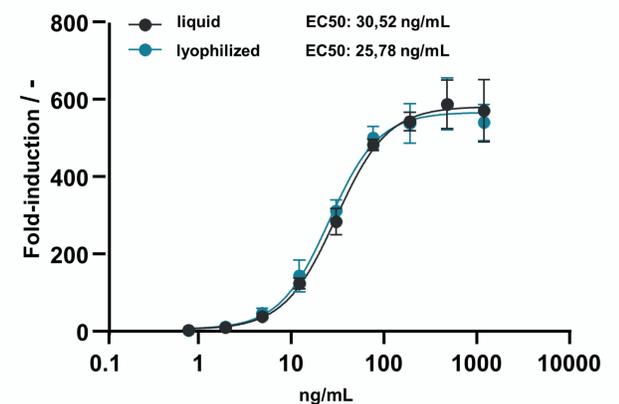
DLS (Dynamic Light Scattering)-Analysis reveals similar molecule sizes and high sample homogeneity in both, liquid and lyophilized clinical-grade Cetuximab format.

Thermal Stability – Spectroscopic & Scattering Techniques



Robust thermal stability and high similarity in liquid and lyophilized clinical-grade Cetuximab was confirmed by thermal unfolding analysis using nano DSF (nano Differential Scanning Fluorimetry), back reflection and DLS/SLS (Dynamic- and Static Light Scattering) measurements. Addition of sucrose even shifted the onset of thermal unfolding to higher temperatures.

Bioactivity - Antibody-dependent Cellular Cytotoxicity Assay (ADCC)



ADCC Assay: Comparison of fold induction (based on normalized firefly luciferase signal) and non-linear four-parameter fit of liquid and lyophilized reference products. Fold induction is plotted against sample concentration. The ADCC assay demonstrates pronounced bioactivity in both liquid and lyophilized formats.

Methodology

Cetuximab (Erbix®), a therapeutically licensed EGFR-targeting monoclonal antibody, was comprehensively analyzed in both liquid and lyophilized formats using multiple analytical techniques. Advanced quality assays included size exclusion chromatography (SEC) for aggregation assessment, turbidity measurements, nano DSF/DLS* for conformational stability analysis, and bioactivity evaluation via reporter gene assays. Physico-chemical attributes were systematically compared to demonstrate analytical equivalence between formats.

Conclusions

Reference products contain therapeutic molecules, serving as biologically relevant controls in bioassays. This study demonstrates that the lyophilized reference product is analytically equivalent to the frozen liquid reference product, offering a new format option for therapeutic antibodies. The dual-platform approach provides greater flexibility for drug development, manufacturing comparisons, and bioassay applications. Both formats serve as reliable reference products for bioassay validation and as benchmarks in pharmaceutical development, supporting quality control, comparability studies, and method validation across diverse biotherapeutic applications.

* Analysis performed by NanoTemper Technologies. We thank NanoTemper Technologies for their support