

Daikyo Crystal Zenith®

Case Study

Solving the Challenge of Cold Storage



The Situation

There is growing demand in the biopharmaceutical industry for advanced drug containment systems for sophisticated biologics. Many new biologics require cold storage environments. While glass has traditionally been used to store and deliver many injectable drugs, it can be unstable in cold and cryogenic storage conditions, and poses a risk of breakage with thawing.

The Challenge

A major obstacle in bringing biologics to market is the need for quality packaging and storage systems that can withstand low temperatures and resist breaking while also maintaining the viability and functionality of a living cell product. Many biologics are stored at extremely low temperatures, and challenges in container closure performance can arise when storing in conditions below -90°C . In a vial-stopper-seal system, the elastomer has to seal properly against the vial flange, which is the interface between the closure and the vial. With extreme temperatures, maintaining tolerances and flange consistency within the whole system can be a challenge.

The Solution

Daikyo Crystal Zenith vials are designed to stand up to ultra-cold and cryogenic environments and help protect the safety and integrity of complex injectable drug products. In extreme environments, flange consistency in terms of size and dimension is more consistent with plastic than with glass. Customers have selected the Daikyo Crystal Zenith vial system with FluroTec® stoppers to help provide a barrier against extractables and protect against the risk of contamination during cryogenic storage. In a study conducted by the Indiana University of School of Medicine, it was determined that freezing Crystal Zenith vials did not affect the mechanical strength and durability of the vials or their closures. Temperature or length of storage did not affect the outcome of the study. In addition, it was found that cells stored for six months exhibited rapid recovery two hours after thawing, with all samples showing greater than 95 percent viability.