

Daikyo Crystal Zenith®

Case Study

Solving the Challenge of High pH Injectable Drug Products



The Situation

Delamination has emerged as a source of concern for the United States Food and Drug Administration over the past several years, resulting in multiple product recalls. Such recalls can cost in excess of \$50 million per incident, and affect public perception of a brand or pharmaceutical manufacturer.

The Challenge

A leading pharmaceutical manufacturer needed a large volume storage system to contain diluent used in an injectable treatment for pulmonary arterial hypertension. The drug's chemistry interacted with glass vials, causing delamination, or flaking, inside the containment system – putting patients at risk for injecting glass particulate. Such interaction is especially prevalent with high pH medication, including many biologics, biopharmaceuticals, and other new and advanced therapies.

The Solution

Unlike glass, Daikyo Crystal Zenith vials, which are made from a cyclic olefin polymer, will not delaminate. A comparison of a glass vial with a Crystal Zenith vial after 57 days at pH 10 found signs of delamination in the glass vial, but not in the Crystal Zenith vial, even at microscopic levels. Crystal Zenith containment systems have a low risk of chemical interactions and are compatible with high pH products thanks to a high resistance to delamination.

“We’re proud to work with one of the world’s leading pharmaceutical companies to help safely and reliably bring critical treatment options to patients. With glass-like transparency and low risk of chemical interactions, especially for products with high pH, Crystal Zenith vials can help ensure the stability, purity and efficacy of injectable drug products.”

Eric M. Green
President & CEO

Additionally, Crystal Zenith can help maintain the purity of packaged drugs by reducing exposure to extractables, which minimizes potential leachables in the drug product. Many biopharmaceuticals and pH-sensitive drug products have unique packaging requirements, and Crystal Zenith polymer-based containment systems offer an option to help improve stability, patient safety and regulatory compliance.