



Maximizing Value

Daikyo Crystal Zenith[®] Vials



High-quality, Break-resistant Container Closure Systems

THE SITUATION

In 2010, several pharmaceutical manufacturers issued voluntary recalls of certain lots of drug products because of the presence of glass flakes or lamellae. While the causes can vary, the most likely explanation is **glass delamination**. This phenomenon, which occurs over a period of time typically ranging from 3 to 24 months, is usually first observed as glass particles and then as glass flakes. The cause of delamination is complex, since breakdown of the internal glass surface can be caused by a combination of factors including pH, type of buffer and the inclusion of other complexing agents that are risk factors for glass. Although this is a concern for all parenteral products packaged in glass, two cases involving biopharmaceutical products (Hylenex[®] and Epogen[®]/Procrit[®]) were reported in 2010. As a result, Hylenex and numerous lots of Epogen/Procrit totaling nearly 324,000 vials were withdrawn from the market.



Glass particles are also generated when the glass tubing stock is sectioned by thermal shock into the selected length when forming a vial or syringe barrel, and these particles may not be fully removed during the washing process. **Glass breakage and defects** are also key areas of concern. Defects in glass tubing (knots, stones, etc.) can be carried over during the formation of the vial or syringe barrel. These are defects from the forming process; however, cracks/breakage can also occur during filling or transportation. Vial to vial collisions on the filling line can create small cracks or minute holes that transverse the syringe or vial wall. These will eventually leak and may not be spotted until the vials reach the customer and lead to product recalls.

In situations like this, it is easy to see how container closure systems can affect your drug product. To avoid potentially costly recalls and investigations from issues such as breakage or particulate contamination, drug manufacturers must have an innovative solution.

THE SOLUTION: Daikyo Crystal Zenith Vials

With the development of cyclic olefin polymers such as Daikyo Crystal Zenith, manufacturers can offer high quality, transparent, break-resistant container closure systems that are likely to be less reactive than glass, and, unlike glass, do not form glass flakes or lamellae. The product is manufactured in an ISO Class 7 clean room and is also 100% vision inspected.

Daikyo Crystal Zenith vials are a logical alternative to glass for biopharmaceutical drug products that may need to be stored and shipped at cold temperatures. The vials also maximize the stability, purity and efficacy of any drug product.



Valuing the Cost of Quality Issues

Material Consistency

Material consistency can be the key to ensuring that a drug product moves quickly from trials to market. Crystal Zenith vials offer a variety of benefits to customers, including:

- 100% vision inspected
- Lower extractables
- Reduced adsorption characteristics
- Helps reduce breakage and hence returns of finished product
- Excellent for packaging biologics and cell therapy applications
- Provides superior barrier properties compared to other plastics
- Ideal for cold storage applications

Regulatory Expediency

Daikyo Crystal Zenith vials are used for both brand and generic drug products in a variety of therapeutic areas, including osteoporosis, oncology, antifungal and radiology. The vials have been proven in the market for more than a decade, and have met or exceeded the quality requirements of regulatory agencies across the globe.

To expedite the testing and approval processes, pharmaceutical companies can select a Crystal Zenith containment solution for the lifecycle management of their drug product:

- Screw-cap containers are available for bulk storage during research and development.
- Vial-based container closure systems can be used in preclinical trials through commercialization.
- Prefillable syringes can be used in commercialization.
- To help differentiate a product, the Crystal Zenith material can be readily molded into a variety of shapes, offering the drug manufacturer the option to design a unique delivery system.

Ease of Filling Line Transition

Your glass filling line can be easily adapted for Crystal Zenith vials (sterile or non-sterile) with minimal changes. Many pharmaceutical companies are currently using Crystal Zenith vials in their glass filling lines. With minor changes to protect against scratching and slower rail speeds, filling of Crystal Zenith vials has been accomplished successfully. Currently, many companies have filed or will shortly file their Crystal Zenith products with the United States, European and Japanese regulatory authorities.



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Daikyo Crystal Zenith vials are the clear choice for mitigating risk while enhancing the quality of your drug's container closure system. For more information, contact West's Technical Customer Support at:

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