

Mitigate Drug Packaging Risks

Biopharmaceutical companies face many difficult decisions when developing, filing and marketing a new drug product. Once the product enters clinical trials, the developer must demonstrate stability over the drug's intended shelf life. Any potential interaction between the drug and its primary packaging system must be evaluated. Extractables and leachables from packaging components could affect the drug. Processing aids such as free silicone oil may cause protein aggregation of a drug product over time. To minimize interactions, maximize drug/packaging compatibility and provide solutions, West and its partners develop packaging system alternatives.

This issue of *The Source* features an innovative prefillable syringe system manufactured from a cyclic olefin polymer. The syringe system is silicone-oil-free and is delivered ready-to-use. We'll also tell you how to request samples of the most modern packaging solutions for your drug product.

West Introduces the Market's First Silicone-Oil-Free, Ready-to-Use Syringe System

West has introduced the market's first silicone-free, ready-to-use prefillable syringe system. The Daikyo Crystal Zenith® syringe offers biopharmaceutical companies a total system solution that can mitigate risks associated with glass syringes.

"More drugs are coming to market in prefillable syringe systems," said Mike Schaefer, Vice President, Marketing, Europe. "Many of these high-value drugs require a delivery system that will protect their potency from the time they are filled to the time of administration. The characteristics of the Crystal Zenith syringe are superior to glass and will provide important benefits to pharmaceutical and biopharmaceutical companies, the people who administer the drugs and, most important, for patients.

"Our first offering is a 1mL luer lock system that is suited for packaging and administering large-molecule biopharmaceuticals and vaccines," said Mr. Schaefer.

West introduced the Crystal Zenith prefillable syringe system to the European market at Interpack 2008 in April. The North American introduction will be at the AAPS National Biotechnology Conference in Toronto, June 23–25.

DAIKYO RU
Crystal Zenith®
First in silicone-free solutions.

The syringe barrel is manufactured from Crystal Zenith, a proprietary cyclic olefin polymer developed by Daikyo Seiko, Ltd., that is market-proven in Europe, Japan and the United States. Crystal Zenith is break-resistant, which helps reduce product loss during filling, shipping, storage and administration. The material is highly transparent and drainable, can be autoclaved at 121°C and has excellent low-temperature characteristics, including tolerance to freeze-drying and liquid nitrogen exposure.

The Crystal Zenith prefillable syringe system includes a piston and nozzle cap with Daikyo Flurotec® barrier film on the drug contact surfaces. Flurotec imparts lubricity, so there is no need for free silicone oil to enhance functionality. As a result, manufacturers can eliminate the possibility of silicone oil from the syringe barrel and piston transferring to the drug product, a cause of protein aggregation and a possible source of immunogenicity risk and product returns. The absence of silicone oil dramati-



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cally reduces the age-related variability of the Crystal Zenith syringe system's functional properties compared to systems currently in the market.

To decrease the risk of incompatibility between the components and the drug, Flurotec film provides an effective barrier against organic and inorganic extractables. The fluorocarbon film reduces sorption of the drug product and improves drainability.

The combination of a Daikyo Crystal Zenith syringe barrel or cartridge and a fully laminated Flurotec piston creates a unique silicone-oil-free system that provides consistency in the critical functional properties of piston release and travel force, making the system the ideal choice for auto-injector applications.

Daikyo Seiko manufactures the Crystal Zenith syringe system at its facility in Japan using automated, world-class processes in a clean room environment. The components are vision-inspected for a virtually defect-free product. Daikyo and West worked together to develop a packaging system that is appropriate for introducing the pistons and syringe barrels directly into aseptic and barrier isolator filling lines.

Sample Kit Includes Delivery Systems for Biopharmaceuticals

West's redesigned and repacked biotech kit is now available for sampling. The West biotech kit contains up to 10 samples of high-quality packaging components, accompanied by a comprehensive information package that describes the benefits and use of each product. The kit also includes information to help you use West to conduct analytical testing for your drug product and delivery system. The kit was developed to allow easy access to innovative primary packaging solutions for new drug products or differentiation of marketed drugs.

The biotech kit is available with 20mm and 13mm stoppers and vials.

The kit includes:

- Injection stoppers with FluroTec barrier film
- Lyo stoppers with FluroTec barrier film
- Flip-Off® seals with TruEdge® technology for proper crimping
- Glass vials and Daikyo Crystal Zenith vials
- Prefillable syringe plungers with FluroTec barrier film
- Needle shields in an innovative anti-cracking formulation (two sizes)
- Easy Turn tip caps in an innovative anti-cracking formulation (two sizes)
- 1mL Daikyo Crystal Zenith silicone-oil-free syringe system
- Two devices for reconstitution and mixing

To request your biotech kit, contact Sascha Karhoefer in Europe or Koh Sok Tiang in Asia Pacific. We can also provide a kit to meet requests for specific product samples.



The West sample kit includes packaging systems and components suitable for biopharmaceutical drug products.

Did you know?

West's long-standing marketing and technology transfer agreement with Daikyo Seiko, Ltd. has broadened both companies' capabilities in global markets. The relationship has enabled West and Daikyo to develop products that help customers mitigate drug product development risks and enhance patient safety. The agreement permits West to market Daikyo products globally outside of Japan and for Daikyo to market West products in Japan.

Daikyo Seiko is Japan's leading manufacturer of high-quality pharmaceutical drug delivery system components. Daikyo's products include serum and lyophilization stoppers, syringe plungers and tip caps, and Daikyo Crystal Zenith vials and syringe barrels. Daikyo has developed market-leading materials and processes such as Flurotec barrier film, Crystal Zenith and B2-Coating.

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