Daikyo Crystal Zenith®

Case Study

Solving Drug & Containment Compatibility Issues

The Challenge

Recently, a customer determined that an acidic drug was causing liquid egress from a Luer-lock syringe into the ribs of the piston during the sterilization process. A root cause investigation determined that the failure was the result of the fill and finish processes used by the customer. While these processes were sufficient for many drugs, they were not compatible with this particular product for maintaining system integrity. Since container closure integrity was at stake, the company reached out to West for guidance.

Considerations

Working closely with its customer, the West Analytical Laboratory team identified and acknowledged the correlation between the fill and finish processes and container closure integrity. A list of recommended process and equipment modifications was established to help ensure that the syringe piston would be handled and placed properly into the syringe to limit or eliminate liquid egress. Numerous line trials were conducted and further recommendations on piston handling and placement were made to help the customer ensure container closure integrity.

The Solution

Using a Daikyo Crystal Zenith 5 mL Luer-lock syringe system, as well as the expertise of the West fill-finish processing team, the customer was able to confirm that the liquid egress occurrences had reached acceptable quality levels. With West's support, the customer achieved success for its drug product, and drove a solution for a specific compatibility issue.

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