DAIKYO
Crystal Zenith®
THE CLEAR SOLUTION

West®

CRYSTAL ZENITH® 2.25mL INSERT NEEDLE PRE-FILLED SYRINGE SYSTEM CASE STUDY

How to protect a modern silicone oil-sensitive biologic drug for self-injection of 2.25mL

OVERVIEW

Modern biologics, such as proteins and monoclonal antibodies, exert demanding requirements on their containment system, which can be difficult to navigate if a platform approach to packaging has been used in the past. This platform approach did no favours for customer X though, because they experienced expensive project delays when they selected their "tried and tested" large volume, glass syringe system to package a drug to be used in an auto-injector for self-administration.

"West & Daikyo have addressed key market needs with the development of silicone oil-free, tungsten-free (Crystal Zenith®) CZ polymer pre-fillable syringe system offering, incorporating a Flurotec™ plunger. CZ, a cyclic olefin polymer, is a clear, biocompatible material that overcame problems associated with glass."

– Device manufacturer

APPROACH

The formulation development team at customer X picked their platform glass syringe system to package their new biologic drug in development, yet subsequent time pulls of stability samples showed the drug was silicone sensitive which, in turn, made the drug unstable. Analytical testing showed the presence of both visible silicone and protein in the drug product forcing the formulation team to reassess the primary packaging system.

The biologic molecule required a pre-filled syringe system with as low silicone oil as possible to maintain drug stability, which included both the syringe barrel and drug facing surface of the plunger. In addition, the new containment system was expected to perform as well as a glass system with respect to functionality, which includes break loose, extrusion and gliding forces-, injection force-, rigid needle shield (RNS) removal force-, and container closure integrity. These were critical performance factors as the pre-filled syringe system would be used within an auto-injector for the final drug delivery system.

RESULTS

- The drug was stable in the CZ syringe system
- The customer was able to show better results for sub-visible particles with CZ than with glass and other polymers
- CZ met USP < 1207 > for Container Closure Integrity
- Functionality expectations of the syringe system were met, despite the absence of intentionally added silicone oil or other lubricants
- No syringe breakage was exhibited

CONCLUSION

Critical time was wasted early in drug development by re-evaluating a new primary containment system due to the unknown sensitive nature of the drug product. The 2.25mL CZ insert needle syringe system provided a safe and reliable containment solution to protect the customers' modern biologic, all the way to administration. The 2.25mL CZ insert needle syringe system is an expansion upon the 1mL insert needle syringe system offering, which is already available in multiple markets.

FOR MORE INFORMATION VISIT
WESTPHARMA.COM/INSERT-NEEDLE

WEST PHARMACEUTICAL SERVICES, INC. 530 HERMAN O. WEST DRIVE | EXTON, PA 19341
NORTH AMERICA 1-800-345-9800 OPTION 8 | **SOUTH AMERICA** +55 11 4055 6061 | **EUROPE** +49 (0) 2403-7960 | **ASIA PACIFIC** +65 6862 3400