Syringe Systems and Components

Chemical and Physical Characteristics of Westar® RU Siliconized Pistons

West supplies ready-to-use (RU) pistons for use with prefillable syringe systems. To determine how gamma irradiation affects the chemical and physical characteristics of the piston, a study was conducted. This study evaluated the pistons over time when stored at room temperature (25 °C/60% RH) and accelerated conditions (40 °C/75% RH). For more information, request technical support bulletin 2008/123.

Functional and Container Closure Integrity Testing for West Syringe Pistons

This study compares the functional characteristics of pistons for pre filled syringes systems that have been processed by West and pistons processed by a syringe supplier. The data in this study shows variability that is seen with both piston release force and piston travel force in glass syringe barrels containing water for injection (WFI). The container closure integrity (CCI) of these syringes was also evaluated using a blue dye ingress test. For more information, request technical support bulletin 2008/124.

Container/Closure Integrity of 1 mL Long Syringes with FluroTec® Plungers with Wrinkles

West Pharmaceutical Services (West) has conducted a study to determine container/closure integrity of prefillable syringes containing FluroTec® plungers with wrinkles. FluroTec plungers were placed in 1 mL long syringes using a vent tube (tube placement). The FluroTec film had visible wrinkles along the edge of the film/rubber interface after being placed in the syringe. This study was to prove that these wrinkles are cosmetic and do not compromise the integrity of the syringe seal. For more information, request technical support bulletin 2006/115.

Comparison of Particle Count in Daikyo Crystal Zenith®, Glass, and Plastic Syringes

The particle load of primary packaging components and containers has a direct impact on final drug product particle load and thus, product quality. West Pharmaceutical Services has compared the number and size of particles produced in the Daikyo Crystal Zenith syringes with the number and size of particles produced in a competitor's glass and plastic syringes. Crystal Zenith syringes are composed of a distinct plastic barrel (cyclic olefin polymer) with several

advantages over traditional glass and plastic syringes, including a reduced particle load. Maintaining a low particle count in parenterals is critical to minimize risk to patient safety through drug administration. This analysis demonstrates the difference in particle count between the Crystal Zenith syringes and traditional glass and plastic syringes. For more information, request technical support bulletin 2008/009.

Westar® RU Piston Stability Study

As dug manufacturers seek to ensure the most robust supply chains possible they have turned to West Pharmaceutical Services as a source of sterile components for pre fill able syringe systems. West supplies pistons for prefillable syringe systems ready-to-use (RU). In order to determine how a low dose of gamma irradiation affects the compendial aspects of the piston, a study was conducted to evaluate the pistons over time when stored at room temperature (monitored conditions) and accelerated conditions (40 °C/75% RH). This report reflects Time 0 results and will be updated at each time pull. For more information, request technical support bulletin 2008/125.

Container/Closure Integrity of Resin CZ® 1 mL LL-S Luer Lock RU Syringes

West Pharmaceutical Services (West) has conducted a study to determine container/closure integrity of Resin CZ® 1 mL LL-S Luer Lock RU syringes. Testing included a dye ingress and microbial immersion challenge. For dye ingress, three tubs of 100 syringes were filled aseptically with Water for Injection (WFI). For the microbial immersion challenge, a total of 40 media filled syringes were exposed to *Brevundimonas diminuta* (*B. diminuta*) and evaluated after 7 days of incubation.

Each syringe consisted of a 1 mL LL-S barrel, 1 mL LL nozzle cap in D21-6-1, and 1 mL piston NF in D21-6-1. The barrels and tip caps received 15 kGy minimum electron beam irradiation. The pistons were steam sterilized for 20 minutes at 121 °C. For more information, request technical support bulletin 2006/004.

Daikyo Resin CZ® and BD Hypak SCF™ Syringes Piston Release and Travel Force Study

Piston release and travel forces of pre filled syringe systems are of paramount importance. Forces must be appropriate and controlled in a manner consistent with suitable administration of the drug or activation of a device. West Pharmaceutical Services' (West) Technical Customer Support Group performed a study of Daikyo Resin CZ syringes which are silicone-free prefillable syringe systems. The unique plastic barrel, in combination with Flurotec® laminated piston and nozzle cap surfaces, result in very low potential extractable substances while providing excellent lubricity for mechanical performance. Standard siliconized syringe systems were tested for comparison purposes. The Daikyo-Seiko Crystal Zenith syringe systems compared favorably with traditional glass Siliconized systems. For more information, request technical support bulletin 2007/006.

Daikyo Crystal Zenith® RU 1 mL LL-S Syringe System Overview and Process Summary

The Daikyo Crystal Zenith® based plastic prefillable syringe is a fully integrated, validated system. The system was designed for the healthcare industry and is delivered ready to use (RU). The syringe system is manufactured, processed, assembled and sterilized using validated processes in cGMP environments. The 1 mL barrel with assembled nozzle cap is delivered in tubs for use on traditional automatic and semi-automatic filling lines. The elastomeric, Flurotec® laminated pistons and nozzle caps are washed, sterilized and assembled according to defined, validated processes. The nozzle caps are assembled onto the barrels as previously indicated. The pistons are supplied sterile; either in bulk double STERILIZABLEBAGS (DSB) of 5,000 parts or in nests of 100 parts for use with small-scale filling systems. For more information, request technical support bulletin 2008/007.

Daikyo Crystal Zenith® 1mL LL-S RU Syringe Components Stability Study

West Pharmaceutical Services, Inc. and Daikyo Seiko, Ltd. provide customers a pre-fillable syringe system with a Crystal Zenith barrel and elastomeric nozzle cap assembly and elastomeric piston. The barrel/nozzle cap assemblies are packaged in tubs of one hundred and electron beam (e-beam) sterilized to be ready for use (RU). The pistons are provided in bulk packaging or nested with one hundred pistons per nest or five thousand pistons per bulk bag and steam sterilized to be ready for use. The pistons are Flurotec® laminated, which reduces the risk of extractables/leachables and allows this system to function without added silicone. This study evaluates package integrity and the chemical characteristics and cleanliness of each component up to 6 months storage at normal conditions, 25 °C/60% RH (± 2 °C/± 5% RH) and accelerated conditions, 40 °C/75% RH (± 2 °C/± 5% RH). For more information, request technical support bulletin 2008/008.

In the Americas: TCS.Americas@westpharma.com (+1 800-231-3000)
In Europe and Asia/Pacific: TCS.Europe-AsiaPacific@westpharma.com (+49 2403 7960)