



West<u>Flurolec</u>.

An Investment in Drug Purity

West FluroTec – An Investment in Drug Protection

Today's high-value drugs demand superior packaging components. Lyophilization and serum stoppers and prefilled syringe plungers with West FluroTec® barrier film and Westar® RU and RS processing can help reduce the risk of product loss and failures. Syringe plungers, serum and lyophilization stoppers with West FluroTec barrier film can help reduce drug product interactions with the container closures.

By choosing West FluroTec stoppers and plungers, you may be able to:

- Improve the shelf life of your packaged drugs
- Reduce visible and subvisible particulates
- Improve the compatibility of the closure and the drug, leading to:
 - Reduced interaction of extractables from the rubber
 - Reduced leachables in the drug formulation

A Globally Established Product

FluroTec film, West's superior barrier technology, is a leading product in all pharmaceutical and biopharmaceutical markets. West manufactures components with FluroTec barrier film from its facilities in Europe, Singapore and the United States.

When You Cannot Afford Risks

West FluroTec film provides an effective barrier against organic and inorganic extractables, minimizing interaction between the drug and the closure while maintaining container closure integrity. The fluoropolymer film reduces absorption and adsorption of the drug product, an important benefit for maintaining the strength and shelf life of most drugs. In addition, the low surface energy of FluroTec film, in combin-

ation with B2-Coating, provides lubricity without the need for free silicone oil, eliminating one potential source of particulate contamination.

When Throughput is Critical

FluroTec film reduces stopper clumping during autoclave sterilization and, when applied to the top of the stopper flange, helps prevent stoppered vials from sticking to the shelves in lyophilization chambers. FluroTec film is applied during the molding process and is conformable to complex-shaped closures, which are typically required for dry powder and lyophilized applications.

Lyophilization closures with West FluroTec film are available in a single-vent design that is proven effective in eliminating mechanical twinning, the interlocking of doublevented stoppers during processing.

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West FluroTec - Product Range

Vial options include sterile glass and Daikyo Crystal Zenith® resin to ensure that a wide variety of drug application needs are met.

Serum Stoppers

• 13mm, 20mm and 32mm

Lyophilization Stoppers

• 13mm and 20mm

Plungers for Prefilled Syringes

• 0.5mL, 1mL long, 1mL standard, 5mL and 10mL

Additional applications are available upon request.

The Added Benefits of Westar Processing

Westar® RU (ready-to-use) and RS (ready-to-sterilize) processing brings an added dimension of value to West FluroTec components. The Westar process is fully validated, adheres to applicable cGMP requirements and is performed in West's facilities in Europe, Singapore and the United States. All Westar products are final-rinsed with Water for Injection and packed in an ISO Class 5 clean room.

Westar RU components are either steam or gamma irradiation sterilized as appropriate for both the item and its end use, giving you the power to transform your filling operation into a lean, efficient process.

Westar RS components are delivered in packaging appropriate for direct sterilization. The RS process ensures consistent component preparation and minimized variability in your sterile operations.

Choosing the Westar process allows pharmaceutical companies to streamline operations by eliminating the wash, rinse and sterilization steps in component preparation.



Every day, injectable drugs are administered to improve the lives of millions of patients around the world. And every day, West is working by your side to design and manufacture drug packaging and delivery systems that will bring your drugs from concept to the patient more efficiently, reliably and safely. West understands your challenges and helps with solutions every step of the way, with cutting-edge production technologies, an unmatched expertise in global regulatory compliance, and an ever-growing knowledge base of pharmaceutical drug product testing, development, packaging and delivery. Whether you want an end-to-end solution or your focus is on one piece of the process, West is by your side for a healthier world.

To learn how components with West FluroTec barrier film and Westar® RS and RU processing can help reduce the risk of product loss and failures, call your West account manager or a West technical representative. We'll help you determine the solution that best meets your needs.

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