



WEST ENVISION™ VERIFICATION PROCESS



WEST *Envision*™

A Risk Mitigation
Solution

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With West Envision components, pharmaceutical manufacturers can help reduce incidences of seal integrity failure caused by lot-to-lot variability in stoppers and syringe plungers.

The West Envision automated inspection system enhances the quality of Westar® ready-to-sterilize (RS) pharmaceutical components by significantly reducing adhered and embedded particulate found in primary pharmaceutical packaging components. The Envision system uses automatic, program-controlled vision inspection technology to inspect all surfaces of elastomeric components for Westar RS stoppers and syringe plungers. Envision inspected products assist in reducing the total cost of goods by minimizing the risk of rejecting drug products because of visible particulates and closure defects.

Each Envision inspected item packed for delivery to your facility meets enhanced quality specifications. What's more, West will work with you to design and validate a closure component from the output of this procedure that is developed to meet your specific needs.

Envision components are inspected for:

- Loose and embedded foreign contamination
- Trimming defects
- Molding defects
- Other defects specified by the customer

You Can Benefit from Envision Plungers and Stoppers:

- Increase product yield by reducing the number of drug product rejects
- Increase your operational efficiency by optimized throughput
- Minimize Cost of Poor Quality
 - Reduced waste
 - Reduced re-work

West Envision Verification Process



West's automated inspection systems are used in an ISO 5 environment. The systems are designed to meet applicable current Good Manufacturing Practices (cGMP) standards.

The Added Benefits of Westar[®] and FluroTec[®]

Westar processing and West FluroTec barrier film deliver added value and are recommended for components used for most drug products and sensitive biopharmaceuticals.

Westar is a documented, validated process for preparing components that helps companies comply with international standards and current regulatory requirements. The Westar process helps ensure consistency of stopper preparation from clinical testing through commercialization.

Pharmaceutical companies using Westar components, can streamline operations by eliminating component preparation steps. Westar RU (ready-to-use) components are packed for easy entry into barrier systems while Westar RS (ready-to-sterilize) components are packed for direct entry into sterilization units.

Customers can also specify components manufactured with West FluroTec barrier film. FluroTec film provides an effective barrier against organic and inorganic extractables to minimize interaction between the drug and the component. The fluoropolymer film reduces sorption of the drug product and provides lubricity without the need for silicone oil.

Your Assurance of Quality

For more than 90 years, West has been a leader in the design, development and processing of primary pharmaceutical closures and components. West meets stringent requirements for quality, assured through validated processes, and adheres to applicable cGMPs to satisfy customers' requirements for high-quality syringe plungers and stoppers.

West Envision stoppers and syringe plungers can help reduce loss of fill/finish products caused by defects in packaging components.



By your side
for a healthier world™

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 West's Envision verification process can provide a virtually defect-free component solution for your manufacturing operation, 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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