

Westar SELECT Components

Next Generation Quality and Service for Ready-to-Sterilize and Ready-to-Use Components

Pharmaceutical manufacturers are challenged to meet increasing quality standards from global agencies. In addition, regulatory filing complexity and supply risk for sensitive drug products can make the move to market difficult – or stop it altogether.

To help customers meet these challenges and reduce risk, West has developed next-generation quality for ready-to-sterilize and ready-to-use components.

Introducing Westar® Select components.

Westar[®] Select builds on West's industry-proven Westar component pharmaceutical washing and sterilization processes that help to reduce the risk of variability and its potential effects on drug quality, safety and efficacy. Westar Select components are supported by a streamlined regulatory strategy and global network to help ensure supply chain security and efficient commericalization.

Westar Select Components offer:

- High quality pharmaceutical wash and sterilized products
 - ✓ Tighter visible particulate specification for $> 100 \mu M$
 - ✓ Enhanced AQL program

- A regulatory strategy designed for risk mitigation
 - ✓ A single, global Drug Master File covering multiple West manufacturing sites
 - ✓ Harmonized Pharmaceutical Wash and Sterilization processes
- Flexible global network
- Modern elastomer formulations and designs

With Westar Select, customers get high-quality, consistent components with a tighter specification through a global product portfolio that enables supply chain flexibility and business continuity support.







- High-quality components manufactured with the validated pharmaceutical wash process to provide customers with consistently prepared, ready-to-sterilize or ready-to-use components
- Accompanied by a Certificate of Analysis as documented evidence of compliance to specifications

- Higher quality offering on pharmaceutical wash and sterilized products
- Defined Global Product Portfolio focused on component capability
- Tighter visible particulate specification for > 100µM
- Enhanced/industry standard specification and AQL program
- Simplified regulatory strategy

- Highest quality offering manufactured using Quality by Design principles
- Incorporates all of West's premium quality enhancements
- Includes a comprehensive information and data package
- Sub-visible particle specifications

Contact West today for a complete list designs and formulations that can be offered to the Westar Select component specification. **westpharma.com**

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