By your side
for a healthier world™

To learn how components with Westar® RU and RS processing can help reduce the risk of product loss and failures, call your West account manager or a West technical representative or visit our website at **westpharma.com.**

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#10419 • 0118

Westar RS
Ready-to-Sterilize Components

Components Prepared for Pharmaceutical Use

Westar® RU and RS Stoppers and Plungers

By your side
for a healthier world™

West
By your side
for a healthier world™

Westar RS
Ready-to-Sterilize Components

Westar RU
STERILE
Ready-to-Use Components

Flexible Solutions for Pharmaceutical Components

Pharmaceutical manufacturers are challenged by ever-shortening production cycle times. A delay in having components prepared can ruin your manufacturing schedule.

To mitigate the risk of component preparation delays, you can apply Westar® RU (ready-to-use) or RS (ready-to-sterilize) components, including syringe plungers and stoppers. Westar components are washed with the validated Westar process.

Choose Westar

Westar components can streamline your manufacturing operations by eliminating many of the processes related to component preparation. As a result, you may benefit from:

- Reduced testing and validation studies
- Increased throughput
- Reduced labor and maintenance costs
- Improved compliance
- A Drug Master File (DMF) to support chemistry, manufacturing and controls (CMC) filing

Westar components are packed in plastic cartons and may be placed on plastic shipping pallets to minimize particle contamination and facilitate handling within your controlled environment.

Choose Ready-to-Use

For faster processing, choose RU components. Ready-to-use components are sterilized and delivered to you in integrity-tested packaging systems, which include rapid-transfer port bags, to ease introduction of components into your filling line.

With RU components, you minimize variability in your sterile operations and may even eliminate component preparation from your plant entirely.

Choose Ready-to-Sterilize

When choosing RS components, you select clean components that comply with applicable USP and Ph. Eur. compendial standards and provide consistency of preparation from clinical trials through commercialization. West performs a portion of your component preparation process.

Our testing and validation work can help improve the speed of product development and manufacturing.

The West Ready Pack® system includes Westar ready-to-use stoppers.

Westar Component Processing

The validated process ensures that components are washed and rinsed with Water For Injection and packed in an ISO 5 clean room.

Validated for Quality Assurance

Westar components are prepared using a documented, validated process that helps companies comply with current regulatory requirements. All product lots are tested and accompanied by a Certificate of Analysis as documented evidence of compliance to specifications, such as:

- Endotoxin
- Bioburden
- Particulate
- Silicone level (if applicable)

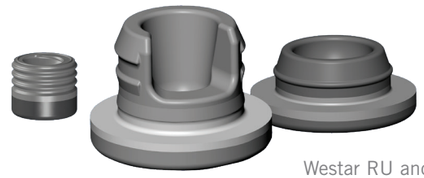
Essential Compliance

The process complies with current FDA thinking on cGMP lot-to-lot closure preparation and testing. The wash process is supported by a DMF filing in the U.S. and Canada.

Since 1995, the Westar RS DMFs have successfully supported our customers' applications. To request a Letter of Authorization to reference the DMF in support of regulatory filings, use the on-line form at westpharma.com/services/loa_form.asp or contact your West representative.

Risk Mitigation

Westar components are available from West's facilities in North America, Europe and Singapore. The facilities adhere to applicable cGMP requirements and produce components with specified bacterial endotoxin, bioburden and particulate levels for primary pharmaceutical closures.



Westar RU and RS
Plungers and Stoppers

The Leading Choice, The World Over

The world's leading pharmaceutical companies choose Westar components to help ensure consistency of preparation from clinical laboratory testing through commercial production. Call your West representative to learn how Westar components can be easily specified into your operations.

Select a Complete Packaging System

For assurance of component fit and optimal container closure integrity, select the West Ready Pack® system. The system includes West's RU Flip-Off® seals that have been sterilized by a validated gamma irradiation or steam autoclave process. The seals are delivered in packages designed to fit into sterile filling and capping lines. Ready-to-use vials and stoppers in small quantity packaging complete the Ready Pack system.

West's Flip-Off® CCS – clean, certified, sterilized – seals, designed for aseptic operations, can help achieve compliance with the European Commission Guide to GMP, Annex 1.