

Resolving Drug Compounding Challenges With Ready-to-Use Quality Components

Compounding pharmacies are now held to higher standards due to evolving FDA regulations. Container closure systems are critical to CGMP compliance and ultimately to patient safety.

- Containers and closures must be qualified as suitable for intended use for each drug product
- Validated processes are required to ensure sterility and cleanliness of containers and closures
- Facilities can source certified sterile and nonpyrogenic ready-to-use containers and closures with a supplier Certificate of Analysis (COA)



Mitigate risk with West's ready-to-use components. Benefits include:

- Sterile container and closure systems prepared using validated processes
- Certificates of Analysis (COAs)
- Reliable supply with a timely delivery direct from West
- Convenient online ordering
- Expert technical support
- Access to West's Knowledge Center for technical documents, specifications and drawings
- Analytical Lab Services
- West's Integrated Solutions program to help you Simplify the Journey™

West is by your side in providing high quality container closure systems for the safe and efficient delivery of injectable drug products.

West's Integrated Solutions Program can help prepare a closure container system to meet FDA guidelines.

Ask your Account Manager or Technical Customer Support team for more information.

Ready-to-Use Components

Ensuring sterility and adequacy for intended use.

West's ready-to-use products are comprised of high-quality sterile primary and secondary packaging components. Available options include glass or Daikyo Crystal Zenith® vials, NovaPure® stoppers and Flip-Off® seals. Components are provided with sterilization validation summaries to help you minimize internal processing upon receipt. With small quantity availability from stock, ready-to-use products are particularly well suited for compounding pharmacy operations.

Selecting West's components can help ensure that compounding pharmacies meet FDA 503A and 503B guidance, as well as state pharmacy and USP <1207> and <797> regulations.



| Component | Product Features | Product Description | Minimum Order Quantity | West Item Number |
|---|---|--|---|------------------|
| Stoppers | | | | |
| NovaPure Serum Stoppers in 4023/50 Gray | <ul style="list-style-type: none"> Ready to use, sterilized Tightest elastomer particulate specifications 100% Envision™ automated inspection FluroTec® barrier film Lot-to-lot extractables testing | 13mm serum bromobutyl formulation | 1,000 pieces per double STERILizableBAG™ | 1970-0360 |
| | | 20mm serum bromobutyl formulation | 500 pieces per double STERILizableBAG | 1970-0361 |
| Seals | | | | |
| Flip-Off Seals | <ul style="list-style-type: none"> Clean, Certified, Sterilized (CCS) Matte finish red, white or blue Gamma stable polypropylene button | 13mm Red button | 1,000 seals / in 3 polyethylene (PE) bags | 5922-1125 |
| | | 13mm White button | 1,000 seals / in 3 polyethylene (PE) bags | 5922-1120 |
| | | 13mm Blue button | 1,000 seals / in 3 polyethylene (PE) bags | 5922-1128 |
| | | 20mm Red button | 500 pieces / double STERILizableBAG | 5922-1143 |
| | | 20mm White button | 500 pieces / double STERILizableBAG | 5922-1141 |
| | | 20mm Blue button | 500 pieces / double STERILizableBAG | 5922-1127 |
| Vials | | | | |
| SG EZ-fill® Sterile Glass Vials | <ul style="list-style-type: none"> Clean, sterilized, depyrogenated vials ready to fill | 3mL fill volume Uses 13mm stopper & seal | 2,280 vials: 228/tray x 10 trays | 6800-0397 |
| | | 8mL fill volume Uses 20mm stopper & seal | 960 vials: 96/tray x 10 trays | 6800-0398 |
| | | 10mL fill volume Uses 20mm stopper & seal | 960 vials: 96/tray x 10 trays | 6800-0399 |
| Daikyo Crystal Zenith Co-Polymer Vials | <ul style="list-style-type: none"> Ready to use, sterilized Break-resistant cyclic olefin polymer Suitable for silicone sensitive drugs, low temperature storage or shipping | 2mL fill volume Uses 13mm stopper & seal | 960 vials: 480/tray x 2 trays | 1955-0057 |
| | | 5mL fill volume Uses 20mm stopper & seal | 448 vials: 224/tray x 2 trays | 1955-0207 |

For more information visit www.westpharma.com

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