

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				
Ompi 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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