NovaPure® Components for Vials

It's all too common. Full lots of injectable drug products are rejected or even recalled due to visible particulate in solution. Increasing awareness of the risks associated with particulate contamination has pharmaceutical manufacturers seeking cleaner, more consistent packaging components.

PACKAGING CAN BE A RISKY BUSINESS

Contamination and particulate attributed to elastomer components and packaging can be a source of risk and variability, putting the quality of your drug product and the ultimate safety of your patients at risk. Sensitive pharmaceuticals and biopharmaceuticals demand high-quality packaging to maintain drug purity and efficacy.

REJECTIONS & RECALLS CAN BE COSTLY

Product rejections impact the bottom line through increased costs, lost batches and manufacturing inefficiencies. Product recalls can have a negative impact on patient confidence, market share and shareholder value.

NO BARRIER IS UNBREACHABLE FOR A LEACHABLE

While technologies such as barrier films may reduce leaching, they do not negate the need for comprehensive extractable/leachable studies. Careful elastomer component selection should be coupled with an understanding of key extractables in order to anticipate leachables over time.

REGULATORY SCRUTINY HAS INCREASED

Global regulatory concern over particulate and resulting actions are evident throughout the industry. Recent research* has shown that 22% of injectable recalls between 2008-2012 were attributable to particle-related issues.

QUALITY PACKAGING BEGINS BY DESIGN

Selecting packaging components manufactured under the principles of Quality by Design can offer exceptional cleanliness and the tightest limits on particulates. Additionally, such components offer reduced risk of variability, product loss and minimized total cost of ownership. When you choose the highest quality elastomer components, you help ensure your ultimate goal – patient safety.

Talk to your West representative and choose the right option for your product, and ultimately, for your patients' health.

*Lynn S. Drug Defects. Presented at the 37th International Good Manufacturing Practices Conference, March 14, 2013, Athens, Ga.

Mitigate Risk with Quality by Design

NovaPure® Components for Vials
Unrivaled Quality...By Design

Components manufactured with Quality by Design principles meet Critical Quality Attributes:

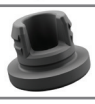
- Sub-visible particle specifications
- Tight visible particle specifications
- Minimized exposure to sources of cellulose
- Critical dimensions measured in CpK

NovaPure components for vials help you:

- Reduce quality issues associated with particulate
- Protect sensitive drug products with exceptional cleanliness and barrier properties
- Address patient needs with an in-depth Quality Target Product Profile (QTPP)
- Minimize Total Cost of Ownership

West offers enhanced transparency to NovaPure Customers via:

- 24/7 access to Customer Connection, a comprehensive online library of process and product documents
- Key extractable reporting to monitor material consistency and minimize variability of leachables
- Regulatory support, including a Drug Master File in Common Technical Dossier (CTD) format for US & Canada

	Configuration	Quality Treatments
	13mm serum stopper	FluroTec® Barrier Film B2 Lubricity Coating Westar® RS Wash & RU Sterilization Processes Envision™ 100% Auto Verification
	20mm serum stopper	
	13mm lyo stopper	
	20mm lyo stopper	

Visit West today at **www.westpharma.com** today to learn more.

West Pharmaceutical Services, Inc. | 530 Herman O. West Drive, Exton, PA 19341

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