



By your side
for a healthier world™

STOPPERS • PREFILLABLE SYRINGE PLUNGERS



West
NOVAPURE®

The New Definition of
High-Quality Components



Science and Technology

West has adopted a continuous verification process that is unrivaled in the industry. NovaPure products are manufactured within an established control space to meet patient-centered CQAs.

West's NovaPure components are supported by an annual product review and integrated regulatory support, including Drug Master File and supporting submission packages in the common technical document (CTD) format that can help expedite your applications and regulatory reviews.

In addition, NovaPure components are backed by the knowledge and expertise of West's Technical Customer Support staff. You'll also have 24/7 access to a comprehensive technical data package allowing you to review current and relevant information from a conveniently located and secure source.

Available documents include:

- Component drawings
- West technical presentations
- Technical bulletins/reports
- Principles in QbD
- Formulation characteristics
- Validation summaries

Proactively Partnering to Mitigate Your Risk

As new, sensitive pharmaceuticals and biopharmaceuticals are prepared for market, regulatory agencies have asked manufacturers to build quality in from the start and ensure consistent quality throughout a drug product's lifecycle. To make sure drug products maintain safety and efficacy from concept to commercialization and to reduce the total cost of ownership, packaging materials must evolve.

Pharmaceutical companies are challenged to find components that not only meet the current regulatory requirements, but also the high expectations of end users – consistent, reliable, high-quality components that are manufactured with the goal of meeting patient and pharmaceutical company needs. Using a holistic, Quality by Design focus provides a thorough product and process understanding that enables the delivery of a product that achieves these goals.



Patient safety is at the heart of the NovaPure Quality by Design process.

Introducing NovaPure: The New Definition of High-Quality Components

NovaPure components have quality built in from the start. West has developed a comprehensive quality target product profile (QTPP) based on the needs of our customers and end users. Critical quality attributes (CQAs), determined with the end user in mind, have been built into the development process to help ensure quality, safety and efficacy throughout a drug product's lifecycle. By following Quality by Design principles, the West process provides a new, unrivaled level of component quality supported by data and science-based decision making.

NovaPure components can help mitigate risk by:

- Helping lower the total cost of ownership through:
 - Reduced compliance risk
 - Reduced filling rejection rate
 - Reduced process costs
- Improving transparency between West and pharmaceutical manufacturers
- Ensuring a higher quality standard that is driven by patients' needs
- Manufacturing with a more thorough product and process understanding

West
NOVAPURE

Designed for Purity

NovaPure components are manufactured from West's modern elastomeric formulations and provide ultimate quality through industry-leading specifications that includes both visible and subvisible particles. West's in-depth process understanding and continuous verification results in products with better consistency, which can help reduce filling line issues and minimize variation while meeting best practice compliance standards.

Designed with purity in mind, NovaPure products incorporate a combination of high-quality processes and features to ensure reliability, including:

- FluroTec® barrier film – a proven, effective barrier against extractables that provides lubricity without the need for silicone oil
- Validated wash and sterilization processes that help ensure consistency of stopper preparation
- 100-percent vision verification
- A comprehensive extractables profile



West
NOVAPURE®

Unrivalled Quality
...by Design





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