

Solutions for Cold-Chain Handling: PTFE Containment is a Viable Option for Temperature Sensitive Drug Substance Protection

Drug manufacturers seeking a more robust solution for single-use cold-chain containers are looking to options made with polytetrafluoroethylene (PTFE) fluoropolymers, which may be less susceptible to failure and breakage at cold temperatures.

There is a growing trend toward development of temperature-sensitive biologic drug substances, such as vaccines, monoclonal antibodies (mAbs), mRNA therapies, gene therapy intermediates and viral vectors. These biologics need to be stored at cold temperatures to maintain their stability and efficacy. However, handling these molecules presents challenges for containment, including breakage. Such challenges are not new to the pharmaceutical industry. Single-use polymer-based containers using conventional materials such as EVA or polyethylene, can become brittle and break under extreme cold temperatures, which are often required when transporting drug substances. Damage sustained to conventional containers can result in lost product and may result in significant costs to manufacturers.

As the industry seeks more robust solutions for single-use cold-chain containers, high strength PTFE (or fluoropolymer) materials provide an appealing option to reduce the risk of product loss due to its mechanical properties over a wide temperature range. Drug containers made from PTFE provide a more robust, cold durable option for storage and transport of frozen biopharmaceuticals.

Challenges of Handling Temperature-Sensitive Drugs

Vaccines, monoclonal antibodies (mAbs), mRNA therapies, gene therapy intermediates and viral vectors. require temperature-sensitive handling to ensure stability when stored and shipped at cold temperatures. Logistical challenges associated with

cold-chain handling and shipping in pharmaceutical manufacturing include transportation and proper storage, and can be very expensive. With temperatures ranging from 5 degrees to -80 degrees Celsius, storage and transportation presents a unique challenge to conventional containment. Containment options such as conventional polymer bottles and bags can break at such temperatures.

Conventional polymer bags or bottles are used widely to store and ship temperature sensitive drug substances. As noted above, conventional polymers used for single-use products in coldchain handling can fail at cold temperatures. These materials may become brittle, resulting in possible breakage or leakage at below-freezing temperatures. Such a loss of biologic drug substance can be costly for the manufacturer and devastating for patients who rely on the drug product. By some estimates, 3% to 5% of conventional containers fail during cold-chain handling based on discussions with biopharmaceutical manufacturers. As the cost of a biologic drug substance could range from \$10,000 to \$500,000 per liter, a failure rate of 3-5% amounts to significant losses. As use of temperature-sensitive biologic drug substances, is projected to expand in the coming years, the industry has begun to look at the benefits of PTFE, a type of temperature-resistant fluoropolymer with chemical properties that make it a better option for cold-chain handling containers.

Fluoropolymers in cold-chain handling

Chemically stable and non-particulating, with a low extractables profile, PTFE is bio- and chemically inert. Gore's expertise lies in manipulating PTFE's structure to control its physical properties. In addition, Gore has developed expertise at surface modifying PTFE or combining with other materials to create functionality for specific uses.

Products such as the GORE® STA-PURE® Flexible Freeze Container offer manufacturers an option for cold-chain handling developed using PTFE. These flexible, single-use storage containers are impact and crack resistant, even after freezing at -86°C (-123°F) and maintain a low extractables profile.

Frozen impact durability testing includes freezing the product in a freezer at -86°C and dropping onto a concrete floor from a height of 36 inches. Integrity testing is then done to ensure no breakages or holes

that may result in a leak. Freeze/thaw cycling tests include storing the product in a freezer at -86°C and thawing it in a water bath at room temperature for five cycles. Long-term frozen storage testing, where the product is stored in a freezer at -86°C for 12 months, and then integrity tested showed that the integrity of the PTFE container was not compromised. GORE® STA-PURE® Flexible Freeze Containers are an ideal product for cold-chain handling, storage and transport.

Learn more about the GORE STA-PURE Flexible Freeze Container here. <https://www.gore.com/products/gore-sta-pure-flexible-freeze-container>.

Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. GORE STA-PURE Flexible Freeze Container, like all products in the Gore PharmBIO Products portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

NOT INTENDED FOR USE in medical device or food contact applications or with radiation sterilization.

All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Gore's terms and conditions of sales apply to the purchase and sale of the product.

GORE, *Together improving life*, STA-PURE and designs are trademarks of W. L. Gore & Associates. © 2022 W. L. Gore & Associates, Inc.

Americas | W. L. Gore & Associates, Inc.
402 Vieve's Way • Elkton, MD 21921 • USA
Phone: +1 410 506 1715 • Toll-free (US): 1 800 294 4673
Email: pharmbio@wlgore.com

gore.com/pharmbio

Europe | W. L. Gore & Associates, GmbH
Wernher-von-Braun-Strasse 18 • 85640 Putzbrunn, Germany
Phone: +49 89 4612 3456 • Toll free: 0 800 4612 3456
Email: pharmbio_eu@wlgore.com

