Nordson MEDICAL

Biopharmaceutical Components

CRYOGENIC COMPATIBILITY

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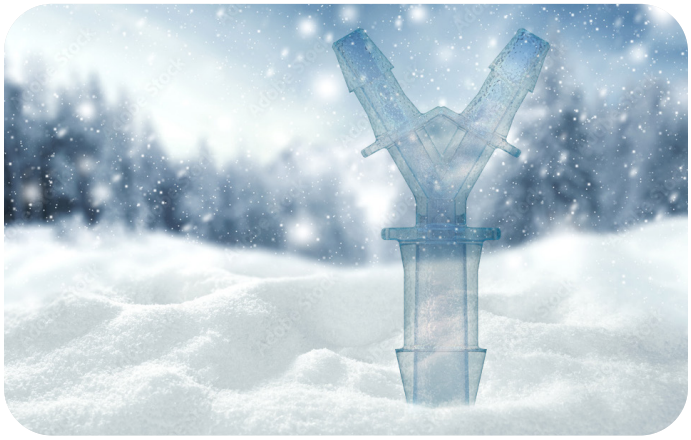
Cryogenic Compatibility

Abstract:

The use of cryogenic storage and transportation is on the rise in pharmaceutical industries. This push for cold storage demands that products used in these pharmaceuticals be compatible with the deep freeze conditions required to preserve the biological products being stored and shipped. Nordson MEDICAL's Biopharma family of products have been tested to function as low as -80°C by exposing them to the extreme cold that they may face during use. This testing is done to ensure that our products are ready to serve in the production of pharmaceuticals and inspire confidence that users will not experience failures as more processes require cryogenically stored material.

Introduction:

Cryogenic storage is becoming a significant issue for Biopharmaceutical manufactures as more products and components must be stored at very low temperatures to be kept functional. The repercussions of these new requirements are felt throughout the Biopharma production industry as there had never been such a huge demand for cold storage and transport. Innovation in refrigeration technology has been pushed especially by the needs of modern vaccine production as we combat the pandemic, with temperatures as low as -80°C being needed to maintain the quality of the vaccinations.[1] This trend toward increasing growth in cold storage is showing no signs of slowing down, with significant numbers of new biologic inventions being reliant on low temperatures and growth in the cold supply chain industry being predicted at 59% by 2023 up from 2019.[2]



Beyond the capabilities of refrigeration, these low temperature products need to be stored in materials that can themselves resist the deep freeze conditions necessary. As such, our biopharmaceutical family of products needed to be shown to be compatible with the potential sheer cold they may need to be stored in. The goal was set to demonstrate performance down to -80°C, the temperature needed by some modern vaccines, such that no failure should be expected in current biopharma applications.

REFERENCES:

1. Shelley, Suzanne. "Pharma Cold Chain: Pushing the Envelope." Pharmaceutical Commerce, 23 Sept. 2021, www.pharmaceuticalcommerce.com/view/pharma-cold-chain-pushing-the-envelope.
2. "2020 Biopharma Cold Chain Sourcebook forecasts a $17.2-billion logistics market" Pharmaceutical Commerce, 27 April. 2021, www.pharmaceuticalcommerce.com/view/2020-biopharma-cold-chain-sourcebook-forecasts-a-17-2-billion-logistics-market

Testing:

A test process was developed to lower the temperature of our selected products beyond the point of -80°C and observe whether they would fail. The products to be tested were chosen to represent the range of products used in biopharma. By passing this test they demonstrate that our biopharma family of products in these materials and configurations are compatible with cryogenic conditions and safe to use.

As it is nearly impossible to accurately monitor the internal temperature of the products during testing it is not as easy as putting the test samples in a cold room and watching to see what happens. On the contrary, to ensure that the entire product is reduced below the desired temperature it needs to be exposed to far colder temperatures such that there is no doubt that the entire body is exposed to the freezing temperature. This was achieved by submerging the test samples in liquid nitrogen at -200°C, which would bring the core temperature of the parts to at least -100°C. This test verifies that the tested material will not fail in the storage or transport temperatures of -80°C.

After being exposed to the extreme low temperatures the parts were inspected for any defects caused by the test including damage to the material and for products containing O-rings a pressure test to ensure the survival of the seal. Material cracking or any loss of function would constitute failure, with the goal being that the cryogenic exposure has no effect of the products.

Results:

No failures were observed in the course of this testing, with all the products run through liquid nitrogen with no adverse effects. Table 1 lists the products and material variations tested in this way.

These results demonstrate that the Nordson MEDICAL biopharma family of products are capable of supporting most modern production processes even in face of the need for cryogenic storage of materials. Our customers can be confident that these products will retain their function during and after storage and transport at temperatures as low as -80°C.

TABLE 1:

Liquid Nitrogen Test		
PRODUCT	**MATERIALS**	**RESULT**
Bag Ports	Polyethylene	Pass
Sanitary Fittings	Kynar, Polypropylene	Pass
Tube Clamps	Glass Filled Nylon	Pass
Tube to Tube Fittings	Kynar, Polypropylene	Pass
Luer Connectors	Polypropylene	Pass

Conclusion:

This shelf-life testing effort, coordinated by the Quality Assurance team at Nordson MEDICAL, represents a commitment to quality design, materials, and compliance to ATSM F1980-16 standards. As a global leader in the biopharmaceutical industry, our goal is to continuously improve in all phases of manufacturing. By providing shelf-life testing data that meets the rigorous standards of the ATSM, we are strengthening the supply chain and our role as leaders in this thriving industry.

As we work through the process of testing product families, Nordson MEDICAL will continue to partner with companies at any point in the product lifecycle – working with component manufacturers, assemblers, and system integrators to establish a shelf-life number for complex multi-product assemblies.

Contact your Nordson MEDICAL sales representative for more information or visit nordsonmedical.com

Nordson MEDICAL is committed to excellence:

As the global expert in the design, development, and manufacturing of complex biopharmaceutical medical devices and component technologies, Nordson MEDICAL offers innovative tools, technologies and solutions that can help your team bring critical technologies and complex devices to market faster and more cost-effectively.

Quality is paramount in everything we do because our components and finished devices are used to save or enhance patients' lives every day. We have developed a culture of continuous improvement and a single global quality system to ensure reliable, consistent product performance. Our commitment to excellence is at the heart of our interactions with customers, suppliers, and coworkers.

About Nordson MEDICAL

Nordson MEDICAL is a global expert in the design, development, and manufacturing of complex medical devices and component technologies. We serve interventional, surgical, and specialized markets with technologies that save or enhance lives. As an integrated, single-source partner, we enable our customers to save costs and speed time to market.

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