

Protect Your Gene Therapy Product with an Approved Container Closure System

The research, development and commercialization of a gene therapy takes years to ensure that products can be safely and effectively used to treat patients. The containment of gene therapies requires a robust system designed to mitigate risks. Nucleic acids and their delivery vehicles, such as adeno-associated virus (AAV) or other viral vectors, have unique sensitivities. Selecting the wrong package could adversely impact the drug and, more importantly, the patient.



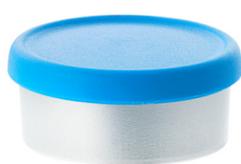
Select a Daikyo Crystal Zenith® vial container to protect your gene therapy and help ensure that every batch of product can be stored – and delivered – effectively.

Benefits include:

- Demonstrated regulatory approval pathway
 - West's components and containers, including Daikyo Crystal Zenith®, have been selected to contain the first gene therapies approved by the FDA for sale in the U.S.
- Lower risk product storage versus glass
 - Container systems perform well at low temperatures and maintain Container Closure Integrity (CCI) down to the vapor phase of liquid nitrogen at approximately -180°C
- Can be directly introduced into filling operations
 - Container and system components are supplied in a ready-to-use sterile format
- Can support gene therapy products in development across multiple dose volumes and allows for transition from early-stage pilot manufacturing to commercial-scale operations
 - Available in 0.5, 2, 5, 10 and 50mL vial sizes

Gene Therapy Products Demand Packaging with Demonstrated Low-Temperature Performance

Ensuring that your gene therapy is delivered safely and effectively requires selecting the right primary package components. Maximize preservation of your product by choosing packaging components with demonstrated performance in low temperature storage conditions required by gene therapies.



Flip-Off® CCS Seals

- Supplied clean, certified and sterilized
- Provide tamper evidence
- Available in a range of colors for product identification



NovaPure® Stoppers

- Protect sensitive drug products with exceptional cleanliness and barrier properties
- Reduce quality issues associated with particulate via sub-visible and visible particle specifications



Daikyo Crystal Zenith® Vials

- The thermal expansion properties of Daikyo Crystal Zenith vials® and West elastomer stoppers are comparable, ensuring the container system maintains CCI at low temperatures
- Break resistance during isolator filling, transport, storage, and end-user handling
- Will not form flakes or lamellae, a common issue with glass

West offers components as part of our Integrated Solutions program that provides the primary containment, laboratory testing and regulatory support you need for pre-clinical and clinical development. Need testing? West Analytical Laboratories can test your package for CCI at low and cryogenic storage temperatures, particulates and extractables and leachables.

For more information visit www.westpharma.com

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