

Protect Your Gene Therapy Product with the Right Container Closure System

Developing a genetic therapy takes years of careful research to ensure that therapies derived from DNA, RNA and RNAi target a specific disease. Adeno associated virus, or AAV, and viral vectors have been used to help deliver these therapies safely and effectively. But containing precious gene therapies requires a robust system designed to mitigate risks. Selecting the wrong package could not only adversely impact the drug, but also the patient.

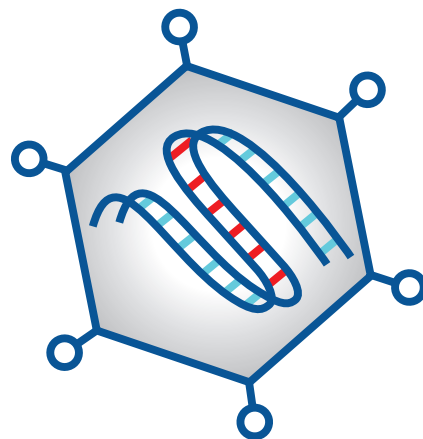
As an alternative to bags and cryovials, West Ready Pack® containers and components have been selected and used to effectively contain the first gene therapy approved by FDA in the U.S. for an inherited disease. Use of the Daikyo Crystal Zenith® vials can minimize risk associated with gene therapy storage, supply chain and delivery.

Benefits include:

- Low risk of breakage and/or loss of container closure integrity at -80°
- No extractables/leachables associated with bags
- Low subvisible particulate when compared to glass

- Recovery of very low concentration of product in optimized formulations
- Availability in a range of sizes for optimal fill volumes
- Ready to use off the shelf in standard sizes for convenient small quantity filling

Don't risk years of research and work, select a Daikyo Crystal Zenith vial container, and help ensure that every batch of product can be stored – and delivered – effectively.



Your Gene Therapy Product Deserves The Best Packaging

Ensuring that your gene therapy reaches the patient safely and effectively requires the selection of primary package components that take the requirements of the starting material into account. For therapies that require AAV delivery, the proper primary containment package is vital to ensuring efficacy.

Ready Pack Components are available:

- In a ready-to-use, sterile format
- In small pack quantities of 500 and 1,000 pieces
- A variety of sizes and configurations to meet your product's requirements
- Off the shelf, ready to ship



Ready Pack Daikyo Crystal Zenith® Vials

- Compatible with low temperature storage needs
- Break resistant material, including while filling in isolators and storage in cryogenic conditions
- Maintain the stability, purity and efficacy of gene therapy related materials
- Will not form flakes or lamellae, a common issue with glass



Ready Pack NovaPure® Stoppers

- Protect sensitive genetic materials with exceptional cleanliness and barrier properties
- Sub-visible and visible particle specifications



Ready Pack Flip-Off® Seals

- Precision industry leading technology completes the package
- Maintains closure integrity of a stopper on a vial

Need testing? West offers Ready Pack components as part of our Integrated Solutions program that provides the primary containment, laboratory testing and regulatory support you need for pre-clinical and Phase I development. In addition, West Analytical Laboratories can test your package for container closure integrity at low and cryogenic storage conditions, as well as for particulates and worrisome extractables and leachables.

For more information, contact West today or visit westpharma.com to purchase products, access technical documents on our **Knowledge Center**, see more information on **West Ready Pack** or sign up for our **blogs**.