

MY STERINITY NASAL: ADVANCING PHARMACEUTICAL GLASS PACKAGING FOR NEXT-GENERATION INTRANASAL THERAPIES

SGD Pharma introduces the company's dedicated ready-to-use Type I glass vial platform, My Sterinity Nasal, which is designed to address the sterility, compatibility, stability and manufacturing demands of preservative-free nasal medicines, as primary packaging increasingly becomes a strategic part of drug development as intranasal drug delivery expands into chronic, high-value and sensitive therapeutic applications.

Intranasal drug delivery is moving beyond its established role in emergency treatment and into a broader range of chronic and high-value applications, such as formulations targeting the central nervous system (CNS), vaccines and systemic therapies, which place increasingly demanding requirements on the primary container. For these products, the vial is not simply a vessel – it must help protect sterility, maintain compatibility with the formulation and support product stability over its intended shelf life.

These requirements are especially relevant for preservative-free products and sensitive formulations. Where a medicine is intended for repeated or long-term administration, the chemical behaviour of the container, its barrier performance and the cleanliness of the supplied packaging become important elements of the overall product strategy.

A DEDICATED READY-TO-USE PLATFORM

To address these needs, SGD Pharma has expanded its ready-to-use (RTU) platform with My Sterinity Nasal, a range of Type I pharmaceutical glass vials developed specifically for

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"SGD PHARMA HAS EXPANDED ITS RTU PLATFORM WITH MY STERINITY NASAL, A RANGE OF TYPE I PHARMACEUTICAL GLASS VIALS DEVELOPED SPECIFICALLY FOR PRESERVATIVE-FREE NASAL DRUG DELIVERY AND SENSITIVE FORMULATIONS."

preservative-free nasal drug delivery and sensitive formulations. The platform brings together the characteristics of pharmaceutical glass with validated preparation and sterilisation steps, providing vials that can be introduced into filling operations and eliminating the need for the manufacturer to perform the conventional container washing and preparation sequence.

My Sterinity Nasal is the first product resulting from a strategic collaboration between SGD Pharma and Prince Sterilization Services (Montville, NJ, US). SGD Pharma brings its pharmaceutical glass manufacturing expertise, while Prince provides capabilities in validated washing, depyrogenation and sterilisation for the North American market. The resulting device is intended to combine container performance with a robust, validated supply chain.

FORMATS AND PRESENTATION

The range is available in 3.5, 7.5 and 10 mL formats, with both clear and amber glass options. The vials are designed for compatibility with standard preservative-free nasal pump systems and are supplied in double-bagged trays. This RTU format is intended to simplify filling operations and reduce the number of container-preparation steps required at the pharmaceutical manufacturing site through the following:

- Controlled particulate and endotoxin levels
- Validated sterility assurance
- Compatibility with standard preservative-free nasal pump systems
- Double-bagged tray presentation for RTU filling.

WHY TYPE I GLASS MATTERS

For advanced nasal therapies, container-product interaction can be a critical consideration. Type I glass offers strong chemical resistance, helping to minimise interactions between the primary container and the drug product. This is particularly significant for formulations intended for repeated or long-term use, where maintaining formulation stability throughout the product lifecycle is essential.

Glass also provides excellent barrier properties and long-term biocompatibility. Together, these attributes support the integrity of sensitive formulations while providing a well-established pharmaceutical packaging material for developers working on increasingly sophisticated intranasal products.

PRODUCT RECOVERY FOR HIGH-VALUE FORMULATIONS

My Sterinity Nasal incorporates SGD Pharma's U-Save vial design, which was developed to maximise product recovery. This feature is particularly relevant for high-value formulations, where residual drug left in the container can represent both an economic loss and an efficiency issue.

By reducing residual volume and improving recoverability, the vial design can help manufacturers make more effective use of the filled drug product. In applications involving costly APIs or limited clinical material, this can become a practical consideration alongside more familiar packaging requirements, such as sterility and compatibility.

STERILITY, CLEANLINESS AND MANUFACTURING EFFICIENCY

The demands placed on primary packaging extend beyond the intrinsic properties of the glass. The condition in which the container arrives at the filling line also matters. The specifications for My Sterinity Nasal include controlled particulate and endotoxin levels and validated sterility assurance, reflecting the needs of preservative-free and sensitive nasal formulations.

The RTU approach is designed to simplify pharmaceutical filling operations. By receiving prepared vials in double-bagged trays, manufacturers can avoid the need to carry out the full conventional sequence of vial washing, depyrogenation and sterilisation in their own facility. This can reduce operational complexity while providing a defined, validated packaging input for development and production.

A SUPPLY CHAIN DESIGNED FROM CLINICAL DEVELOPMENT TO COMMERCIAL PRODUCTION

Packaging decisions made during development need to remain practical as programmes advance towards larger production volumes. My Sterinity Nasal is supported by a supply chain that is intended to serve pharmaceutical companies from clinical development through commercial production.

The glass vials are manufactured at SGD Pharma's Saint-Quentin-La-Motte facility in France. This established manufacturing capability is complemented by sterilisation services provided by Prince in North America. The collaboration therefore combines pharmaceutical glass production with dedicated sterilisation capabilities for the North American market.

"THE SPECIFICATIONS FOR MY STERINITY NASAL INCLUDE CONTROLLED PARTICULATE AND ENDOTOXIN LEVELS AND VALIDATED STERILITY ASSURANCE, REFLECTING THE NEEDS OF PRESERVATIVE-FREE AND SENSITIVE NASAL FORMULATIONS."

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"BY COMBINING HIGH-QUALITY TYPE I GLASS WITH VALIDATED RTU PROCESSING, MY STERINITY NASAL OFFERS A DEDICATED PACKAGING SOLUTION FOR PRESERVATIVE-FREE NASAL PRODUCTS AND SENSITIVE FORMULATIONS."

PRIMARY PACKAGING AS PART OF THE DRUG-DEVELOPMENT STRATEGY

The growth of intranasal delivery for treating neurological disorders via the CNS, as well as delivering vaccines, biologics and other high-value therapeutics, is increasing the importance of selecting the right primary packaging. As formulations become more valuable and increasingly sensitive, drug developers must consider how the container supports product quality, manufacturing efficiency and long-term stability rather than treating packaging as a late-stage commodity decision.

My Sterinity Nasal has been developed around this shift. Its combination of Type I glass, controlled cleanliness, validated RTU processing, pump compatibility and improved product recovery addresses several of the practical requirements associated with advanced nasal formulations in a single packaging platform.

SUPPORTING THE NEXT GENERATION OF NASAL MEDICINES

Intranasal delivery offers new opportunities for medicines that require rapid, convenient or non-invasive administration, while the expansion into CNS therapies, vaccines and other high-value applications raises the technical expectations placed on every component of the drug-device system. Primary packaging must be capable of protecting the formulation while also fitting efficiently into pharmaceutical manufacturing processes.

By combining high-quality Type I glass with validated RTU processing, My Sterinity Nasal offers a dedicated packaging solution for preservative-free nasal products and sensitive formulations. For developers seeking to move intranasal products from clinical programmes towards commercial manufacture, the platform is positioned to provide a consistent container solution focused on safety, product integrity, product recoverability and operational efficiency.

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