

# HIGH QUALITY READY-TO-USE MOLDED GLASS VIALS POWERED BY SG EZ-FILL®

## Sterinity

### WHY DO PHARMACEUTICAL COMPANIES CHOOSE STERINITY VIALS ?



#### Trust

SGD Pharma and Stevenato Group are recognized industry leaders in primary packaging for injectable drugs. Each vial follows strict validated steps from manufacturing to final delivery to protect the **physical and microbiological integrity while minimizing the risk of contamination of the aseptic area**. The SG EZ-fill® platform is a proven solution used for a variety of primary packaging components.



#### Flexibility and agility

By choosing Sterinity vials, Pharmaceutical companies **can focus on their core business** of developing and offering new products to market faster. They can also extend their product portfolio to new primary packaging options. SG EZ-fill® provides access to a broad range of Ready-To-Use primary packaging components, all with the same validation standards and packaging process.



#### Increased quality and safety

Molded glass is a proven solution for vial sizes from 20ml and above. The Type I molded glass from SGD Pharma offers a **higher mechanical resistance** that reduces the risk of particles contamination due to breakage during the fill/finish and Lyophilization steps. The **improved chemical performance** minimizes the risk of extractables to meet United States Pharmacopoeia (USP) <660> and USP <1660> guidelines.



#### Reduced Total Cost of Ownership (TCO)

Sterinity allows pharmaceutical companies to outsource their non-core activities. By doing this the investment in facilities and equipment is avoided as well as all the associated operational costs.

SGD Pharma has partnered with SG EZ-fill®  
to offer washed, depyrogenated and sterilized  
«Ready-to-Use» Type I molded glass vials.





## Vial manufacturing

Molded glass vials for injectable drugs are produced in an SGD Pharma state-of-the-art facility in France. All glass is 100% inspected in an ISO 8 room. The vials undergo an additional inspection prior to entering SG EZ-fill® process located in Italy.

## Washing

SGD Pharma vials are washed with WFI (Water For Injection) and dried in an ISO 8 class area.

## Depyrogenation

Vials are depyrogenated in a tunnel accordingly to Pharmacopoeia requirements.

## Loading into the secondary packaging

Vials are placed into final packaging: either in a Nest & Tub or in a tray. Both options are handled in ISO 5 and ISO 7 environments.

## Tyvek® sealing & steribag bagging

The secondary packaging is sealed with a Tyvek® lid under ISO 5 classification, packed in steribags and then placed into a box in an ISO 7 / ISO 8 environment. Final configuration includes packaging in pallets.

## Sterilization

All the components are sterilized by EtO using a validated process meeting ISO 11135 requirements. This final step grants the highest cleanliness of all the packaging components and reduces the risk of microbiological contamination of the aseptic area.

## Storage & delivery

Vials are stored at SGD Pharma with a shelf life of 5 years for human use. SGD Pharma manages the delivery and releases the certificate of conformity.

## SGD PHARMA HIGH QUALITY READY-TO-USE MOLDED TYPE I GLASS VIALS

	ml	ISO	mm	mm	Type I	Type I	Type of secondary packaging	Vials per secondary packaging
EasyLyo	20.0	ISO 20	56.0	30.0	●	●	Tray	60
	25.0	ISO 20	64.9	30.0	●	●		60
	50.0	ISO 20	68.5	42.5	●	●		28
ISO	50.0	ISO 20	73.0	42.5	●	●	Tray	28
	100.0	ISO 20	94.5	51.6	○	○		Tray
EasyLyo	20.0	ISO 20	56.0	30.0	○	○	Nest & Tub	24



Vials are placed Upside - Down inside the secondary packaging.

● Available upon order receipt      ○ Under development

For additional vial options, please contact your local SGD Pharma representative.

