

STERINITY

SPEED TIME TO MARKET WITH
CONFIDENCE & RELIABILITY.








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.
- **Increased quality and safety**
Molded glass is a proven solution for vial sizes from 10 ml 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.
- **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.
- **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 empty molded glass vials.

				PharmaCo
Primary Packaging	Washing	Depyrogenation and sterilization	Storage and delivery	Fill & Finish

A proven industrial process for injectable drugs



Vial manufacturing

Empty 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 according to European and US pharmacopoeias 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.



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

							Type of secondary packaging	Vials per secondary packaging
ISO	10.0	ISO 20	53.5	25.4	●	●	Tray	80
	20.0	ISO 20	58.0	32.0	●	●	Tray	54
	50.0	ISO 20	73.0	42.5	●	●	Tray	28
	100.0	ISO 20	94.5	51.6	●	●	Tray	18
EasyLyo	20.0	ISO 20	56.0	30.0	●	●	Tray	60
	25.0	ISO 20	64.9	30.0	●	●	Tray	60
	50.0	ISO 20	68.5	42.5	●	●	Tray	28
EasyLyo	20.0	ISO 20	56.0	30.0	●	●	Nest & Tub	24



Vials are placed side-up inside the nest & tub



Vials are placed down - upside inside the tray

● Available upon order receipt
For additional vial options, please contact your local SGD Pharma representative.



EasyLyo provides stronger glass vials that is more resistant and suitable to extreme conditions encountered during the lyophilization process steps. EasyLyo is a range of lyophilized Type I glass vials combining the strength of molded glass with superior aesthetics quality and weight reduction.



For more information, please visit our website
www.sgd-pharma.com