



STERINITY

SPEED TIME TO MARKET WITH
CONFIDENCE & RELIABILITY.





Why do pharmaceutical companies choose Sterinity vials?

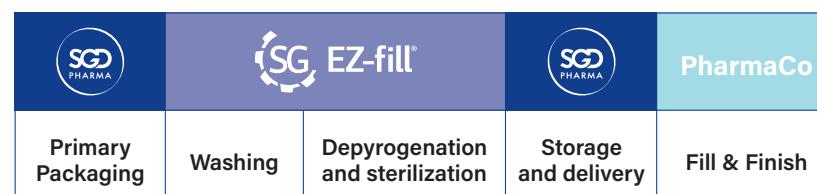
● Trust

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.

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



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 on 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
	20.0	ISO 20	58.0	32.0	●	●	Tray
	50.0	ISO 20	73.0	42.5	●	●	Tray
	100.0	ISO 20	94.5	51.6	●	●	Tray
EasyLyo	20.0	ISO 20	56.0	30.0	●	●	Tray
	25.0	ISO 20	64.9	30.0	●	●	Tray
	50.0	ISO 20	68.5	42.5	●	●	Tray
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