

# STERINITY, HIGH QUALITY STERILE AND DEPYROGENATED MOLDED GLASS VIALS OFFER POWERED BY OMPI EZ-FILL®



## Sterinity

### How can Sterinity, powered by Ompi EZ-fill®, create value for your business?



#### More flexibility & safety of supply

Choose Sterinity, powered by Ompi EZ-fill®, and access a strong and large platform of Ready-To-Use products under the same validation standards and packaging.



#### Faster to market

By removing the first steps of aseptic filling process, Sterinity provides you with readily available molded vials to manage both clinical trials and industrialization phase.



#### Increased quality and safety

Unique SGD Pharma Asolvex® Type I molded glass minimizes interaction risk. The specific design of the tray and the final packaging solution reduce breakage during storage, transport & handling. It also prevents particles and additional cosmetic non conformities which may be triggered by glass to glass contact.



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

Sterenity allows pharmaceutical companies to outsource their non-core activities, to lower their footprint and reduce the costs related to their employees and utilities.

SSP	(SG, Om	PharmaCo	
Primary Packaging	Washing	Sterilization	Filling

#### Incoming materials

Parenteral vials for injectable drug products are produced and 100% inspected in clean room environment within SGD Pharma facility. SGD Pharma high quality Type I molded vials undergo an additional inspection prior to enter Ompi EZ-fill® process.

SGD Pharma vials are then supplied to the Ompi EZ-fill® area.



#### Washing

Vials are washed with WFI (Water For Injection) and dried in an ISO 8 class.



#### **Depyrogenation**

Vials are depyrogenated in a tunnel working accordingly to the Pharmacopea requirements.



#### <u>Tray loading</u>

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



#### Tyvek® sealing & steribag bagging

Everything is sealed with a Tyvek® lid in an ISO 5 class, packed in steribags and then placed into a box allowing for EtO sterilization in an ISO 7 / ISO 8 surrounding to ensure the highest cleanliness of the packaging components. Final configuration includes packaging in pallets.



#### Sterilization

Sterilization is made through EtO and a process validated according to ISO 11135.

#### SGD Pharma high quality Type I molded vials range

- Available in clear and amber glass

Design	Nominal capacity	Height	Diameter	Neck finish	Type of glass	Pcs per pack		Type of pack
\	20 ml	56	30 °	20 mm	Туре I	60	Tray	
EasyLyo	25 ml	64.9	30	20 mm	Туре І	60	Tray	
	50 ml	68.5	42.5	20 mm	Туре I	28	Tray	
ISO	50 ml	73	42.5	20 mm	Туре I	28	Tray	
	100 ml	94.5	51.6	20 mm	Туре I	Under development	Tray	
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EasyLyo	20 ml	56	30	20 mm	Type I	Under development	Nest & Tub	

Vials configuration .



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► Upside - Down

All vials provided in ISO 20mm neck finish.

For other vial type, please contact your local SGD Pharma representative.