

SGD Pharma speeds up time to market with industry first Ready-to-Use SG EZ-fill® Nest & Tub packaging solution for molded glass vials for parenteral drugs

Puteaux Cedex, FRANCE – 16th June 2021:

SGD Pharma announces that its 20ml [EasyLyo](#) molded glass Type I vials are now available Ready-to-Use (RTU) in [SG EZ-fill®](#) Nest & Tub – an industry-recognized state-of-the-art secondary packaging format.

Increased demand for parenteral drugs generated by the Covid-19 pandemic has resulted in additional pressures being placed on biopharmaceutical companies to accelerate their time-to-market. This new RTU primary and secondary packaging combination from SGD Pharma offers biopharmaceutical producers the flexibility they need to deliver innovative medicines to patients significantly faster.

SGD Pharma was the first molded glass manufacturer to offer RTU vials at an industrial scale for injectable drugs in 2019, and its partnership with Stevanato Group has enabled the company to be the first to market with 20ml EasyLyo molded glass Type I vials in EZ-fill® Nest & Tub. RTU Type I molded glass vials are delivered pre-sterilized in Nest & Tubs ready for automated fill and finish, skipping up-front washing and depyrogenation steps in an aseptic environment and allowing pharma companies to focus on core business activities to expedite product launches.

Nest & Tub is a secondary packaging solution required for combi-lines used for fill and finish. It is largely adopted by contract manufacturing organizations (CMOs) and contract development manufacturing organizations (CDMOs) for processing a variety of primary packaging containers including vials, syringes, and cartridges for optimal manufacturing flexibility. The Nest & Tub solution avoids glass-to-glass contact, protecting the sterility and the integrity of each vial. With the introduction of SGD Pharma's RTU molded glass packaging solution in EZ-fill® Nest & Tub, drug manufacturers can accelerate their time-to-market for small to medium batches with minimal filling line changes.

SGD Pharma identified 20ml EasyLyo molded glass Type I vials, part of the [Sterinity](#) platform, as a priority for development in Nest & Tub packaging due to the specific needs of biopharmaceutical companies to protect the safety of lyophilized drugs. EasyLyo's optimized heel radius reduces the risk of costly breakages in the freeze-drier and by removing the vials' base mold marks, manufacturers can achieve uniform cakes through maximized heat transfer. The uniform wall thickness of EasyLyo vials improves their cosmetic appearance, providing better inspectability compared with standard molded glass.

Alexander Bautista, Product Manager Sterinity Platform, confirms: *“Our new 20ml EasyLyo molded glass Type I RTU vial in Nest & Tub is an optimal packaging option for biologics and innovative treatments that require glass vials with large volumes for parenteral use. The chemical and mechanical resistance of our Type I molded glass vials ensure reduced risk of delamination and breakages; in particular for drugs manufactured via lyophilization. This meets the needs of innovative*

drug manufacturers through all the stages of drug development, especially the early phases and the transition from clinical to commercial.”

With the same external dimension as 20R tubular vials, adopting 20ml EasyLyo molded glass Type I vials will only require minor changes on the filling line and allow the same freeze-drier shelf configuration. This makes it simple for drug manufacturers to adopt a multi-source approach or add molded glass vials to their primary packaging portfolio. Customers looking to add Type I molded glass vials as an alternative packaging solution are advised to start stability testing to ensure supply chain continuity in the event of shortages.

Molded glass represents approximately 40% of the injectable vials market: its higher mechanical resistance reduces the risk of breakages during fill/finish and harsh processing conditions such as lyophilization, safeguarding valuable drug products and sensitive molecules, such as oncology therapies. Improved chemical performance minimizes extractables and particle contamination to meet United States Pharmacopoeia (USP) <660> and USP <1660> guidelines.

The new 20ml EasyLyo molded Type I glass vials in Nest & Tub are in stock and available in both flint and amber glass. The Letter of Authorization (LOA) to the Drug Master Files (DMF) for our Ready-To-Use molded glass vials, pre-sterilized in the EZ-fill® platform of SG Ompi, will be available from early July. For more information about RTU molded glass vials from SGD Pharma, please watch our webinar on-demand [here](#) or download our white paper [here](#).

FAQs:

What is the primary activity of SGD Pharma?

SGD Pharma is a global leader in glass pharmaceutical packaging, answering to the needs of a diverse range of markets including parenteral, nasal, and oral drugs, as well as beauty and nutrition.

How many plants does SGD Pharma have?

Five manufacturing plants across four countries (France, India, Germany, China). We combine control of the glass process with the implementation of GMPs for pharmaceutical primary packaging in all our manufacturing facilities.

What are the specialisms of each of your factories?

Two plants are best-in-class facilities dedicated to Type I glass (Saint-Quentin-Lamotte (SQLM) in Northern France and Vemula in India). SQLM is a Center of Excellence for Type I molded glass. Type II glass for anesthetics is produced in Sucy-en-Brie, France and Kipfenberg, Germany. Type III amber glass for analgesics is produced in Sucy-en-Brie. All manufacturing facilities are ISO 15378 certified. Vemula, India is also ISO 14001 and 18001 accredited.

Does SGD Pharma manufacture both molded glass and tubular glass?

Yes. Our state-of-the-art manufacturing plant in Vemula near Hyderabad in India, completed in 2013, is registered to manufacture Type I glass compliant with Japan, European, India and US pharmacopeias. The best-in-class tubular vials and ampoules manufactured at Vemula are used in India for COVID-19 vaccine vial packaging. As well as its local and national supply of tubular vials, the Vemula site also has a major output of Type I molded glass for the Asian, EMEA and USA markets and is used as part of the global supply chain for many pharmaceutical companies.

ENDS

About SGD Pharma

Founded in 1896 in France, SGD Pharma is a global producer of molded and tubular glass for pharmaceutical primary packaging, operating worldwide with five factories and a network of more than 90 partners and distributors. The company has a long-term investment plan to regularly leverage its manufacturing facilities and develop workforce capabilities to remain at the cutting edge of technology. SGD Pharma commits to achieving consistent standards in all its facilities. In 2020, all plants are certified according to ISO 15378 standards, are pharma Good Manufacturing Practice (GMP) compliant and are equipped with ISO 8 clean rooms. With a global footprint and a strong sales force, SGD Pharma is recognized worldwide as a key player that customers can rely on to support new product development, day-to-day delivery, and quality and regulatory support. SGD Pharma benefits from over a century of expertise and a best-in-class manufacturing footprint, cementing its leading position in pharma, biopharma, veterinary, alternative medicine, and beauty and care markets. For more information, please visit www.sgd-pharma.com.

