

SGD Pharma continues customer-led innovation with range extension for Sterinity Ready-to-Use molded glass vials: adds amber 50ml size ISO and EasyLyo in Tray

Puteaux Cedex, FRANCE – 8th April 2021: Worldwide glass primary packaging supplier SGD Pharma announces the continued expansion of its Ready-to-Use (RTU) [Sterinity molded glass vial platform](#) with the introduction of amber glass 50ml volume option in Tray, now available ex-stock.

The addition of 50ml amber molded glass vials to the Sterinity platform, developed at industrial scale by a leading molded glass manufacturer, allows global pharmaceutical companies to accelerate the time-to-market of their high-value parenteral drugs with an RTU primary packaging solution for large brimful capacities, for which molded glass has historically been the preferred option.

Alexander Bautista, Product Manager Sterinity Platform, confirms: *“Not only is our Sterinity 50ml RTU vial now also available in amber glass – which protects sensitive drugs from the harmful effects of light– but we are able to offer customers the immediate lead times that are currently not available elsewhere for Type I vials in large brimful capacities. The Sterinity 50ml vials in both amber and flint versions are already validated according to Good Manufacturing Practice (GMP) standards and compliant with US and European Pharmacopoeias, and the DMF (drug master files) will be available in May 2021, making this the optimal pharmaceutical packaging container choice for drugs from early development through to commercial phases. Our global customers are reassured that their time-to-market will not be impacted by the stock availability of 50ml RTU molded glass vials.”*

The range extension for the Sterinity platform answers the potential need of the pharmaceutical industry to alleviate any supply chain pressures for parenteral primary packaging materials. Having a reliable secondary supplier to provide high-quality alternative packaging options helps to mitigate supply chain risk and ensure Business Continuity in the event of shortages, which is facilitated by the U.S. Food and Drug Administration(FDA)’s March 2021 Guidance for Industry: COVID-19 Container Closure System and Component Changes: Glass Vials and Stoppers.¹ This guidance combines the various documentation issued in the past to support SGD Pharma’s customers in any change in vial type.

Molded glass represents approximately 40% of the injectable vials market and is becoming an increasingly popular solution: its higher mechanical resistance reduces the risk of breakages during fill/finish and safeguards against harsh processing conditions such as lyophilization, while improved chemical performance minimizes extractables and particle contamination to meet United States Pharmacopoeia (USP) <660> and USP <1660> guidelines.

The robust mechanical and chemical resistance of molded glass makes the SGD Pharma’s 50ml ISO version an optimum solution for hazardous liquids like cytotoxic drugs. The 50ml EasyLyo version is an optimized solution for sensitive drugs manufactured through lyophilization/freeze drying, such as some oncological treatments. The Tray and its secondary packaging design are a state-of-the-art solution that eliminates glass-to-glass contact, reducing the risk of particles contamination while granting the sterility and physical integrity of each vial.

The Sterinity platform, which already included 20–25ml [EasyLyo](#) in Tray (both flint and amber) and now 50ml [ISO/EasyLyo](#) in Tray (both flint and amber), offers high quality pre-sterilized Type I molded glass to speed up aseptic filling processes and reduces time-to-market for high value parenteral drugs.

SGD Pharma was the first molded glass manufacturer to offer RTU vials for injectable drugs. Its long-serving partnership with Stevanato Group has enabled the company to introduce 50ml amber glass vials powered by [SG EZ-fill®](#) – an industry-recognized secondary packaging platform that supports end-to-end RTU processes. Upfront washing, depyrogenation, and sterilization steps are taken care of, with RTU Type I molded glass vials arriving in Trays or in Nest & Tubs ready for manual, semi-automatic, or automating fill/finish, allowing pharma companies to focus on core business activities to expedite product launches.

Large size amber glass RTU format vials add to the extensive Sterinity range, providing the pharma industry with access to 20ml, 25ml and 50ml vials available ex-stock and a reliable supply source for primary packaging. This range extension in amber is the first of several to be announced by SGD Pharma in 2021, including the upcoming 100ml ISO RTU in Tray and the 20ml EasyLyo in Nest & Tub.

For more information about RTU molded glass vials from SGD Pharma, please register for our webinar [here](#) or download our white paper [here](#).

References:

1. COVID-19 Container Closure System and Component Changes: Glass Vials and Stoppers, U.S. Food and Drug Administration, March 2021. <https://www.fda.gov/media/146428/download>

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.

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About SGD Pharma

Founded in 1896 in France and 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, quality or regulatory support. SGD Pharma benefits from a long know-how and a best-in-class manufacturing footprint. The company has a long-term investment plan to regularly leverage its manufacturing facilities and develop people competencies to be at the cutting edge of the technology. SGD Pharma commits to have the same standard in all its facilities. In 2020, all plants are certified according to ISO 15378 standard, pharma GMP's compliant and equipped with ISO 8 clean rooms. SGD Pharma is a producer of molded glass for pharmaceutical primary packaging, operating worldwide with five factories and a network of more than 90 partners and distributors. For more information, please visit www.sgd-pharma.com

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