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Implementing Ready-to-Use Glass Vials for Flexible Aseptic Filling

As the first commercial ready-to-use (RTU) molded glass vial system that reduces costs while simultaneously improving quality, the new Sterinity platform is an efficient solution to the challenges associated with aseptic filling.

Parenteral Delivery on the Rise

Parenterally delivered drugs have gained in popularity over the last several years. According to IQVIA MIDAS, in 2018, parenterals accounted for 32% (by volume) of the global drug market.[1] The parenteral packaging market is projected to grow at a robust compound annual growth rate of 11.4% between 2018 and 2024.[2] Parenteral delivery of drugs is often preferred because it allows absorption directly into the body at the site of delivery. Parenteral administration is the route typically associated with biological drugs, but it can also be used for small molecule drug products, especially those that present solubility issues, and for the delivery of nutrition and vitamins.

Addressing the Challenges of Aseptic Fill and Finish with RTU

The increased demand for personalized medicines and biologics drugs and the consequent flexibility in manufacturing capacity has led to a growing demand for RTU systems. While washing, depyrogenizing and sterilizing glass primary packaging are non-core activities for a pharma company, which should focus on drug development, a need for fill/finish solutions that can ensure sterility without significant investment or operational demands has emerged. In RTU systems, packaging is pre-prepared so that the only step left in the process is to fill and finish the container, which eliminates the majority of process challenges. While an RTU solution has largely been implemented for small-volume containers, another option for larger-volume containers (defined as those in the 20–500 mL range) is a crucial need in the market.

As industry leaders specialized in the manufacture of molded glass packaging, SGD Pharma has introduced the Sterinity platform – the first commercial solution for RTU molded vials – as a flexible solution for scale-up. Sterinity is a key differentiator because it allows for the commercial availability of RTU molded glass vials for the first time. The Sterinity platform leverages the well-established EZ Fill® system by Ompi, Stevanato Group (Padua, Italy) to extend the benefits of RTU across a range of applications.

Quality First

Our Sterinity platform focuses on quality and flexibility. We use Type I glass in production and are committed to bringing new solutions to the market by steadily expanding our portfolio to include even more products in a broad range of sizes. Over the next 1–2 years, we will be releasing an RTU system in partnership with Ompi with two central design options, one featuring a premium quality ISO design and one with an optimized EasyLyo product.

The SGD Pharma Expanded Portfolio

All of our ISO vials are made from a premium quality molded glass RTU option. The EasyLyo product relies on molded glass technology and has an aesthetic appeal, along with the chemical durability needed to store sensitive drug products (in a host of potentially extreme conditions) with minimized risk of breakage, leakage or quality issues. In addition to being stronger than traditional molded glass, the vials are also 30% lighter on average and are also optimized for heat transfer during lyophilization. The RTU solution has an ISO 20-mm neck finish, which is a model measurement for stoppering and securing the product and is also optimized for heat transfer during lyophilization.

Sterinity offers a selection of secondary packaging configurations, and boasts a diverse glass vial portfolio that meets all industry standards and customer requirements.

SGD Pharma is currently adopting both nest-and-tub and tray secondary packaging presentations from Ompi EZ-Fill® to provide our clients with even more options. Our vials are packaged without glass-to-glass contact to ensure product integrity. Tray configuration is generally a preferred packaging solution for a dedicated line, while a nest-and-tub configuration can support multiple filling technologies to process vials, cartridges and syringes in a single solution.

The Sterinity Solution

Sterinity offers a selection of secondary packaging configurations, and boasts a diverse glass vial portfolio that meets all industry standards and customer requirements. As the need for flexible filling increases, companies will be seeking a cost-effective quality solution to streamline production and increase the speed of changeover. As the first commercial solution for RTU molded glass, SGD Pharma's Sterinity platform is a viable answer to this pressing issue. P

References

1. IQVIA MIDAS, Actual 2018 – Global market database covering 93 countries and over four million pharmaceutical packs.

2. *Global Parenteral Packaging Market Will Reach USD 18.20 Billion By 2024.* Rep. Zion Market Research. 4 Sep. 2018. Web.