WHITE PAPER

Ready-to-Use Cartridges

Ensuring Compatibility for GLP-1-based Drugs

Stevanato Group

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Obesity becoming a healthcare priority?

Obesity is considered a chronic, complex disease. According to IQVIA, global spending on weight management drugs is expected to exceed USD 70 billion by 2028, representing a double-digit compound annual growth rate (CAGR) from 2024, which is the highest among all segments of the pharmaceutical market.

The main reason for this expected growth is the emergence of GLP-1 (glucagon-like peptide 1) agonists, which were originally developed for the treatment of diabetes and often lead to weight loss in patients. Several companies have developed these GLP-1 agonists as novel weight loss treatments that are comparable in efficacy and safety to traditional bariatric surgery.[1]

References

1. Source: IQVA Global Use of Medicines 2024, Outlook to 2028 and Stevanato Group internal Analysis

Drug, container and device compatibility will be the biggest challenge

Market preference will determine the system chosen for delivery of GLP-1 drugs to patients. For multi-dose applications, pen injectors using cartridges are expected to be the preferred solution.

To meet market demand, pharmaceutical companies and contract fillers will need to invest in new filling equipment.

But which technology to choose? Bulk or ready-to-fill? And how will different types of containers be handled?
In addition, pharmaceutical companies are looking for ways to reduce their footprint and lower the total cost of ownership.
Especially for new GLP-1 factories, the cost aspect over the lifetime of the product is crucial.

Ready-to-use cartridges

As the global demand for GLP-1 based drugs rises, a reliable container supply, smooth operations, and safe and easy self-administration become more crucial.

Ready-to-fill cartridges are a viable solution for GLP-1 applications for both auto-injectors and pen injectors such as Alina®, our user-friendly disposable pen injector platform for variable and multi-dose treatments, based on proven technology.

EZ-fill®: a proven solution

The EZ-fill® platform has been developed in close co-operation with manufacturers of fill and finish machines to ensure smooth operational processes.

Ready-to-fill containers are in growing demand. As they are supplied pre-washed and pre-sterilized, they can be fed directly into the aseptic fill and finish line, eliminating several downstream processes such as washing, drying and depyrogenation.

For pharmaceutical companies, this means minimizing risk, maintaining quality and reducing complexity! Stevanato Group's EZ-fill® platform has long set the industry standard for pre-sterilized, ready-to-fill containment solutions. And why?
EZ-fill® solutions ensure automated processes and less human intervention to preserve the integrity of the pre-sterilized containers. EZ-fill® enables the use of different primary containers and multiple fill-and-finish technologies – reducing total cost of ownership (TCO) for equipment, labor, validation and space. No waste of time in infeed change – the open platform ensures compatibility of packaging from different manufacturers. Over the past years, more than 250 lines have been installed with EZ-fill® packaging technology. The platform has been adopted by 30 global filling machine manufacturers and is used on 80 different machine models.

EZ-fill® cartridges

Nexa® EZ-fill® cartridges represent the highest quality level offered by Stevanato Group for cartridges.

Superior cosmetic quality and mechanical performance are both critical to ensure process efficiency and reduce quality risks during the filling phase and final assembly in injection devices such as auto-injectors and pen injectors.
In addition, Nexa® EZ-fill® cartridges feature an innovative baked-on siliconization technology that results in a homogeneous silicone layer with uniform thickness and distribution. The siliconization recipes have been developed to minimize the release of sub-visible particles and reduce the content of inorganic extracts from glass without compromising break-loose and gliding forces. This results in improved stability and minimizes interactions between the drug (i.e. GLP-1) and the container.

Data and results

Thanks to the capabilities of the Technology Excellence Centers at Stevanato Group, a characterization study was performed using 3ml EZ-fill® cartridges filled with a representative GLP-1 agonist formulation (Semaglutide) as a mimic solution.

The stability was assessed over a period of 6 months at 5°C ± 3°C.
Below are the key results of the study.

Nexa® EZ-fill® 3ml cartridges have a **homogeneous silicone layer** in terms of thickness and distribution, resulting in a consistent gliding performance over time, with less variability between samples at any given time point.

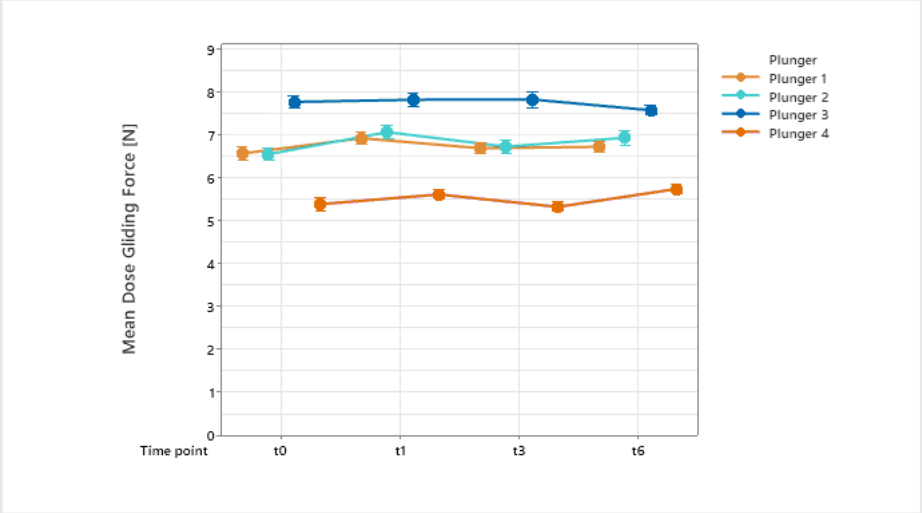

Figure 1: Results of Mean Dose Gliding Force at 5±3°C over six months

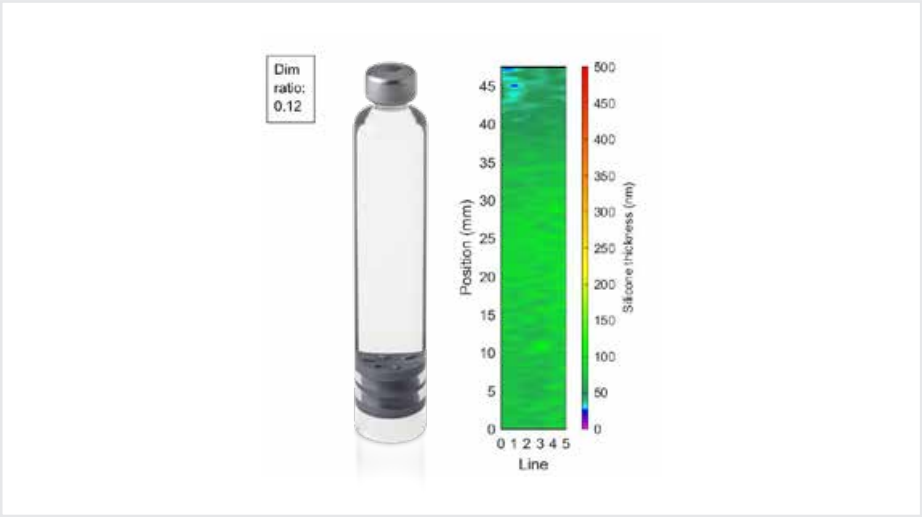

Figure 2: Results showing homogeneous silicone layer in terms of thickness and distribution

Sub-visible particles release test on filled cartridges

Nexa® EZ-fill® 3ml cartridges, tested according to USP <788>, show a low Sub-visible particles release, always below USP limits: 6000 particles/ container ≥ 10 µm and 600 particles/ container ≥ 25 µm.

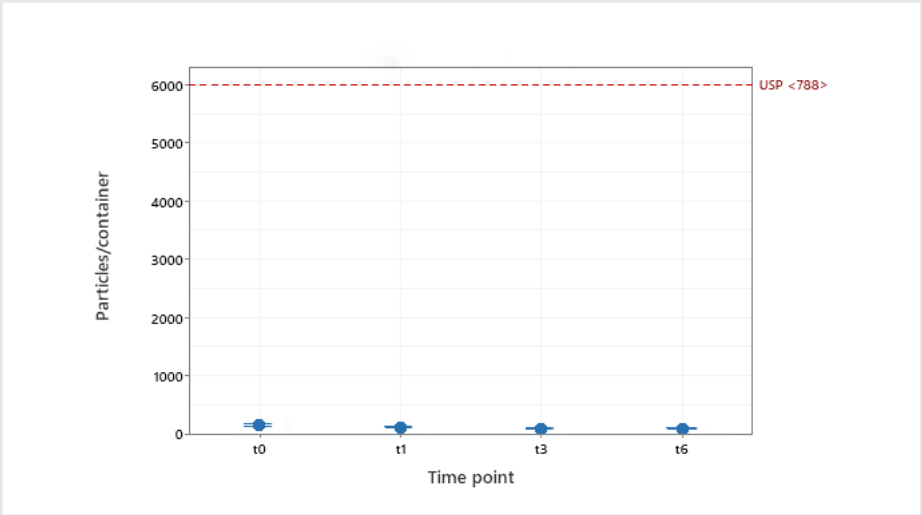

Figure 3: Results of Sub-visible particle testing ≥ 10 µm at 5±3°C over six months

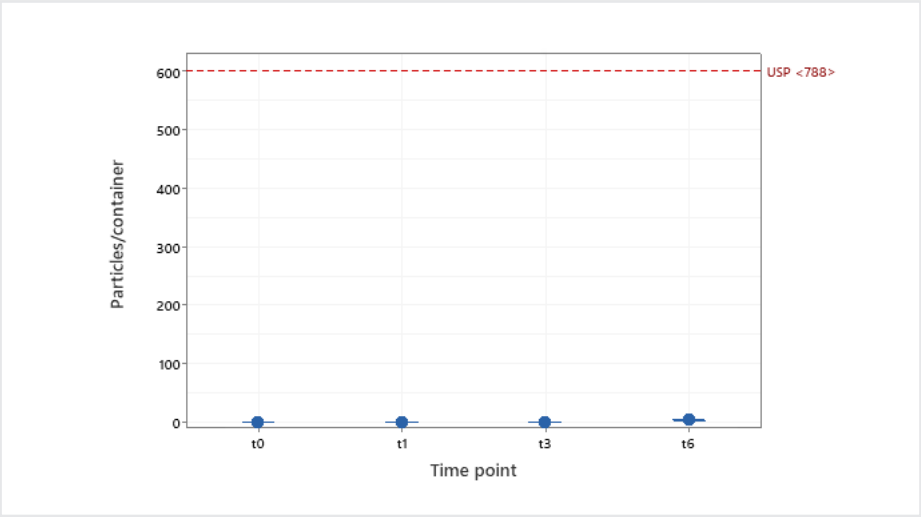

Figure 4: Results of Sub-visible particle testing ≥ 25 µm at 5±3°C over six months

Main inorganic glass extractable elements test on filled cartridges

The major glass extractable elements are: Aluminum (Al), Boron (B) and Silicon (Si).
Nexa® EZ-fill® 3ml cartridges, tested according to Stevanato Group's internal method, showed comparable mean extractable values over time.

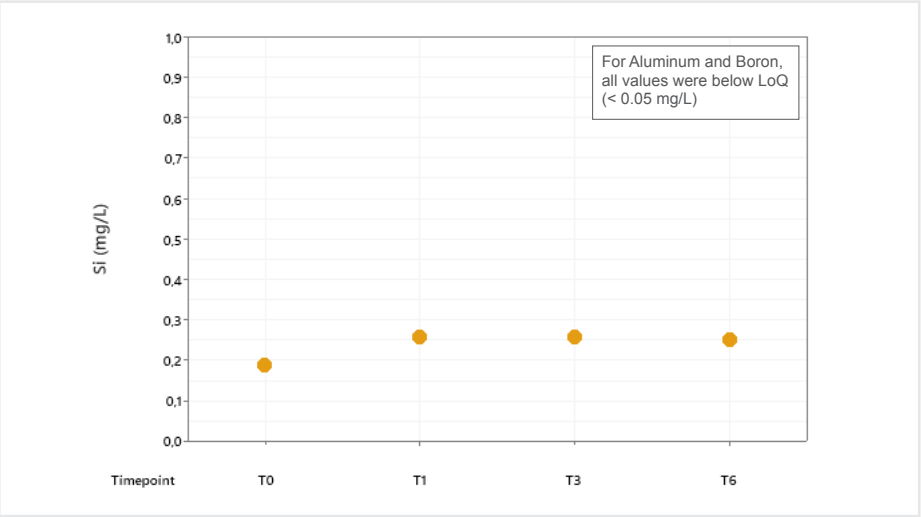

Figure 5: Results of Mean Silicon Value (mg/L) at 5±3°C over six months

Further development to ensure smooth operational processes

Stevanato Group EZ-fill® technology is continuously improved ensuring maximum performance during the product's life, optimizing process parameters for nest production and enabling selection of the design giving the best performance.

Conclusions

EZ-fill® cartridges are the most suitable solution for GLP-1 applications, offering increased flexibility, faster time to market and lower total cost of ownership.

The ready-to-fill cartridges are available in nest and tray configurations that comply with ISO 21881 and ISO 11040-7 standards and guarantee high mechanical and cosmetic properties. The EZ-fill® platform is compatible with a variety of auto-injectors and pen injectors – speeding up time to market and boosting operational efficiency for pharma companies of all sizes. These conclusions confirm the advantages of EZ-fill® cartridges as an optimal containment solution for GLP-1 applications.

Find more information at:
stevanatogroup.com/en/offering/drug-containment-solutions/ez-fill-platform/

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Chiara is the Product Manager for the Cartridge Platform at Stevanato Group. She is responsible for developing and defining the go-to-market strategy of glass cartridges (ready-to-use and bulk). After her Economics and Business Administration studies at Udine University and Copenhagen Business School, she built extensive knowledge working as a Product Manager for medical devices for injectable products. Since 2016 - when she joined Stevanato Group – Chiara Mussoi has been in charge of evaluating and promoting new products that meet the customer's needs and expectations.

About Stevanato Group

Founded in 1949, Stevanato Group is a leading global provider of drug containment, drug delivery and diagnostic solutions to the pharmaceutical, biotechnology and life sciences industries. The Group delivers an integrated, end-to-end portfolio of products, processes and services that address customer needs across the entire drug lifecycle at each of the development, clinical and commercial stages. Stevanato Group's core capabilities in scientific research and development, its commitment to technical innovation and its engineering excellence are central to its ability to offer value-added solutions to clients.

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