

Ompi launches LDP (Low Delamination Propensity) Vials in a Ready-to-Use configuration

Piombino Dese, Padua - Ompi widens its product portfolio launching LDP (Low Delamination Propensity) Vials. In addition to the flexibility offered by the Ez-fill® portfolio, LDP Vials have the advantage of a minimized delamination propensity reducing the risk of drug product recalls to pharmaceutical companies.

The delamination of pharmaceutical glass is a serious issue, as it can cause glass lamellae to appear in vials, a problem that leads to several drug product recalls in recent years. The first stage of delamination is always the formation of an altered layer due to the **glass-liquid interactions that may lead, after a long period**, to the separation of thin **glass layers** that appear as shiny, needle-shaped particles **floating** in the filling liquid.

Ompi's solution to mitigate delamination

After an extensive investigation **on the chemical performance of the inner surface** of vials and on the **critical glass forming process parameters** that influence the final delamination propensity of vials performed by SG Lab, OMPI launches LDP Vials as a result of an optimized forming process that minimizes the surface inhomogeneities formation.

This improved manufacturing process is combined with quantitative and qualitative tests, aligned with USP <1660> Guidelines, proving the quality, the stability and the reduced risk of glass delamination of LDP Vials.

Ompi launches LDP in a RTU configuration: LDP EZ-fill® Vials

Besides bulk configuration, Ompi offers a full range portfolio with a low delamination propensity in a ready-to-use configuration, extending the LDP concept to EZ-fill® vials ensuring consistent chemical performance and no degradation of the inner glass surface after the EZ-fill® process.

Ompi EZ-fill® is the widest range platform of clean, sterile, depyrogenated and ready-to-fill glass containers for pharmaceutical use. The EZ-fill® solution, which includes vials, syringes and cartridges, is available with a double configuration in Nest & Tub and Tray.

EZ-fill® is the perfect solution to be managed both during clinical trials and during the industrialization phase: it allows pharmaceutical companies to outsource their non-core activities, to lower footprint and to reduce costs related to personnel and utilities.

Since LDP Vials are produced with Type I Borosilicate glass and have no coating applied, they ensure no need to re-file to Official Authorities: they can easily be applied to already registered products.

When can LDP be adopted?

Andrea Zambon, Marketing Director Pharmaceutical Systems division at Stevanato Group, states that *“Official Regulation & Authorities strongly recommend investigating glass delamination propensity to ensure patient safety and product quality: in fact, an early delamination propensity prediction avoids product recalls and time-to-market delays. EZ-fill® LDP is the ideal solution for new drug products where the selection of the container plays a crucial role in the early phase of development. In addition, pharmaceutical companies can benefit of a container with improved inner glass surface to respond to authorities’ requirements regarding container-drug interaction”*.

EZ-fill® LDP Vials are already available in 2R, 10R, 25R, 30R format both EZ-fill® and bulk, while 4R, 6R, 8R, 15R, 20R formats will be available soon.

About Ompi A Stevanato Group Brand:

Ompi is part of the Pharmaceutical Systems division of Stevanato Group. It offers the widest range of glass primary packaging, from the traditional ones, such as vials and ampoules, to the high-value ones as syringes and cartridges for auto-injectors and pen-injectors. Vials, cartridges, and syringes are available, sterile and ready-to-fill (Ompi EZ-fill®).

Ompi boasts a global footprint with high-quality production plants in Europe (Piombino Dese and Latina in Italy, Bratislava in Slovakia), Mexico (Monterrey), China (Zhangjiagang, near Shanghai) and a plant in Sete Lagoas, (Brazil).

www.sg-ompi.com

About Stevanato Group:

Founded in 1949, Stevanato Group is committed to creating systems, processes, and services that guarantee the integrity of parenteral medicines.

*It comprises two operational divisions dedicated to serving the pharmaceutical industry: **Pharmaceutical Systems** with Ompi specializing in glass primary packaging and Balda, focused on specialty plastics and delivery devices; **Engineering Systems** with Spami, Optrel, InnoScan and SVM, specializing in glass processing, inspection systems, assembly and packaging solutions.*

These two divisions enjoy a close, synchronous relationship, featuring daily exchanges, which ensure that Stevanato Group has complete control over the entire production process.

The Group also benefits from the SG Lab activity that provides technical and analytical services on the potential interaction between drug and container.

www.stevanatogroup.com