

Press release

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## Gerresheimer COP Vials: Ice-cold solution for the challenges of biologics

- Suitable for cryogenic storage
- High break resistance
- Prevention of delamination

**Düsseldorf/Barcelona, October 11, 2023. Gerresheimer, innovative system and solution provider and global partner for the pharma and biotech industry launches with COP (Cyclic Olefin Polymer) vials a particularly satisfactory solution for the filling and storage of highly sensitive biologics. They are suitable for mRNA active ingredients at -80°C and cryogenic temperatures. Gerresheimer is expanding its RTF portfolio of glass vials in various qualities with a product made of high-quality polymer which combines the best material properties of glass and plastic. The vials are crystal clear, particularly break-resistant and have good oxygen and moisture barriers. They can be filled and packaged in various filling systems, for example in multi-filling systems or isolators.**

"Many new active ingredients are personalized medicine and "smart biologics." Most of them need to be frozen to keep them stable throughout the supply chain, from their filling to their administration to the patient. At the same time, they also place high demands on the storage and administration of the drugs," says Dr. Wolfgang Dirk, Vice President Product Innovation at Gerresheimer Primary Packaging Plastic.

### **Suitable for storage at cold and cryogenic temperatures**

It is specifically challenging for packaging materials to be cooled down to deep freezing temperatures like -80°C or even below, e.g., liquid nitrogen: -196°C, which are common storage temperatures for mRNA-based pharmaceuticals. The cooling down of most of known materials results in a shrinking of it, which is expressed by the thermal expansion coefficient and is different from material to material. The inverse effect means the heating of a material leads to the expansion of the material. Both processes are usually reversible. Considering the effect of a deep freeze cooling on a vial-closure system the material of vial and the stopper should shrink with the same magnitude to avoid loss of container-closure integrity. For COP vials and rubber stoppers it is given that the shrinking factor, which derives from the thermal expansion coefficient, is very similar.

This also plays a role in the practical application of the vial and stopper system: It has to be frozen after filling and thawed to e.g., room temperature before use to enable the nurse or doctor to withdraw the injectable drug product. Both processes freezing and thawing apply additional stress to the container material. Various tests have demonstrated that COP vials are very robust to such treatments when compared with glass vials. Therefore, the container closure systems with COP vials are a very stable for mRNA-based drug products.

### **A high moisture barrier**

Cyclic Olefin Polymer (COP) has a high moisture barrier compared to conventional polymers, which promotes stability of reagent concentrations and allows longer shelf life of moisture-sensitive components.

### **As RTU vials - ready to use**

With the COP vials, Gerresheimer is adding a product made of plastic to its well-known RTF portfolio. The Ready-To-Use polymer injection vials are formed in controlled environment and packed in the ISO7 classified clean room conditions, packaged in tray and soon in nest and tub and gamma irradiated. This allows filling to begin without any further process steps.

### **In ISO like format**

The monolayer vials are available in 2, 5-, 10-, 20- and 50-mL sizes with matching dimensions such as height, diameter, or neck diameter according to ISO 8362. A new additional size of 100mL is under development.

### **High breaking strength**

Based on an internal study COP vials have 5 to 10 times higher break strength compared to conventional glass vials. (Can you illustrate this more). The exceptional impact resistance provides unmatched container strength, protecting against leakage, which means even more safety, especially when using cytotoxic compounds.

### **Delamination prevention**

The COP contact surface improves stability for sensitive drugs by eliminating the presence of heavy metal ions in the polymer, and the highly nonpolar, reaction-inert surface further reduces potential interactions. They can be used for parenteral formulations with a wide pH range and are an ideal solution for all drugs and formulations that attack glass surfaces and detach glass particles.

### **Low drainability/residual water**

Due to its chemical nature, COP is hydrophobic, or water repellent. The advantage is less overflowing to compensate for loss of active ingredient due to adhesion. Therefore, water adheres less to the surface of COP than to a glass surface. The low water adhesion of the hydrophobic surface enables almost complete retraction of the drug.

## Gerresheimer at CPHI Barcelona

Gerresheimer is an exhibitor at CPHI 2023 in Barcelona, Spain, from October 24-26, presenting its products and solutions in Hall 2 at Booth 2H50.

### About Gerresheimer

Gerresheimer is the innovative system and solution provider and global partner for the pharma, biotech and cosmetic industry. The company offers a comprehensive portfolio of pharmaceutical containment solutions, drug delivery systems and medical devices as well as solutions for the health industry. The product range includes digital solutions for therapy support, medication pumps, syringes, pens, auto-injectors and inhalers as well as vials, ampoules, tablet containers, infusion, dropper and syrup bottles, and more. Gerresheimer ensures the safe delivery and reliable administration of drugs to the patient.. With 36 production sites in 16 countries in Europe, America and Asia, Gerresheimer has a global presence and produces locally for the regional markets. With over 11,000 employees, the company generated revenues of around €1.82bn in 2022. Gerresheimer AG is listed in the MDAX on the Frankfurt Stock Exchange (ISIN: DE000A0LD6E6).

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