H&T PRESSPART

vytal

Innovative RTU Snap-Fit Closure

At H&T Presspart we are committed to long-term partnerships with both our customers and suppliers. We have been supporting the growth of global pharmaceutical companies across different markets for 50 years. We partner with our customers to provide dedicated single-source supply and contingency concepts.

We deliver long-term value through continuous improvement and nurture partnerships through dedicated customer care.

Working Together

1.4Bn
Assembled devices and plastic components produced

60+
Injection molding machines with up to 64 cavities and 25+ automatic assembly lines

50+
Years experience in manufacturing components and devices for the healthcare market

800+
Employees across our 4 sites and global functions

7200
Sqm of ISO 7, ISO 8 and ISO 8 equivalent cleanroom space

We are a world leader and specialist in manufacturing drug delivery devices and pharmaceutical components. Our extensive skills and experience cover drug delivery device development and Industrialization. With 50 years' experience in partnering with the world's leading pharma companies, we have developed a strong reputation for precision and reliability – critically important when patients' quality of life depends on our products.

Bringing your product to market

As a partner at every step of the development process, we tailor our services to meet your individual requirements of each project.

From idea generation stage to product design and manufacturing process definition through to validation, we take your drug delivery device and primary packaging concepts to commercial supply.

From low volume manual or semi-automatic solutions for concept devices or clinical batches through to automated commercial production, we can support you.

Working with clearly defined development, risk management and regulatory processes our close knit teams ensure a seamless transition from design to manufacturing.

Discover how we can bring your product to market

www.presspart.com

Flip Away

Clip Cover End

Clip Cover Cage

Rubber Stopper

Glass/COP Vial

vytal

Vytal®: The innovative snap-fit RTU closure

Vytal® has been designed as a unique and innovative solution for small molecules, biologics, viral vectors, mRNA, antibody-drug conjugates, orphan drugs, cell & gene therapies and other advanced therapy products manufactured in small-medium batches under the highest containment requirements.

Vytal® has been developed in compliance with ISO13485 standards and is designed to fulfil GMP Annex I criteria, delivered sterile for ready-to-use (RTU) applications. Vytal® meets the demand of new filling technologies and reduces time-to-market the highest quality standards.

- Snap-fit closure system
- Ready-to-use (RTU)
- ISO dimensions
- Glass & COP vial compatibility
- Bulk & nested configurations
- Anti-counterfeiting: Tamper evidence
- CCI assured even at low temperature (-80 °C)
- Compatibility to standard marketed CSTDs
- Low particle generation
- Low residual volume
- Full vial visability
- Anti-counterfeiting: Laser marking

The state-of-the-art container closure solution

In recent years, the pharmaceutical industry has experienced a transformative shift, with biologics and advanced therapies emerging as key drivers of global healthcare advancements. However, the production of these complex biotherapeutics presents unique challenges, including their inherent instability and specific containment requirements. As a result, aseptic filling has become essential to ensuring the integrity and safety of these products. Vytal® offers a robust and efficient solution that addresses these challenges.

Low particle generation

Vytal® has been developed in compliance with ISO13485 standards and is designed to fulfil GMP Annex I criteria, delivered sterile for ready-to-use (RTU) applications. Crimping has become one of the most concerning steps in the filling and finishing process of injectable medicines in vials. Beyond the numerous cosmetic defects and potential integrity failures, the generation of particles during crimping necessitates conducting the process in a separate environment from capping, jeopardizing the final product.

With Vytal®, a snap-fit concept solution, crimping is eliminated, allowing the stoppering and closing to occur in a single step under the highest containment requirements. Additionally, Vytal® is provided in a nested format, preventing direct 1-to-1 contact during transport and storage, which significantly reduces particle generation.

Anti-counterfeiting technologies

Industry estimates suggest that counterfeit pharmaceuticals represent the most profitable segment of the global trade in illicit imitation goods. The deception associated with counterfeit pharmaceutical products results in annual losses of billions of dollars globally, severely impacting the brand reputation and financial performance of pharmaceutical companies. The primary risk, however, is for patients to receive incorrect drugs or dosages, which can result in fatal outcomes.

Vytal® provides a solution with laser marking on the clip cover end for single-unit coding, serving as an initial barrier against counterfeiting. Furthermore, our design incorporates an innovative tamper-evidence feature, visible through the window on the flip away button, even before opening.

Less residual volume

The Vytal® design resembles a standard Container Closure System (CCS) from the perspective of healthcare providers and patients, facilitating its adoption. For drug manufacturers, Vytal® not only minimise the effort and resources needed to train and support end users but also reduces costs associated with full visibility during vial inspection.

A crucial benefit of Vytal's design is its ability to provide unobstructed visibility of the vial neck, enabling the recovery of every milliliter during dosing. This feature results in reduced residual volume and minimizes overfilling, both essential for manufacturing complex molecules due to the high costs of new therapies.

Container Closure Integrity assured even at low temperatures (-80 °C)

Container Closure Integrity (CCI) has become a crucial factor in the development of a molecule, as it assesses the primary packaging system's capability to preserve a sterile barrier against contamination, thereby ensuring safety and stability. Integrity defects can affect the drug, jeopardizing its efficiency, leading to unforeseen side effects, and potentially compromising patient health.

Vytal® features a unique design with three distinct sealing areas, ensuring CCI even at low temperatures of -80°C, and is compatible with both glass and COP vials.

Compatibility with Closed System Transfer Devices

Closed System Transfer Devices (CSTD) are utilized during the compounding and administration of hazardous drugs, such as chemotherapy, and should be employed throughout the entire hazardous drug-handling process, from compounding to administration to patients.

With interface dimensions matching those of an ISO vial, Vytal® ensures compatibility with standard Closed System Transfer Devices already available on the market. The main function of a CSTD is to minimize potential exposure to hazardous drugs and prevent contamination.

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Vytal®: Excellent results on comprehensive design and performance tests

H&T Presspart has undertaken an extensive range of tests with Vytal® in different configurations with glass and COP vials, which ensures that it is the perfect solution even for the most complex molecules.

Helium leak tests – ambient temperature

Figure 1: Glass Vial
Helium leak test with glass vial and Vytal® at ambient temperature

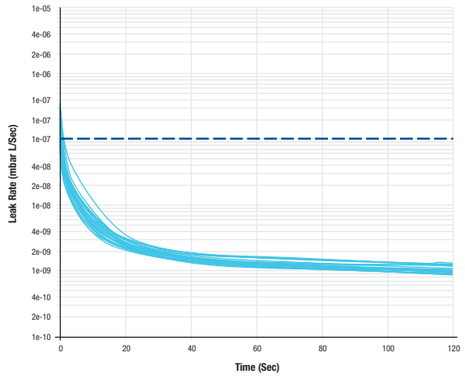
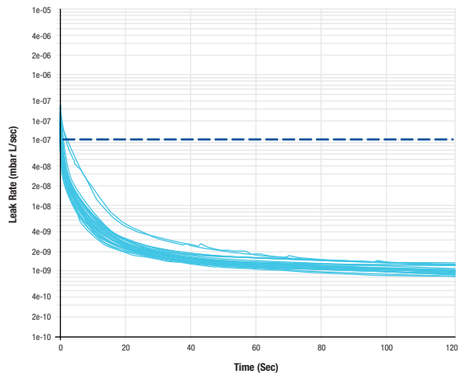


Figure 2: COP Vial
Helium leak with COP vial and Vytal® at ambient temperature



Helium leak tests – extreme temperature (-80ºC)

Figure 3: Glass Vial
Helium leak test with glass vial and Vytal® at low temperatures (-80ºC)

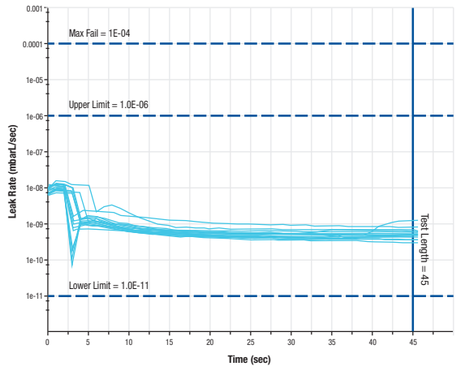
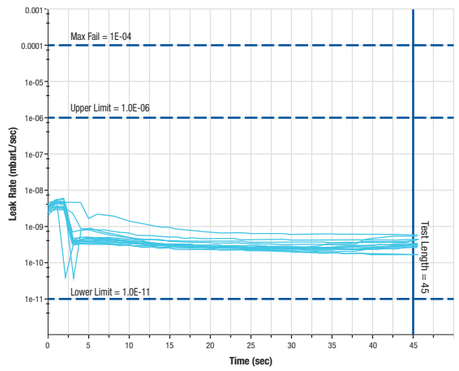


Figure 4: COP Vial
Helium leak test with COP Vial and Vytal® at low temperature (-80ºC)



Full visibility and less residual volume

Figure 5: Extractable Volume Test

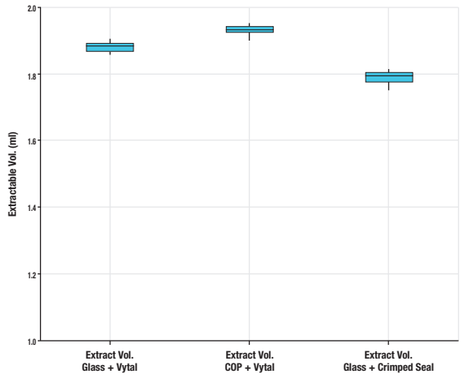
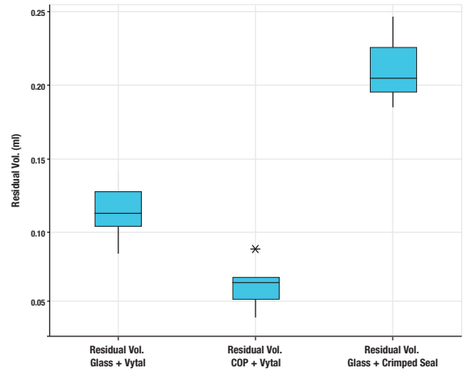


Figure 5: Residual Volume Test



Extractable and residual volume tests (Figure 5) were undertaken with WFI and 21G/1” (0.8 x 25 mm) needle BD in three different configurations:
(1) Glass vial + Vytal with coated stopper
(2) COP vial + Vytal with coated stopper
(3) Glass vial + coated stopper + crimped Seal.

The test results were positive, showing that Vytal® was superior compared to crimped closures.

H&T PRESSPART

Impacting Tomorrow. Together.

Let's work together

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