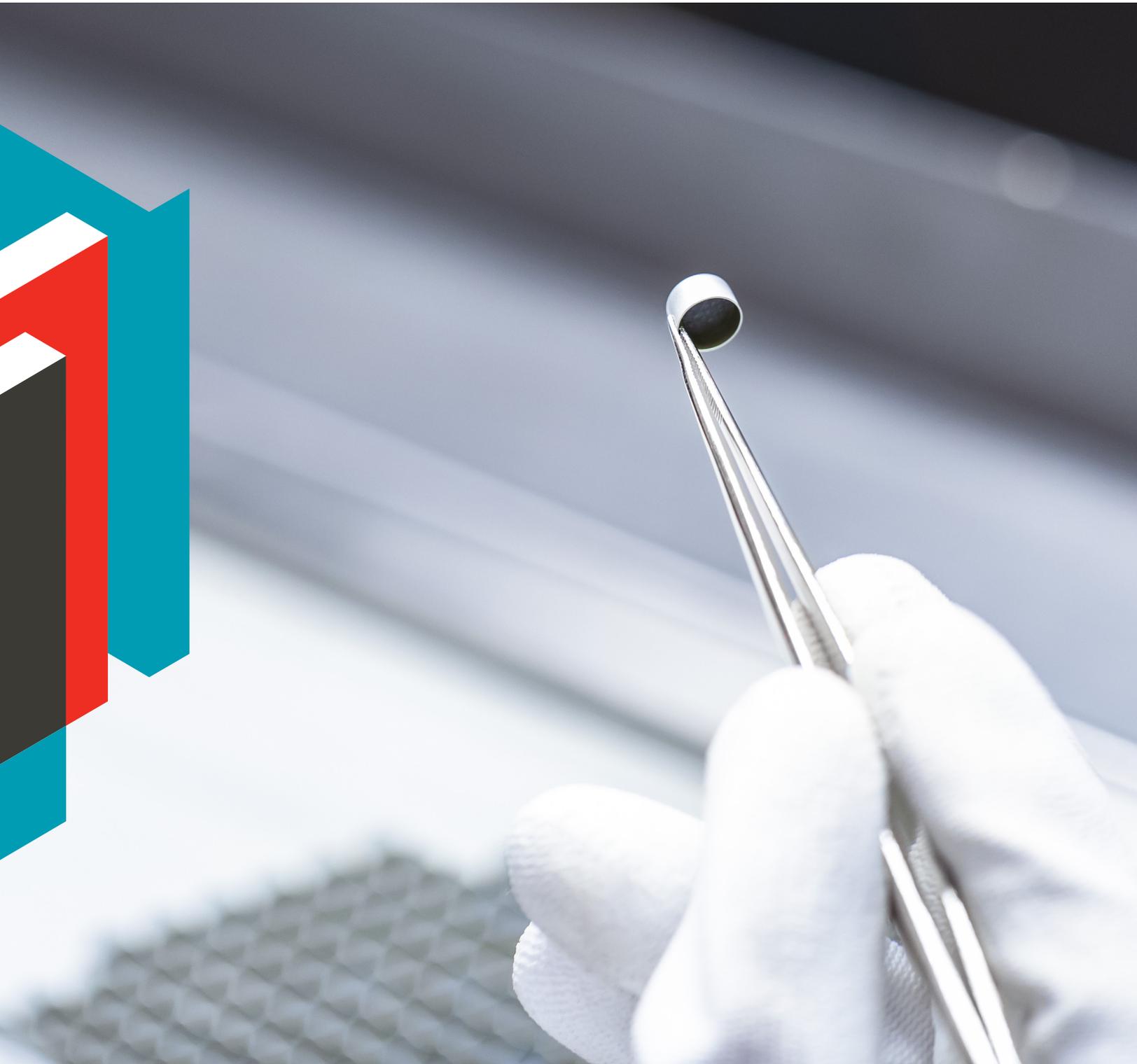


DuraCoat™ COMBISEALS:
THE OPTIMAL SOLUTION FOR
HIGH-END CARTRIDGE APPLICATIONS



THE NEXT GENERATION IN ALUMINUM SEALS

With an advanced and industry-leading lamination for combiseals, Datwyler offers the best solution for cartridge applications. Datwyler's DuraCoat™ combiseals combine high-quality alloy with a protective laminate creating a higher-quality end product.

Datwyler's lamination technology provides a protective barrier to external forces, reducing the risk of abrasion during manufacturing and handling.



As a leading industrial supplier and key player in the global healthcare industry, Datwyler's efforts are to continually improve their products and processes. Datwyler's unique portfolio includes the most innovative elastomer formulations, coatings, aluminum seals, and processing technologies.

For cartridge applications, Datwyler developed an innovative laminated aluminum solution designed to meet the most stringent requirements for customers and authorities – DuraCoat combiseals.

INNOVATIVE SOLUTION FOR COMPLETE PROTECTION

Datwyler's laminated aluminum combiseals help improve product robustness while reducing the risk of drug product contamination. DuraCoat combiseals combine a high-quality alloy with a protective laminate, providing customers with the cleanest product currently available on the market.

Datwyler's DuraCoat combiseals are produced using best-in-class production technologies matching the quality and regulatory expectations of the pharma markets. All components are manufactured in a controlled environment. The production facilities are geared towards optimal manufacturing processes and operate under a zero-defect philosophy.

LESS ABRASION THAN STANDARD ALUMINUM SEALS

The aluminum alloy used for the manufacturing of the laminated aluminum combiseals conforms with ISO 8872. Datwyler is applying strict earing specifications to its aluminum suppliers. By avoiding cutting the aluminum after deep drawing, less aluminum particles are generated than with standard procedures. These specifics protect the combiseals in the most effective way.

The lamination process begins with a high-quality epoxy-based lacquer being applied to the aluminum. This step is followed by a protective polypropylene film being laminated on top of the lacquered layer. Depending on customer specifications, the lacquer may be pigmented for coloration. Unlike laminated aluminum, standard epoxy-based lacquers are not very robust regarding flaking during production, transport, and filling. When it concerns a silver cap, the transparent lacquer will also shed particulates, but they are hardly visible. In the case of other colors like blue, green, or red, flakes can be created that eventually end up on the liner and ultimately contaminate the drug product. The protective laminate eliminates this issue.

The abrasion-resistant film also provides a protective barrier to external forces, reducing the risk of abrasion during manufacturing and handling. As a result, DuraCoat combiseals have less abrasion than standard aluminum seals. Abrasion can create visual defects like scratches and can also produce flakes in the drug product, which is unacceptable, particularly for high-end products. Datwyler offers a significantly low AQL (Acceptable Quality Limit) for defects associated with DuraCoat combiseals.

TESTED TO MEET THE HIGHEST EXPECTATIONS

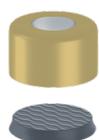
A full suite of tests have been completed to ensure effectiveness and functionality of the laminated aluminum. Depending on the customer's requirements, a combiseal can undergo different steps before use. In order to make sure that the material withstands the different pre-conditioning processes, such as washing, sterilization, and drying before filling, a number of worst-case scenario tests have been conducted to ensure that the material maintains its quality specifications.

Combiseals covered with Datwyler's innovative lamination provide a robust application with a low level of particulates and visual defects, as well as flawless processability at very competitive prices since the aluminum is not cut after deep drawing.

KEY BENEFITS OF DuraCoat™ COMBISEALS

- Highest-quality materials
- Clear reduction of particles during processing and handling
- Less abrasion than standard aluminum seals
- Tested to ensure robustness and durability
- Flawless processability on standard filling lines

DuraCoat™ COMBISEALS



Dimension	From 1 ml to 3 ml	From 1 ml to 3 ml	From 1 ml to 3 ml
Type	Bi-layer	Mono-layer	Bi-layer
Design	ACS0003	ACS0004	ACS0006
Compound	FM257 + H1-7-207 FM457 + H1-7-207	FM257 FM457	H5-23-5 + H1-7-207 FM257 + H1-7-207 FM457 + H1-7-207

DuraCoat™ combiseals are the ideal solution for cartridge applications within the pharmaceutical and biotech markets.

Datwyler Sealing Solutions is a leading industrial supplier and a key player in the global healthcare industry with a strong sense of future trends and the ability to set new standards. Datwyler offers state-of-the-art solutions for parenteral packaging with more than 100 years of multi-industry experience.

Partnering with the world's top pharmaceutical and medical companies, Datwyler stands by its mission to improve patients' lives by constantly striving for zero defects in all its products. The company's state-of-the-art cleanroom manufacturing technologies exceed the most stringent industry requirements.

As a solution partner, Datwyler assists its customers in mastering the challenges of global healthcare and helps them act on opportunities of new and personal therapies.

Find out more about Datwyler's pharmaceutical and biotech solutions in other brochures:

Sealing Solutions for Healthcare
Product Portfolio
Sealing Solutions for Vials
Sealing Solutions for Prefilled Syringes
Sealing Solutions for Cartridges
FirstLine®
Coated Sealing Solutions
Packaging & Sterilization
Services
StarterPack™



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