

StarterPack™.

A COMPREHENSIVE
PACKAGING SOLUTION



StarterPack™:

SOLUTIONS FOR SMALL QUANTITY COMPONENT NEEDS

Datwyler offers a comprehensive solutions package to its customers for every step of drug development.

Datwyler provides high-quality components for primary and secondary packaging solutions.



As a responsible solution partner, Datwyler enables its customers to realize their full healthcare potential. Datwyler's goal is to offer comprehensive packaging solutions to ensure drug efficacy and stability, and, ultimately, patient safety.

Datwyler's StarterPack is the ideal offering to tackle small quantity component needs. Specially designed to provide its customers with sealing solutions for every stage of drug development, Datwyler offers a single source solution to take the drug from discovery through delivery.

Datwyler developed the StarterPack to provide its customers with a range of compatible primary and secondary packaging components to be used in every drug development application. Datwyler enables its customers to incorporate high-quality components and commercial packaging solutions into their testing and clinical trial strategy, including diagnostic research, clinical trials, and product launch. Once the drug product is ready for commercial launch, the quantities can then be ramped up.

Datwyler's global team of cross-functional experts is aware of the challenges that customers are facing in their respective fields. Considering all critical aspects within the product development, Datwyler helps its customers make the right decision for their appropriate primary and secondary packaging solution.

SERVICE OFFERING TO MEET TESTING NEEDS

Datwyler completes its high-quality product portfolio with a broad range of services intended to reduce overall cost of ownership. The company also provides analytical and rubber compounding expertise during product selection and testing.

The implementation of these in-house programs presents Datwyler’s customers with a comprehensive solution for parenteral packaging.

DATWYLER’S SERVICE OFFERING INCLUDES:

- Pharmacopoeia and normative testing
- Functionality testing
- Container Closure Integrity testing
- Other relevant testing

You can read more about Datwyler’s Service Offering in the Services brochure.

THE RIGHT PARTNER FOR CLINICAL TRIAL READINESS

CLINICAL TRIAL PHASES	QUANTITIES REQUIRED	DATWYLER OFFERING
Pre-clinical Testing of drug in non-human subjects to gather efficacy, toxicity, and pharmacokinetic information	From hundreds to thousands of pieces per year	Datwyler’s team of experts provides support to determine the primary packaging best suited for initial testing. This packaging includes a range of ready-to-use vial stoppers, PrimeCaps™, and glass vials.
Phase 0 Pharmacokinetics; particularly, oral bioavailability and half-life of the drug		
Phase I Testing of drug on healthy volunteers for dose-ranging		
Phase II Testing of drug on patients to assess efficacy and side effects		
Phase III Testing of drug on patients to assess efficacy, effectiveness, and safety		

StarterPack™ COMPONENTS

All products provided are ready-to-use (RTU) and have been sterilized in accordance with pharmaceutical and regulatory guidelines. The Datwyler StarterPack includes ready-to-use OmniFlex Stoppers, ready-to-use PrimeCaps, and ready-to-use Vials by SCHOTT.

STATE-OF-THE-ART FLUOROPOLYMER SPRAY COATING

Datwyler’s proprietary fluoropolymer spray coating provides exceptional value to customers dealing with parenteral drug development:

Quality: Exclusively manufactured in facilities incorporating the FirstLine standard that follows the most stringent quality standards of European and US regulatory authorities

Enhanced drug safety: Full coverage of the entire component eliminates the need for siliconization. Strong barrier characteristics minimize the possibility for potential interactions and presence of subvisible particles

Container closure integrity: Specific designs, long-time proven elastomeric substrates, and a uniform total coating ensure an excellent and robust container closure system

You can read more about Datwyler’s spray coating technology in the Coated Sealing Solutions brochure.

FM457: MODERN AND HIGH-LEVEL FORMULATION

Based on a unique polymer, Datwyler’s modern bromobutyl formulation FM457 is specifically developed for stopper and plunger applications. Considering the highest level of rubber compound purity and compatibility, FM457 represents the best-in-class solution to match the needs of sensitive drugs. The formulation is characterized by:

- Very high chemical purity and ultra-low extractable compound
- High resistance to Gamma irradiation
- Superior functional characteristics



1. READY-TO-USE OmniFlex® STOPPERS

All of Datwyler’s vial closure solutions are produced, controlled, and tested under the most stringent conditions, enabling the company to meet pharmaceutical requirements to guarantee the highest degree of customer satisfaction and patient safety.



Datwyler’s proprietary fluoropolymer spray coating technology meets the highest demands for quality and performance for highly sensitive, large molecule drugs. It includes the following key features:

- Proprietary, inert fluoropolymer spray coating
- Total coverage trim edge included for all designs
- Covalent bond to rubber
- Barrier properties
- Thin and flexible: ≈ 20 µm
- Low coefficient of friction, no siliconization needed

SERUM STOPPERS

		
Dimension	13 mm	20 mm
Design	V9401	V9407
Compound	FM457	FM457
Coated	Yes	Yes
Quantity per box	800 pcs	500 pcs

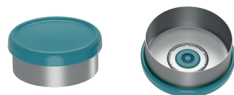
LYO STOPPERS

		
Dimension	13 mm	20 mm
Design	V9402	V9397
Compound	FM457	FM457
Coated	Yes	Yes
Quantity per box	800 pcs	500 pcs

2. READY-TO-USE PrimeCaps™

PrimeCaps are Datwyler’s solution for flawless machineability on high-speed filling lines. All of the company’s facilities worldwide deliver PrimeCaps in the same quality and with all existing specifications, including:

- Highest quality alloy
- 13 and 20 mm in five standard aluminum colors
- Center-gated disc for enhanced machineability, available in 40 standard colors, matte and glossy
- Optimized design: straight skirt edge (Accurim)
- Standard and flush disc configurations
- Camera inspection
- Low bioburden and particulate levels
- CCI match with Datwyler’s elastomers
- RFS/RTU/Rapid Transfer Port bags



Dimension	13 mm
Design	FBC13.0001
Quantity per box	500 pcs



Dimension	20 mm
Design	FBC20.0002
Quantity per box	250 pcs

3. READY-TO-USE VIALS BY SCHOTT

The SCHOTT adaptiQ® ready-to-use vials are packaged in an innovative nest with an industry standard tub (SCHOTT iQ® Platform). These can be processed on a wide range of new and existing fill & finish equipment, allowing the vials to remain nested also during lyophilization. The vials are TopLine quality and offer the following benefits:

- Made of best in class FIOLAX® borosilicate glass tubing
- Produced in cGMP environment
- Statistical in-process control, 100% camera inspection
- ISO 9001 & 15378 certified / compliant to Ph.Eur., USP and JP international standards



Overflow capacity	4 ml ± 0.5 ml	13.5 ml ± 1 ml
ISO format	2R	10R
Design	No Blowback	No Blowback
Quantity per box	400 pcs	192 pcs

The StarterPack™ provides a complete packaging system, easy to be ordered and ready to be globally delivered in small quantities. This allows Datwyler’s customers to use high-quality component solutions in their testing and clinical trials.



THE IDEAL PACKAGING SOLUTION

Datwyler's StarterPack is designed to provide its customers with products able to provide a complete Container Closure Integrity (CCI). The combination of the Datwyler OmniFlex stopper, PrimeCap, and SCHOTT glass vial, provides an ideal sealing compatibility, preventing leaks and other seal integrity concerns throughout manufacturing and handling.

Using standard CCI testing methods required by pharmaceutical and regulatory authorities, Datwyler's team of experts can recommend a total packaging solution for housing its customers' sensitive drug products.

The included products have been thoroughly tested, with conclusions noted in the attached technical documentation.

For more information, refer to Datwyler's Services brochure.

Datwyler's expert team uses standard CCI testing methods required by pharmaceutical and regulatory authorities to recommend the best total packaging solution for housing its customers' sensitive drug products.



Datwyler provides its customers with sealing solutions for every stage of the product life cycle, from drug discovery to drug delivery.

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
DuraCoat™ Combiseals
Packaging & Sterilization
Services

**To order a StarterPack™, please contact:
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www.datwyler.com

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