

PROSEAL+

SEAL. PROTECT. PRESERVE.





Patient safety starts with drug stability

Nearly 50% of medicinal products degrade due to moisture⁽¹⁾. Sensitive oral formulations such as antibiotics, vitamins and nutritional supplements are vulnerable to humidity and oxygen.

Even brief exposure can compromise stability, reduce effectiveness and increase patient risks.

Reliable protection is critical. Glass bottles are trusted to preserve product integrity, and when combined with advanced sealing, it extends shelf life and supports patient safety.

PROSEAL+ was developed to meet this need, delivering proven hermetic sealing for oral formulations.

(1) Dhondale MR, Thakor P, Nambiar AG, et al. Co-Crystallization Approach to Enhance the Stability of Moisture-Sensitive Drugs. *Pharmaceutics*. 2023;15(1):189. doi:10.3390/pharmaceutics15010189.

What makes PROSEAL+ unique?

PROSEAL+ is an external surface treatment developed specifically for Type III molded glass bottles. It creates a hermetic sealing surface against oxygen and moisture, ensuring stability of sensitive oral formulations and reinforcing patient safety.

- Tailored for sensitive oral formulations**
Especially powders, solids (antibiotics, vitamins, minerals) and liquids.
- On Type III molded glass vials**
Available in Clear & Amber, from 10 mL to 1 L.
- Wide range of neck finishes**
Available in PP28, MCA2, R3/28, R3/24.
- Unique expertise**
With over 15 years of know-how.
- Pharmaceutical grade & compliant process**
External treatment conforms to US & EU Pharmacopeias, GMP, and food-contact standards (US CFR 21 FDA).
- Shelf life**
Bottles can be stored up to 1 year before sealing without loss of performance.
- Manufactured in France & Germany**
Produced at SGD Pharma's Sucy-en-Brie plant and Kipfenberg plant.

Value for Pharma & Patients

Drug protection through a proven hermetic seal, preventing oxygen and moisture penetration

- Oxygen permeability < 1µL/vial/day (vs. 840 µL for capped-only vials)**
- Water vapor transmission < 0.3 mg/vial/day (vs. 0.45 mg for capped-only vials)**
- Consistent barrier performance across multiple neck finishes (PP28, MCA2, R3/24, R3/28)**



Oxygen Permeability and Water Vapor Transmission Rate (WVTR) with and without Hermetic Sealing

Product integrity

Comparison of oxygen permeability and water vapor transmission according to the closure configuration.

- Cap only → 840 µL/vial.day / 0,45 mg/vial.day
- Cap & hermetic seal → <1 / <0,3

The results demonstrate that PROSEAL+ bottles/vials with a seal but no cap, still provide strong protection from water vapor transmission and oxygen.

Test conditions:
Cap: HDPE PP28 cap, PE foam liner, Ø 16.7 × 3.0 mm,
Closing torque 175 N·cm
Seal: Coextrusion Aluminum & PE, Conduction heat sealed
H₂O test: 25 °C – 75% HR
O₂ test: 22 °C – 50% HR – 21% O₂

Permeability values for non-capped bottles with seal only and various neck-finishes

Neck-Finish
thermosealed without cap

R3/24

- Oxygen permeability** µL/(vial.day) → <1
- Water Vapor Transmission** mg/(vial.day) → < 0,3

MCA2

- Oxygen permeability** µL/(vial.day) → <1
- Water Vapor Transmission** mg/(vial.day) → < 0,3

PP28

- Oxygen permeability** µL/(vial.day) → <1
- Water Vapor Transmission** mg/(vial.day) → < 0,3

Test conditions:
Seal: Coextrusion Aluminum & PE,
Conduction heat sealed
H₂O test: 25 °C – 75% HR
O₂ test: 22 °C – 50% HR – 21% O₂

R3/28

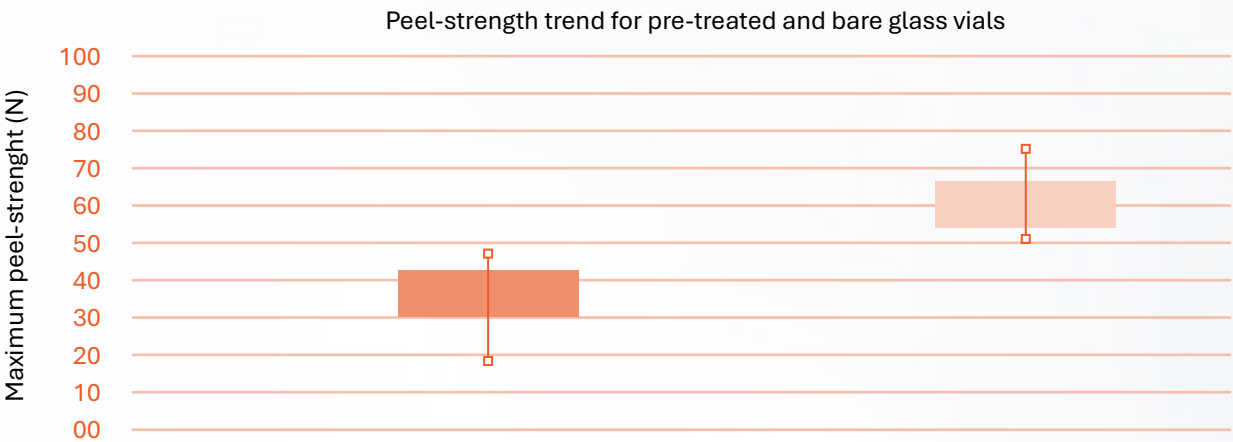
- Oxygen permeability** µL/(vial.day) → <1
- Water Vapor Transmission** mg/(vial.day) → < 0,3

Tamper evidence feature

Reinforced adhesion for tamper-evident sealing, reducing risks throughout the supply chain.

- Peel-strength: significantly higher adhesion vs. bare glass
- Strong resistance to leakage
- Visible seal trace after removal

Peel-strength study



- Bare Glass**
40% in between cohesive and adhesive peeling
60% adhesive peeling
- Pre-treated**
100% cohesive peeling

Peel-strength test parameters:
Angle: 90° to the plane of the neck
Peeling speed: 110 mm/min

Compliance

Global regulatory compliant process with full documentation package.

- US & EU Pharmacopeias (USP <660>, EP 3.2.1)
- GMP compliance & full manufacturing traceability
- Heavy metals & REACH regulations
- Food contact compliance (US CFR 21 FDA)
- Shelf-life statement, ISPM 15 pallet compliance, CSR (Ecovadis)
- Toxicological Safety

For more information, request our regulatory package.

Suitable for all sealing processes

Compatibility with both induction and conduction sealing processes, ensuring adaptability in production.

- Induction sealing (cap + seal)
- Conduction sealing (seal alone)
- Works with several lid materials (e.g: PE, Al-PE).

Child Resistant Senior-Friendly closures

Full compatibility with CRSF closures, supporting patient safety and addressing global public health issues.

- CRSF systems help prevent accidental child poisoning

Did you know?

In the US, 2 children die each day due to accidental poisoning (CDC).
In the EU, accidental poisoning is the 5th leading cause of unintentional child death.

Supply chain efficiency

Improved operational performance.

- Consistent sealing quality.
- Reliable barrier properties preventing product loss.



For more information, please visit our website
www.sgd-pharma.com