



- Established primary packaging solutions reach their limit when protecting sensitive drugs from glass leachables in the high alkaline pH range.
- With EVERIC® care, SCHOTT offers a vial with an exceptional ion barrier coating that minimizes leachable levels to the highest extent possible, designed for use in a wide range of pH conditions, even highly alkaline solutions.
- Applied using patented and proven plasma impulse chemical vapor (PICVD) coating technology (known from SCHOTT TopLyo® and SCHOTT Type I plus® coatings).
- Two additional release criteria have been specifically developed.



Si-O-C-H layer applied via PICVD



Contact angle for water > 90° (hydrophobic surface without silicone)



Long-term layer stability



Coating bonds covalently to the glass substrate



Suitable for depyrogenation



Dense coating (i. e. non-porous)



Surface shows excellent barrier properties in reducing ion leaching, also in high pH solutions



Stable after washing process



Compliant with all current standards, such as Ph. Eur, USP, JP and CP

### Secured drug stability

The excellent barrier reduces ion leaching, providing drug stability even for extreme conditions such as high pH

\* adsorption behavior needs to be tested case by case

### Improved dosage accuracy

Improved residual emptying and reduced protein adsorption\*

#### Reduced rejects

For lyophilized products, no fogging occurs and an elegant cake is achieved due to the hydrophobic surface



# 1. Fast performance test



# 1) Coating attack

Autoclaving filled with 0.005 M KOH (pH 11.7 at start).

# 2) Coating attack and leaching

Autoclaving filled with 0.1 M HCI (pH 1 at start).

#### 3) Determination of sodium via AAS

Certified release criterion for solution (Na) – limit value defined per format.

# Verifications: Superior leachables results for dissolved glass elements in 10R vial with nominal filling volume\*

SCHOTT Type I plus<sup>®</sup> vials served as benchmark. These vials have an SiO<sub>2</sub> inner coating acting as an ion barrier against glass leachables.

Shown here are glass elements in sodium bicarbonate (pH 8.5) after 12 and 48 weeks at 40°C.

As shown in the figure, for high pH, the barrier properties of EVERIC® care are superior.

Please contact SCHOTT for further information

# 2. Drain-off test for hydrophobicity



Autoclaving filled with H<sub>2</sub>O.



Half-filled with white milky test fluid and stoppered. Shaken overhead three times.







\* Multiple tests have been performed with different buffer solutions.

General ordering information	
Quality level	TopLine + additional release tests
Packaging	<ul> <li>Tray, optionally with divider</li> <li>Pre-washed &amp; pre-sterilized: adaptiQ®*</li> </ul>
Palletizing	Standard Euro pallet ( $1200 \times 800 \text{ mm}$ ) contains $15-27$ layers of nine trays each
Formats	10R*
Pieces per tray	154

\* Discuss the availability of other formats with your local SCHOTT representative and the availability of ready-to-use formats (SCHOTT adaptiQ®) – coming soon Many configurations are available in small quantities as "Fast Track Articles".

SCHOTT Type I plus®

Visit our online shop or speak to your sales representative for more information.

schott-pharma.com/vials

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