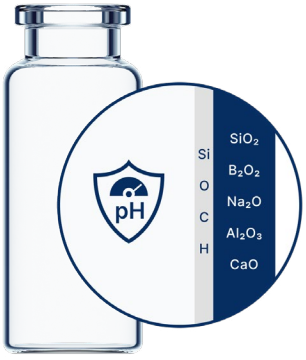
EVERIC® care

Pharmaceutical glass vial with hydrophobic barrier coating for high pH fillings



- Established primary packaging solutions reach their limit when protecting sensitive drugs from glass leachables in the high alkaline pH range.
- With EVERIC® care, SCHOTT Pharma 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 deposition (PICVD) coating technology (known from SCHOTT EVERIC® lyo and SCHOTT EVERIC® 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

Improved dosage accuracy
Improved residual emptying and reduced protein adsorption*

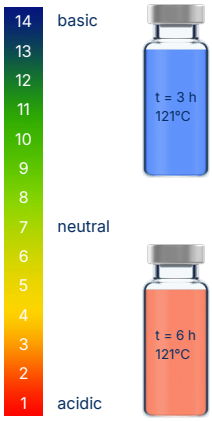
Reduced rejects
For lyophilized products, no fogging occurs and an elegant cake is achieved due to the hydrophobic surface

* adsorption behavior needs to be tested case by case

SCHOTT PHARMA

Release tests

1. Fast performance test

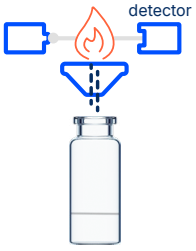


1) Coating attack

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

2) Coating attack and leaching

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



3) Determination of sodium via AAS

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

2. Drain-off test for hydrophobicity

Autoclaving filled with H_2O.

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

In specification

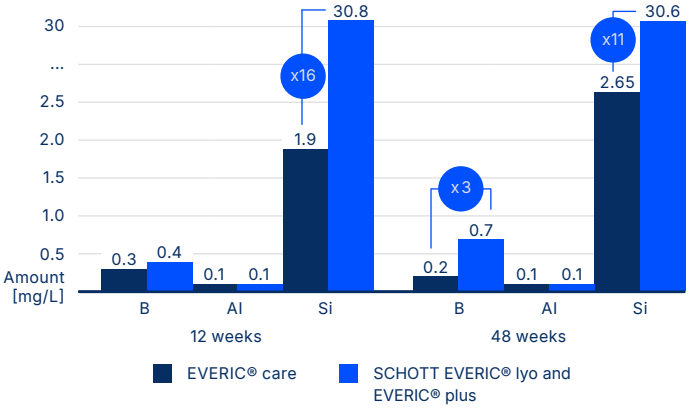
Not in specification

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

SCHOTT EVERIC® lyo and EVERIC® plus vials served as benchmark. These vials have an SiO2 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.



* Multiple tests have been performed with different buffer solutions. Please contact SCHOTT Pharma for further information

General ordering information				
Quality level	TopLine + additional release tests			
Packaging	▪ Tray, optionally with divider ▪ Pre-washed & pre-sterilized: adaptiQ®*			
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15–27 layers of nine trays each			
Formats	2R	6R	10R	20R
Pieces per tray (non sterile)	344	186	154	95

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