EVERIC® plus

Pharmaceutical glass vial with barrier coating against leachables for sensitive formulations

- For highly sensitive drugs, leachables of the primary packaging into the drug product need to be minimized in order to protect their stability.
- The adsorption of proteins to the glass surface can result in conformational changes, denaturation, aggregation, and loss of effectiveness.
- EVERIC® plus vials have an ion barrier coating that can reduce adsorption and ensures low leachable levels for pharmaceutical products in the neutral and acidic pH ranges.
- Inner coating is applied using patented and proven plasma impulse chemical vapor deposition (PICVD) technology.
- An additional “release criterion” has been specifically developed.

SiO_2 layer applied via PICVD

Layer thickness of ~ 100–200 nm

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: Na, Ca, B, Si, Al

Stable after washing process

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

Secured drug stability
Ion barrier provides stability for leachable sensitive drugs (e.g. radiopharmaceuticals and aluminum-sensitive drugs)

Reduced adsorption
For certain proteins, adsorption can be reduced thanks to a specialized inner surface*

Avoidance of pH-shift
Particularly relevant to WFI

* adsorption behavior needs to be tested case by case

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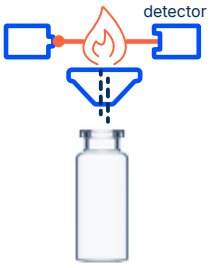
Release test

1) Leaching

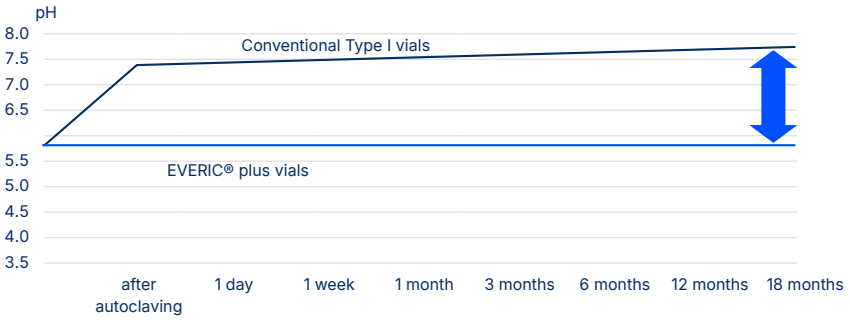
Autoclaving filled with 0.1 M HCl (pH 1 at start).



2) Determination of sodium via AAS

Certified release criterion for sodium (Na) – defined limit value.

Verifications: Avoidance of pH shift



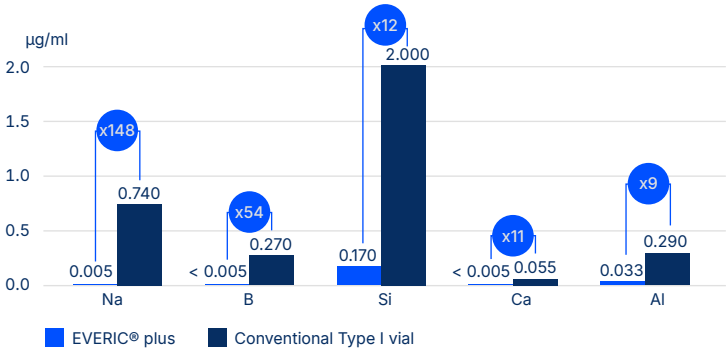
Method

10 ml vials, washed in accordance with ISO 4802. Autoclaving 1 h at 121°C. Storage at room temperature. Measurement of pH value prior to and after autoclaving (directly after, one day, one week, one/six/12/18 months).

Result

After autoclaving, conventional Type I vials show pH shifts from 5.5 up to 7.5. EVERIC® plus vials fully prevent pH shift.

Verifications: Secured drug stability



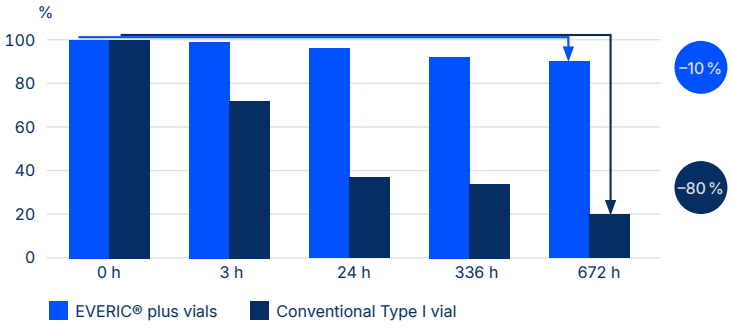
Method

10R vials, filled with purified water, 1 h autoclaving at 121°C. Leached ions in µg/ml by ICP-MS (ICP-OES for Si).

Result

The ion barrier is effective for all other elements of the glass matrix.

Verifications: Reduced adsorption



Method

Nicotinic acetylcholine receptor, concentration: 150 µg/ml, see: "A. Schrattenholz: Drug loss through adsorption of a nicotinic acetylcholine receptor in EVERIC® plus and standard vials".

Result

Tested protein shows less tendency to adsorb to EVERIC® plus vials.

General ordering information											
Quality level	TopLine with additional release test										
Packaging	▪ Tray with optional divider ▪ Pre-washed and pre-sterilized: adaptiQ® (tray, cup nest)										
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15–27 layers of nine trays each										
Formats	2R	3R	4R	6R	8R	10R	15R	20R	25R	30R	50R
Pieces per tray	344	344	344	186	186	154	154	95	95	95	40

Many configurations are available in small quantities as **"Fast Track Articles"**.

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