

# SCHOTT Type I 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.
- SCHOTT Type I 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<sub>2</sub> 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

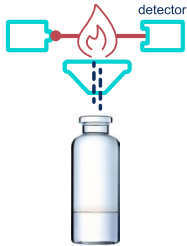
**SCHOTT**  
PHARMA

## Release test



### 1) Leaching

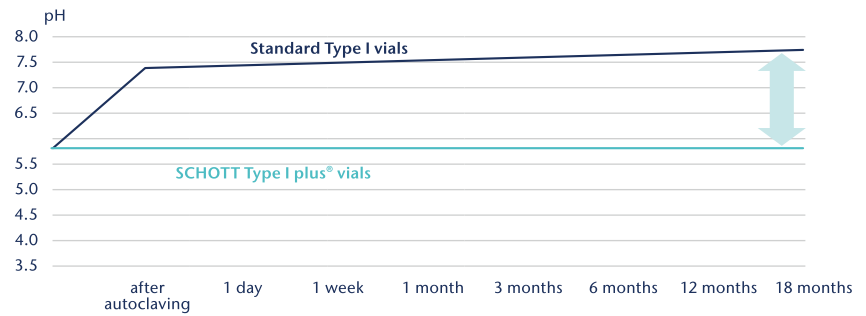
Autoclaving filled with 0.1 M HCl (pH 1 at start).



### 2) Determination of sodium via AAS

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

## Verifications: Avoidance of pH shift



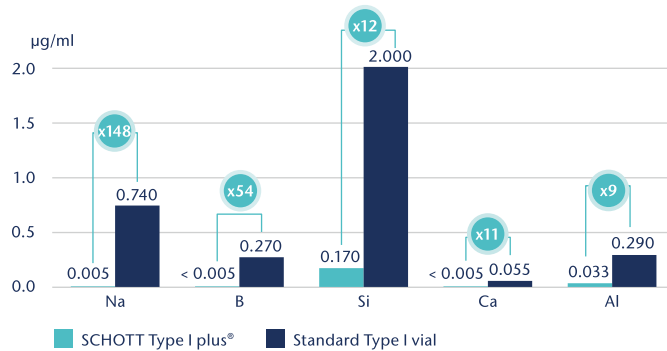
### Method

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, standard Type I vials show pH shifts from 5.5 up to 7.5. SCHOTT Type I plus® vials fully prevent pH shift.

## Verifications: Secured drug stability



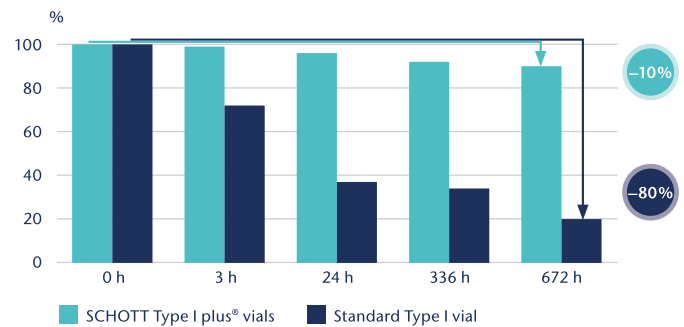
### Method

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 SCHOTT Type I plus® and standard vials".

### Result

Tested protein shows less tendency to adsorb to SCHOTT Type I plus® vials.

## General ordering information

|                 |  |     |     |     |     |     |     |     |     |     |     |
|-----------------|--|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Quality level   | TopLine with additional release test   |     |     |     |     |     |     |     |     |     |     |
| Packaging       | <ul style="list-style-type: none"> <li>Tray with optional divider</li> <li>Pre-washed and pre-sterilized: adaptiQ® (tray, cup nest)</li> </ul> |     |     |     |     |     |     |     |     |     |     |
| 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".

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

[schott-pharma.com/vials](https://schott-pharma.com/vials)

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**SCHOTT**  
PHARMA

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