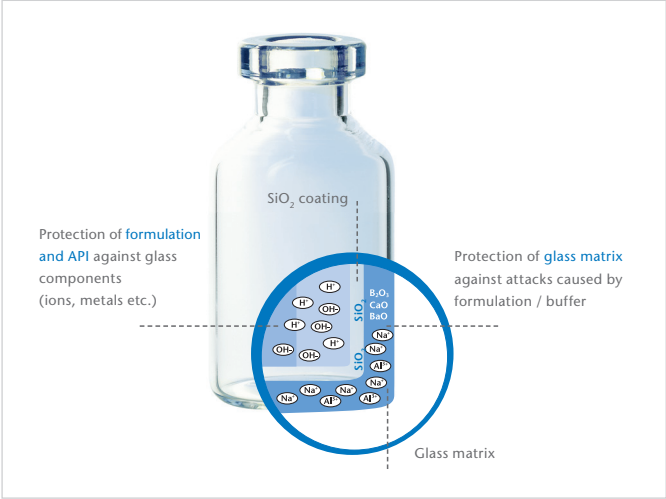
SCHOTT Type I plus®



General Product Information

SCHOTT Type I plus® vials consist of SCHOTT Type I glass combined with the purity and inertness of a quartz-like inner surface (100% SiO_2 coating). They comply with all current standards, such as Ph. Eur., USP and JP.

Due to the excellent properties of the layer, this product can be used in highly specific application ranges, especially biopharmaceuticals. Unlike ammoniumsulfate treatment or baked-on silicone, the SiO_2-layer has a high barrier improvement factor against ion leaching and thereby minimizes drug-container interaction.

SCHOTT Type I plus® vials are available in all dimensional specifications upon customer request.

Physical & Chemical Product Properties

The layer of SCHOTT Type I plus® vials is characterized by the following properties:

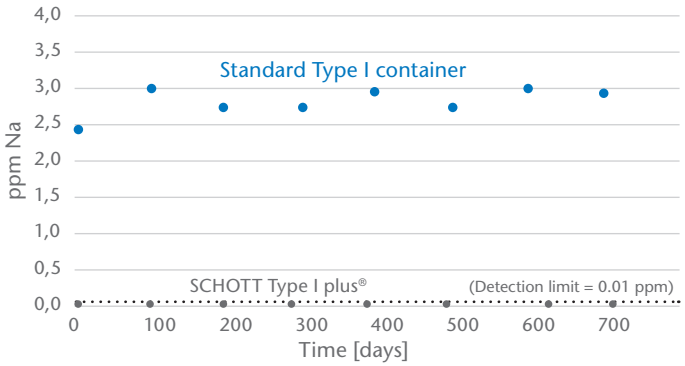
Physical Data
Layer thickness of approx. 100 – 200 nm
Stable against mechanical load
Stable washing process
Stable sterilization: · Autoclaving (121 °C) · Depyrogenization (dry heat treatment at 250 °C – 330 °C)

Chemical Data
Chemical layer properties: SiO_2
Long-term stable layer system during storage proven by accelerated aging at 40 °C.
Pure silica surface bond covalently to the material and chemically uniform
Dense coating (non porous)
Surface shows excellent barrier properties in avoiding ion leaching: Sodium, Calcium, Boron, Silicon and Aluminium

Verifications

Verified stability

Method:
Long term sodium leaching after 6 h initial autoclaving with 0.1 M HCl at 121 °C
Result:
The SiO_2 layer is stable for more than 2 years



Verified reduction of ion exchange

Method:
1h autoclaving 0.4 M HCl at 121 °C: Leached ions in µg/ml by AAS
Result:
The diffusion barrier is effective for all other elements of the glass matrix. All metallic ions are suppressed to a level below their respective detection limit.

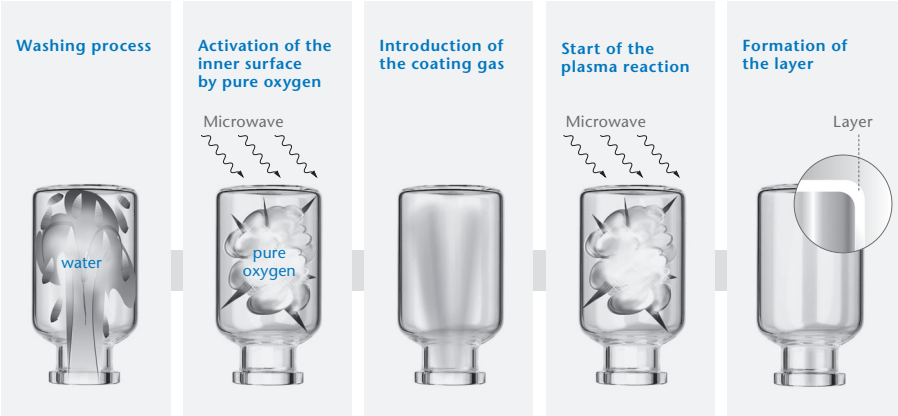
	Type I vials	SCHOTT Type I plus	Improvement Factor
Sodium (Na+)	3.5	< 0.01	> **350**
Calcium (Ca2+)	1.1	< 0.05	> **22**
Boron (B3+)	3.5	< 0.10	> **35**
Silicon (Si4+)	5.0	< 0.30	> **15**
Aluminium (Al3+)	2.3	< 0.05	> **45**

SCHOTT
glass made of ideas

Production-oriented Product Information

Thanks to our patented coating technology, a very high barrier improvement factor against ion leaching is achieved.

SCHOTT PI Coating® Process



PI Coating®: Maximum inspection – validated process

Stage 1
Two 100% in situ inspections on each reactor (temperature, optical plasma emission)

Stage 2
Control of process parameters (on-line including gas flow, vacuum, microwaves)

Stage 3
Automatic System Monitoring of long-term stability (maintenance, calibration of the actuators and sensor, data acquisition and long term storage)

Value-adding Benefits and Services

Application Ranges

Resistant to glass delamination
Barrier layer prevents corrosion of glass container by drug formulation and related delamination risk

High pH values formulations
Show less glass corrosion of containers by drug formulation and related delamination risk (even at pH ≥ 9.0)

Radioactive Diagnostics
Reduction of residual radioactivity due to less adsorption of radioactive molecules

Proteins & Antibodies
Show reduced protein adsorption on the inner glass surface Avoids expensive overfilling especially for low concentrated protein solutions

Highly pure substances
Are preserved even at long stocking periods, as the quartz-like coating is chemically inert

Enzymes
Reactivity is unaffected as no metal ion can be solved out of the glass

WFI & alcali sensitive products
Unbuffered reagencies, e.g. water for injection, are better protected against shifts in pH

Sensitive formulations
Formulations that are sensitive to metal ions leaching out of the glass

Packaging

- SCHOTT Type I plus® vials are delivered in special, reusable trays
- A standard Euro Pallet (1200 x 800 mm) contains 15 – 27 layers of 9 trays each

Capacity	2 ml	4 ml	6 ml	8 ml	10 ml	20 ml	30 ml	50 ml	100 ml
Pieces / tray	344	344	186	186	154	99	99	51	35

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