SCHOTT TopLyo® Vials

General Product Information

SCHOTT TopLyo® vials consist of SCHOTT Type I glass combined with a transparent and nonporous Si-O-C-H layer. They comply with all current standards, such as Ph.Eur., USP and JP.

Due to the coating along with an optimized container geometry, this vial is especially recommended for lyophilization. SCHOTT TopLyo® offers the advantage of less rejects and minimized residual volume after reconstitution. Furthermore, the removal of the drug is improved.

Physical & Chemical Properties

The ultra thin layer of SCHOTT TopLyo® vials is characterized by the following properties:

Physical Data
Layer thickness of ~ 40 nm
Stable against mechanical load
Stable washing process
Stable sterilization: · Autoclaving (121 °C) · Depyrogenation (dry heat treatment at 250 °C – 350 °C)

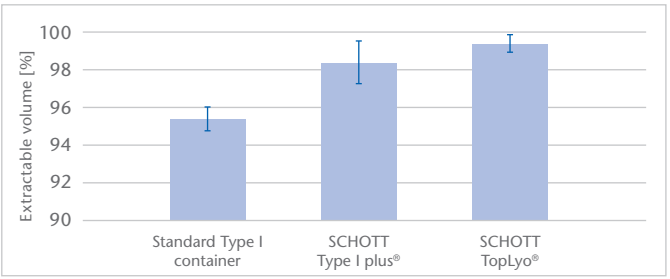
Chemical Data
Chemical layer properties: Si-O-C-H
Long-term stable layer system during storage proven by accelerated aging at 40°C and room temperature after 3 years
Bond covalently to the material and chemically uniform
Dense coating (i.e. non porous)
Contact angle for water: ~100° (hydrophobic surface)

Verifications

Extractable volume

Method:
- Take out 4 ml solution from 10 ml vials containing 12.5 mg/ml IgG1 and 12.5 mg/ml mannitol dissolved in a histidine/glycine mixture
- Buffered to pH 6.0 with a needle through the stopper
- Extractable volume determined gravimetically (n = 3)

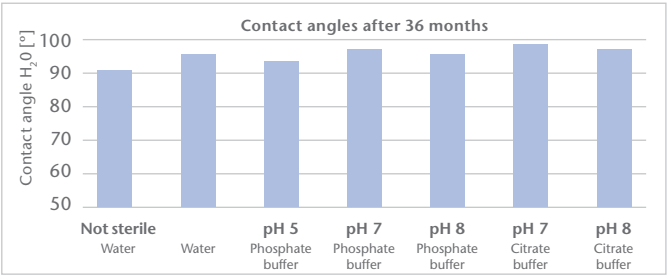
Result:
- ~4 % more extractable volume from hydrophobic SCHOTT TopLyo® compared to standard Type I glass
- 4 % equals 160 µl and contains 2 mg of protein



Contact angles measured over 36 months at room temperature

Method:
- 1400 SCHOTT TopLyo® vials, 2 ml
- WFI, phosphate and citrate buffer (pH 5, 7, 8)
- Sterilization at 121 °C, 30 min
- Samples stored at 40 °C

Result:
- Contact angle > 90°

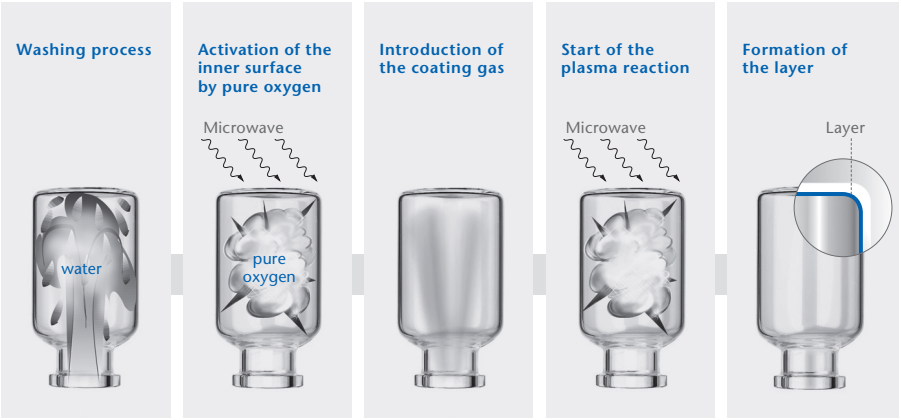


SCHOTT
glass made of ideas

Product Information

Thanks to our patented coating technology, vials are endowed with a stable and covalently bond hydrophobic interior. This coating promotes efficient liquid removal and enhanced drug stability.

SCHOTT PI Coating® Process



Maximum inspection – validated process

Stage 1
Two 100 % on-site 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 Product Benefits and Services

Application ranges

Improved lyo cake
Less disruption and production losses due to reduced climbing at vial edges

Optimized yield
Reduced adsorption at the inner glass surface minimizes the residual volume after reconstitution

High process stability
Diminished glass breakage as stress risk is low due to special geometry design

Process time reduction
Optimized bottom geometry allows for better heat transfer during the freeze drying process

Dimensional changes not required
Due to the very thin coating layer (~40 nm), no dimensional changes are needed

Packaging

- SCHOTT TopLyo® vials are delivered in special trays with optional separators to avoid glass to glass contact
- A standard Euro Pallet (1200 x 800 mm) contains 15–27 layers of 9 trays each

Capacity	2 R	6 R	10 R
Pieces/tray	344	186	154

Pharmaceutical Systems
SCHOTT AG
Hattenbergstrasse 10
55122 Mainz
Germany
Phone +49 (0)6131/66-1589
Fax +49 (0)6131/66-1916
pharmaceutical_packaging@schott.com

www.schott.com/pharmaceutical_systems

SCHOTT
glass made of ideas