SCHOTT TopLyo®

Pharmaceutical glass vial with hydrophobic coating to avoid fogging

- For stability reasons, more than 50 % of all biologic drugs are lyophilized.
- Fogging is a widely known undesirable phenomenon that occurs during lyophilization, which results in elevated levels of rejects.
- Overfilling vials to compensate for drug loss through unsatisfactory residual emptying after reconstitution leads to higher costs.
- SCHOTT TopLyo® is unique in combining hydrophobic behavior and the avoidance of free silicone.
- Inner coating is applied using patented and proven plasma impulse chemical vapor deposition (PICVD) technology.
- An additional “release criterion” has been specifically developed.

Si-O-C-H layer applied via PICVD

Layer thickness of ~ 40 nm

Long-term layer stability

Coating bonds covalently to the glass substrate

Suitable for depyrogenation

Dense coating (i. e. non-porous)

Contact angle for water > 90° (hydrophobic surface without silicone)

Stable after washing process

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

No fogging
Particularly suitable for anti-body drug conjugates (ADCs) thanks to hydrophobic inner surface

Elegant lyo cake
Reduced rejects due to improved lyo cake aesthetics

Improved emptying
Less residual volume so no overfilling necessary

Drug stability
No free silicone thanks to residual free technology

SCHOTT PHARMA

Release test: Drain-off test for hydrophobicity

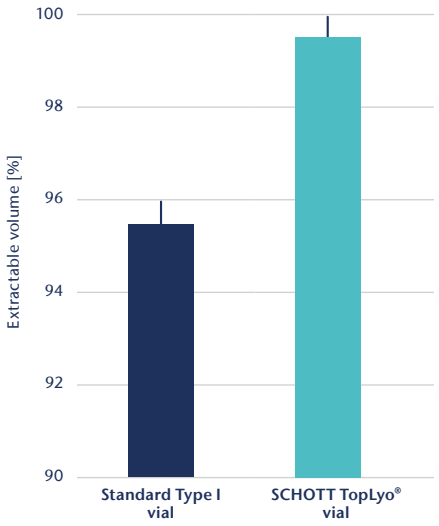
Autoclaving filled with H_2O.

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

In specification

Not in specification

Verifications: Improved emptying



Result
Less residual volume after reconstitution with SCHOTT TopLyo® vials

Verifications: No fogging and elegant lyo cake

Lyophilization in standard Type I vials

Lyophilization in SCHOTT TopLyo® vials

Verifications: Stress tests have proven stability

		TopLyo® 10R	TopLyo® 15R	TopLyo® 10R, depy-rogenated	TopLyo® 15R, depy-rogenated
ca. 5 mm*	average	103	102	99	101
	stand. dev./range	±2/±4	±2/±4	±2/±5	±2/±4
ca. 15 mm*	average	102	102	98	100
	stand. dev./range	±2/±5	±2/±4	±2/±5	±1/±3
ca. 25 mm*	average	106	103	101	101
	stand. dev./range	±4/±9	±1/±3	±3/±5	±1/±3

Method
10R vials Type I glass and SCHOTT TopLyo® vials.
5.0 ml formulation dried in 10R vials with different surfaces.
0.15 mg/ml human growth hormone, 40 mg/ml mannitol, and 10 mg/ml sucrose. Phosphate/glycine buffer (pH 7.0).
Sterilization using 0.2 µm PES Filter, 25 °C, 30 min.

Result
Less cake disruption and dry material pulling from the edge with SCHOTT TopLyo® vials.

Method
TopLyo® vials: 10R (> four years of storage) and 15R (three months storage). Contact angle measurement at three lateral positions (bottom, middle, and neck area)*: Reference vs. depyrogenated (30 min at 330 °C). 15 vials measured per sample type.

Result
All analyzed vials show hydrophobic behavior with stable contact angle > 90°. No significant differences were observed for different storage times.

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"**.

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

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schott-pharma.com/vials

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