

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

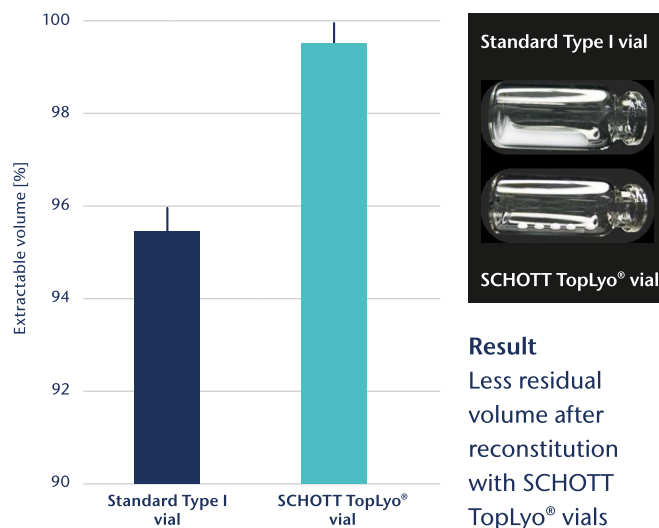
No free silicone thanks to residual free technology

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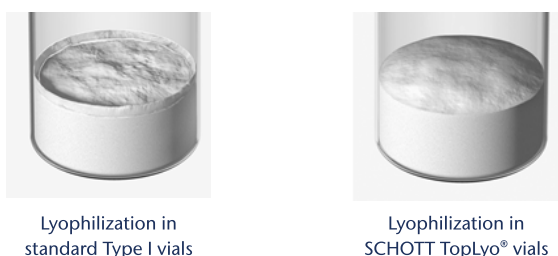
Release test: Drain-off test for hydrophobicity



Verifications: Improved emptying



Verifications: No fogging and elegant lyo cake



Verifications: Stress tests have proven stability

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

Method

10R vials Type I glass and SCHOTT TopLyto® 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 TopLyto® vials.

Method

TopLyto® 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	<ul style="list-style-type: none"> 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.

schott-pharma.com/vials

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PHARMA

carbon neutral
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