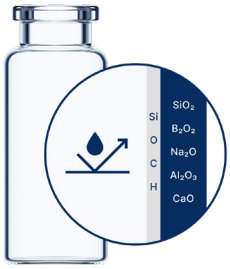
EVERIC® lyo

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.
- EVERIC® lyo 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 antibody-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

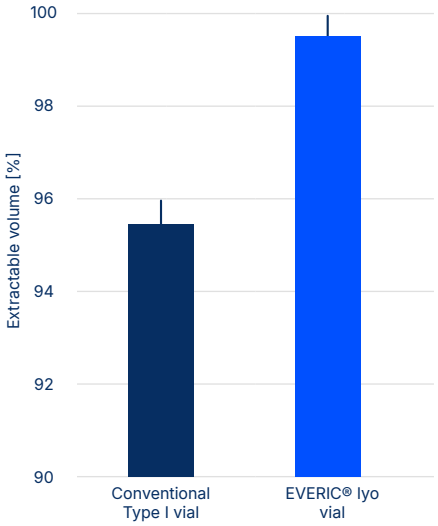
Autoclaving filled with H_2O.

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

In specification

Not in specification

Verifications: Improved emptying



Conventional Type I vial

EVERIC® lyo vial

Result

Less residual volume after reconstitution with EVERIC® lyo vials

Verifications: No fogging and elegant lyo cake

Lyophilization in conventional Type I vials

Lyophilization in EVERIC® lyo vials

Verifications: Stress tests have proven stability

		EVERIC® lyo 10R	EVERIC® lyo 15R	EVERIC® lyo 10R, depy-rogenated	EVERIC® lyo 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 EVERIC® lyo 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 EVERIC® lyo vials.

Method

EVERIC® lyo vials: 10R vial (> four years of storage) and 15R vial (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 (non sterile)	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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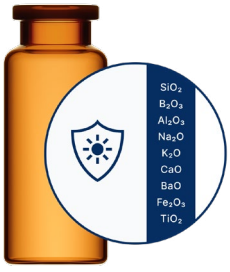
EVERIC® amber

Reliable light protection and regulatory compliance



- While every protein is sensitive to light, the more complex the molecule, the higher the possibility of light-induced aggregation or degradation.
- Antibody-drug conjugates (ADCs) are particularly sensitive to light due to their fragility. Even light exposure during filling prior to lyophilization can cause issues.
- Adapting the lighting set-up during filling is cumbersome and may not be sufficient.
- Existing solutions do not comply with USP, Ph. Eur., and JP light transmission requirements, so multiple primary packaging articles may be necessary.
- EVERIC® amber offers a solution that provides reliable light protection while remaining compliant with USP, Ph. Eur., and JP standards.

FIOLAX® amber glass tubing – absorption of light

Improved forming process: tight control of dimensional parameters and temperature ranges

Unchanged glass composition – Type I Borosilicate Glass

Full compliance with light transmission requirements of Ph. Eur., USP and JP

Light protection
Protection against ultraviolet rays and short-wave visible light

Global compliance
Suitable for pharmaceutical companies operating in multiple regulatory environments

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Release test

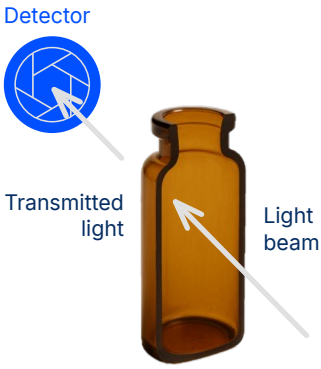
01 Mechanical cut & cleaning

Vial is:

1) Cut in vertical direction
2) Cleaned to get a quasi-plan, contaminant-free surface

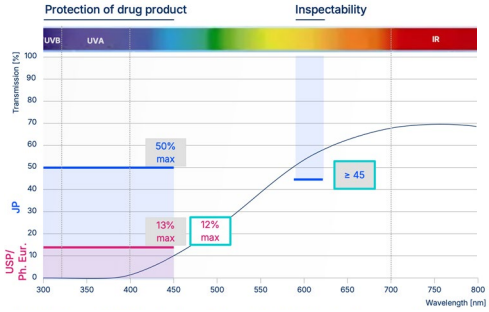
02 Spectral screening

Light transmission is measured through the middle of the vial body



03 Spectral evaluation

Certified release criteria acc. to wall thickness and filling volume



Threshold for the range of 590 – 610 nm depends on wall thickness. Indicated photo-induced reactions are not considered transmission-rate dependent in this illustration.

= 10 ml, 1.0 mm WT = 20 ml, 1.2 mm WT
% = JP % = USP/Ph. Eur.

Verifications: The right production set-up is key to achieving global compliance

Annealing after hot-forming is necessary to avoid residual stress, but it influences transmission.

Light transmission compliance with Ph. Eur., USP and JP standards can be achieved for amber vials with a 1 mm thick wall (2–10R) via tight process control.

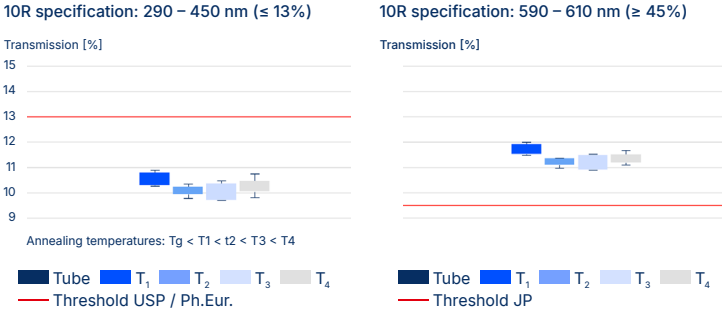


Figure 1: Light transmission compliance for 10R vial (wall thickness 1 mm)

By reducing the wall thickness of a 20R vial to 1 mm, compliance with USP, Ph. Eur., and JP standards can be achieved.

Strength-optimized parameters with tight dimensional tolerances, dedicated inspection and packaging with dividers ensure strength similar to conventional vials.

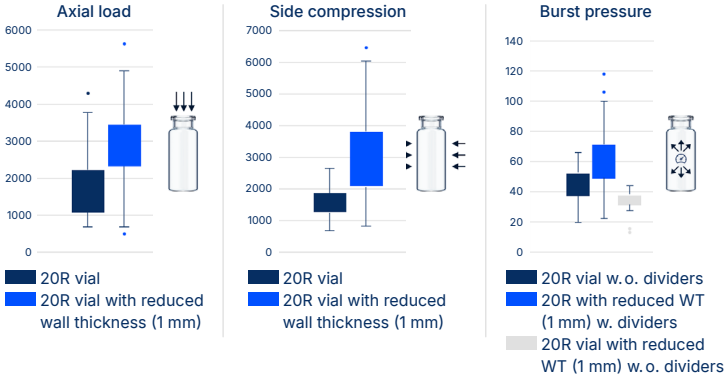


Figure 2: Strength tests for 20R vial with a reduced wall thickness (1 mm)

General ordering information				
Quality level	StandardLine & release test			
Packaging	▪ Tray (with divider for 10R and 20 ml format) ▪ Pre-washed & pre-sterilized: adaptiQ® (tray, cup, nest)			
Possible combinations	EVERIC® amber can be combined with EVERIC® lyo			
Palletizing	A standard Euro pallet (1200 x 800 mm) contains 15–27 layers of 9 trays each			
Formats	2R	6R	10R	20 ml
Pieces per tray (non sterile)	344	186	104	77

Order now:
www.schott-pharma.com/vials

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