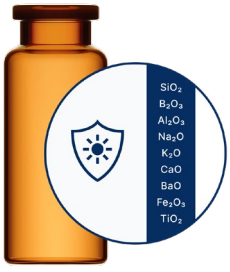
EVERIC® amber

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

SCHOTT PHARMA

Release test

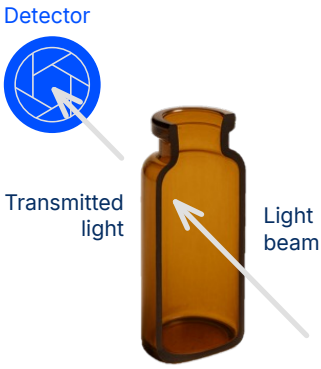
01 Mechanical cut & cleaning

Vial is:

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

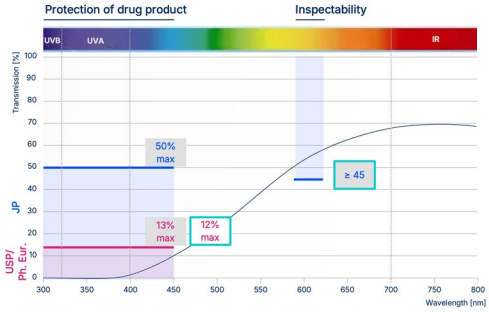
02 Spectral screening

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.

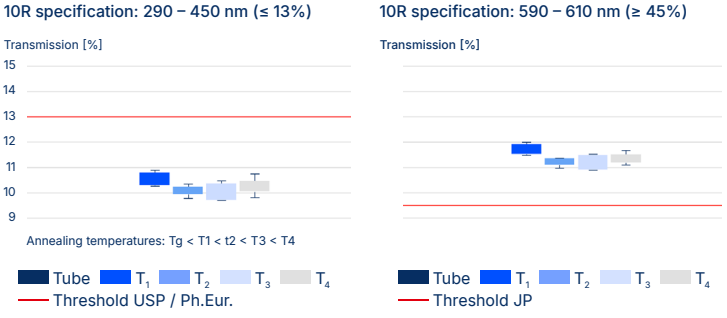


Figure 1: Light transmission compliance for 10R vial (wall thickness 1 mm)

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.

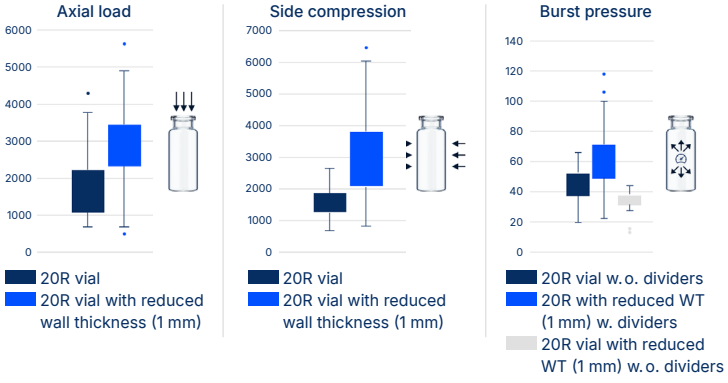


Figure 2: Strength tests for 20R vial with a reduced wall thickness (1 mm)

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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SCHOTT Pharma AG & Co. KGaA, Hattenbergstrasse 10, 55122 Mainz, Germany
pharma@schott.com

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