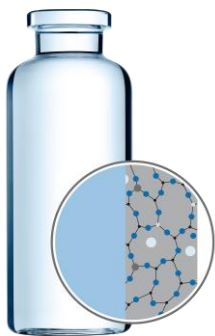


EVERIC® pure Datasheet



EVERIC® pure – Pharmaceutical glass vial with homogenous inner surface leading to unmatched drug stability

- The conventional vial converting process can lead to a near-bottom region with a changed inner surface, possibly resulting in:
 - ... proportionately increased leachable level for low-fill volumes
 - ... increased risk of pH shift
 - ... increased delamination risk
- This risk is even higher the more risk factors apply (e.g. terminal sterilization, general sensitivity towards leachables, storage at room temperature).
- EVERIC® pure vials provide a homogenous inner surface with improved leaching behavior.



FIOLAX® CHR glass tubing for improved hydrolytic resistance



Improved forming process due to patented delamination controlled technology



Unchanged glass composition – Type I borosilicate glass



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

Low leachables level

Especially relevant for low-filled drugs

Delamination under full control

Particularly important for formulations that are terminally sterilized (diluent, WFI) or phosphate buffer-based

Lower pH shift and conductivity

Especially suitable for low-fill volumes

No re-registration necessary

SCHOTT
PHARMA

Release test



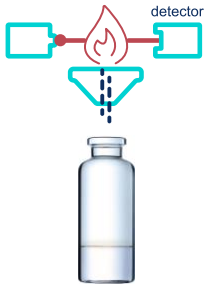
1) Glass attack

Autoclaving, empty head first.



2) Leaching

Autoclaving filled with H₂O.

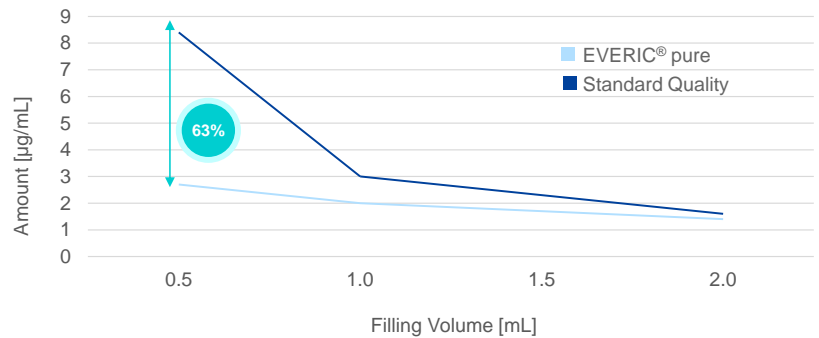


3) Determination of sodium via AAS

Certified release criterion for Sodium (Na) – limit value defined per format.

Verifications: Unmatched drug stability for low-filling volumes with EVERIC® pure vials

Na in purified water after for 48 weeks at 40 °C



Vials produced with a standard converting process served as benchmark.

Shown here is the amount of sodium leaching (µg/ml) in purified water after 48 weeks at 40 °C for different filling volumes (ml).

Result: The unique low leachable level of EVERIC® pure vials becomes more relevant the lower the filling volume.

Verifications: Allowed conductivity (based on EP) fulfilled only with EVERIC® pure

Vials produced with a standard converting process served as benchmark.

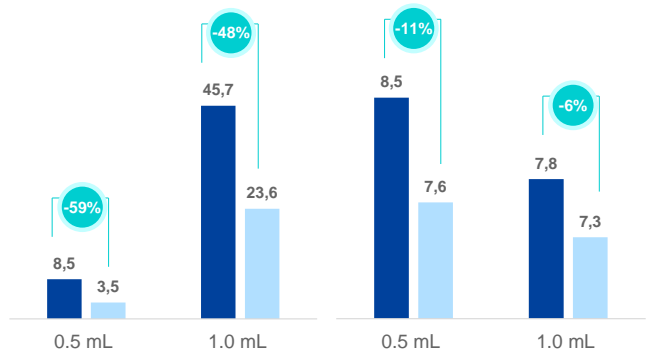
2R vials were filled with purified water. Terminal sterilization at 121 °C for 30 min at worst case has been conducted.

Shown here is conductivity in µS/cm and pH after 48 weeks at 40 °C.

Result: EVERIC® pure vials lead to lower pH shift and superior conductivity.

Conductivity µS/cm

pH



General ordering information

Quality level	TopLine with release test										
Packaging	<ul style="list-style-type: none"> Tray with optional divider Pre-washed and pre-sterilized: adaptiQ® (tray, cup nest, clip nest*) 										
Possible combinations	EVERIC® pure can be combined with EVERIC® strong and EVERIC® smooth										
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

*50R not available in clip nest configuration

Many configurations are available in small quantities as “**Fast Track Articles**”.

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

FIND OUT MORE:
www.schott-pharma.com/vials

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