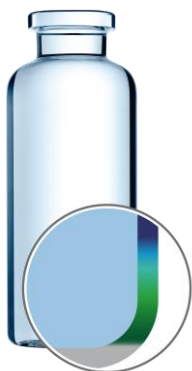


EVERIC® strong

Datasheet



EVERIC® strong – Pharmaceutical glass vial with optimized strength for reduced risk of breakage

- During conventional bulk fill-and-finish processing, vials are continuously subjected to side compression (e.g. during depyrogenation, on rotary table) and axial load (e.g. during crimping).
- In addition, vials used in injection devices have to prove their reliability with regards to strength.
- Breakage rarely occurs, but leads to unwanted interruptions and downtimes, resulting in increased manufacturing costs.
- EVERIC® strong provides improved vial strength without changing the glass composition or applying additional chemical treatments.
- An additional “release criterion” has been specifically developed.



FIOLAX® OS (“optimized strength”) glass tubing with tighter scratch and fissure specification



Improved forming process (tighter tolerances in critical areas) and specialized inspection (100 % bottom inspection via camera and sensor)



Unchanged glass composition – Type I borosilicate glass



“Flawless” processing: No glass-to-glass contact, automated back-end (packaging robot), packaged with separators



Geometry within ISO specification



Bottom thickness homogeneity and footprint defined as additional parameters in dimensional specification

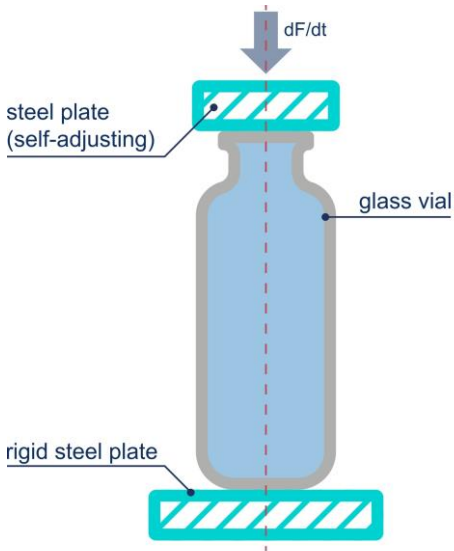
Optimized strength

Within existing ISO tolerances with unchanged glass matrix

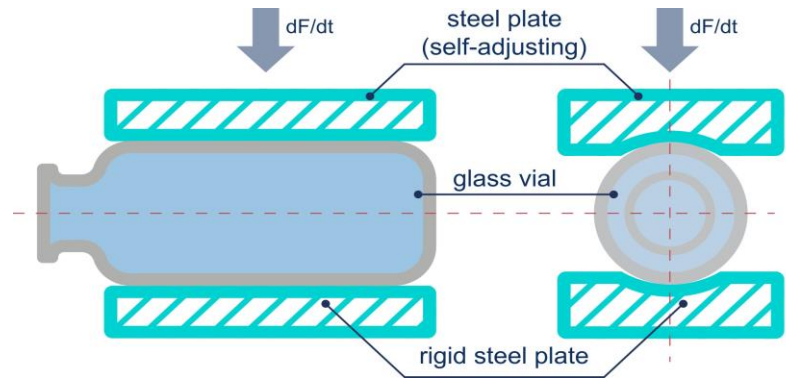
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Release Test

Axial load strength (minimum 2000 N)*



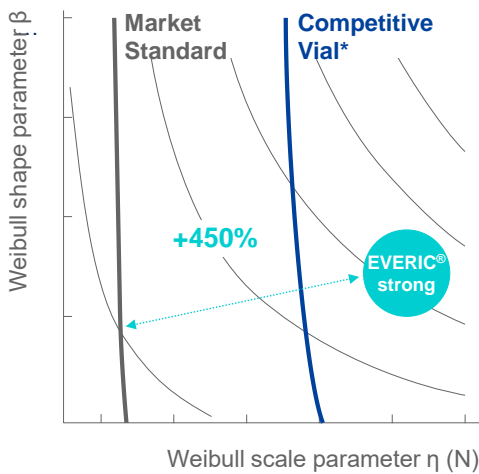
Side compression strength (minimum 1000 N)*



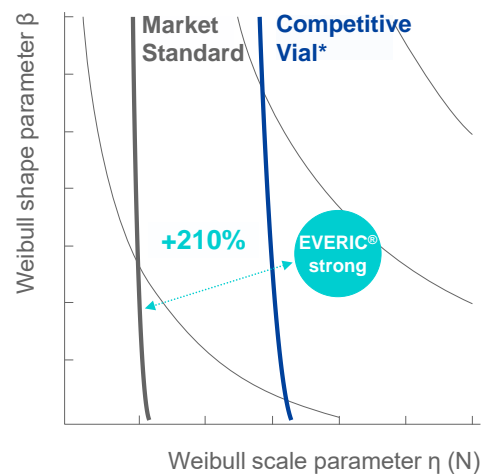
*Statistical in-process testing; AQL 4.0

Verifications: Competitive sample testing – superior strength in all aspects

Axial load strength



Side compression



*Borosilicate vials, untoughened, proposed in the market, competitive to EVERIC® strong

General ordering information

Quality level	TopLine with additional release tests									
Packaging	Tray with divider									
Possible combinations	EVERIC® strong can be combined with EVERIC® pure 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
Pieces per tray	187	187	187	126	126	104	104	77	77	77

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

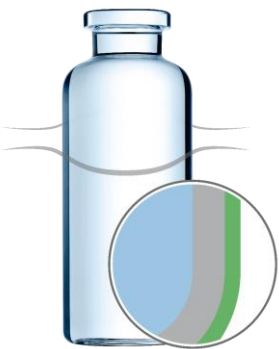
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FIND OUT MORE:
www.schott-pharma.com/vials

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EVERIC® smooth silicone

Datasheet



EVERIC® smooth silicone – Pharmaceutical glass vial with low friction outer coating for improved line efficiency

- Conventional bulk fill-and-finish lines don't often operate at maximum efficiency. The main reason for this is continuous glass-to-glass contact, potentially leading to:
 - ... sticking and climbing in and after the depyrogenation oven
 - ... increased cosmetic defects, resulting in higher final reject rates and higher risk of breakage
 - ... reduced line speed
- Consequences are downtimes, interruptions, and increased costs.
- The outer coating of EVERIC® smooth silicone vials provides a protected outer surface that smoothly runs through the fill-and-finish process, resulting in improved line performance.
- An additional "release criterion" has been specifically developed.



Coating up to the shoulder



Layer thickness 10 – 70 nm



High mechanical resistance



Coating applied via dip coating process



Coefficient of friction ≤ 0.3



Fully transparent



Particle-free



Stable after washing process



Stable sterilization:
Autoclaving (121 °C for 1 h)
Depyrogenation (up to 350 °C for 1h)



No migration of coating to the vial's inner surface

Increased line speed

Smoother and faster transportation due to optimized gliding behavior

No sticking and climbing

Due to lower coefficient of friction

Lower final reject rate

Reduction of cosmetic rejects thanks to protective outer coating

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Release test: Presence of outer coating

1) Marking

To determine the surface tension, a test ink with a defined surface energy (28 mN/m) is used. Recommendation: arcotest® test inks.

2) Evaluation of outer surface



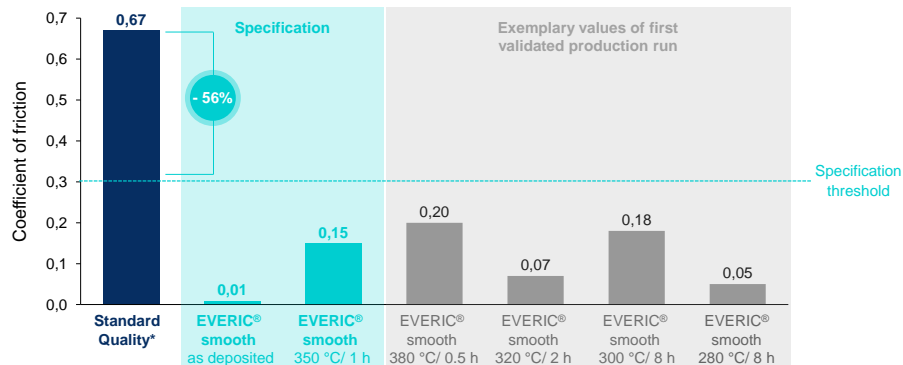
Not in specification



In specification

Verifications: Low coefficient of friction for improved gliding behavior even after depyrogenation

- Comparison of coefficient of friction of standard vials vs. EVERIC® smooth silicone vials after different depyrogenation conditions (1 h for 300 °C/ 320 °C/ 350 °C).
- Result: Coefficient of friction stays under specification threshold.



* production average over time, all substrates with comparable surface due to pre-treatment

Verifications: Significant increase of line speed with EVERIC® smooth silicone vials

Set-up

- Place: OPTIMA pharma, in Schwäbisch Hall, Germany.
- Date: 30.07.2020.
- Samples: ~ 34,000 2R EVERIC® strong & smooth vials, standard vials from unknown manufacturer as reference.

Machine

- Test bulk filling machine.
- Round-run throughput, vials were processed multiple times.
- Depyrogenation tunnel, rotary buffering table, star wheel transport (no washing, filling stoppering, crimping).
- Speed was successively increased to 750 vials/ min.

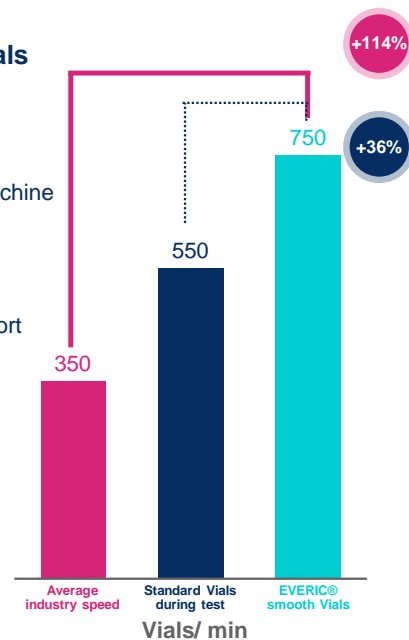
Results

Standard vials

- Abortion of test at 550 vials/ min → test machine could not be operated properly anymore.

EVERIC® vials

- Ran smoothly at reached maximum transport speed (750 vials/ min).
- Decreased disruptions.
- No breakage.
- Less exerted force → decreased wear and tear on format parts can be assumed.



General ordering information

Quality level	TopLine with additional release test									
Packaging	Tray with optional divider									
Possible combinations	EVERIC® smooth can be combined with EVERIC® strong and EVERIC® pure									
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
Pieces per tray	344	344	344	186	186	154	154	95	95	95

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

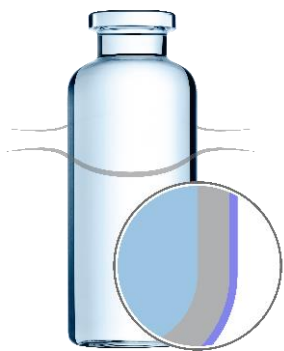
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FIND OUT MORE:
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EVERIC[®] smooth silane

Datasheet



EVERIC[®] smooth silane – Pharmaceutical glass vial with low friction outer coating for reduced final rejects

- A huge number of high-value drugs such as biologics are filled in vials using conventional bulk fill-and-finish lines.
- Unavoidable glass-to-glass contact leads to a continually increasing number of introduced cosmetic defects, resulting in an elevated number of final rejects and increased costs.
- Due to these drugs' potential sensitivity towards silicone, certain pharmaceutical companies ban any kind of silicone from their facilities.
- The covalently bonded, silicone-free monolayer outer coating of EVERIC[®] smooth silane vials protects the outer surface from cosmetic defects, resulting in reduced reject rates.
- An additional "release criterion" has been specifically developed.



Coating up to the shoulder



Layer thickness 5 – 50 nm



High mechanical resistance



Coating applied via dip coating process



Coefficient of friction ≤ 0.3



Fully transparent



Particle-free



Stable after washing process



Stable sterilization:
Autoclaving (121 °C for 1 h)
Depyrogenation (up to 350 °C for 1h)



No migration of coating to the vial's inner surface

Lower final reject rate
Reduction of cosmetic rejects thanks to protective outer coating

No sticking and climbing
Due to lower coefficient of friction

Increased line speed
Smoother and faster transportation due to optimized gliding behavior

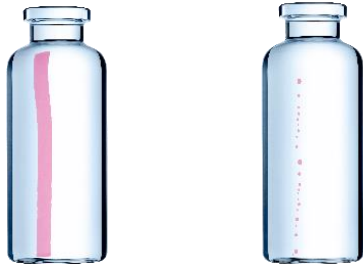
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Release test: Presence of outer coating

1) Marking

To determine the surface tension, a test ink with a defined surface energy (28 mN/m) is used. Recommendation: arcotest® test inks.

2) Evaluation of outer surface



Not in specification

In specification

Verifications: Results of line trial at Hoffmann-La Roche

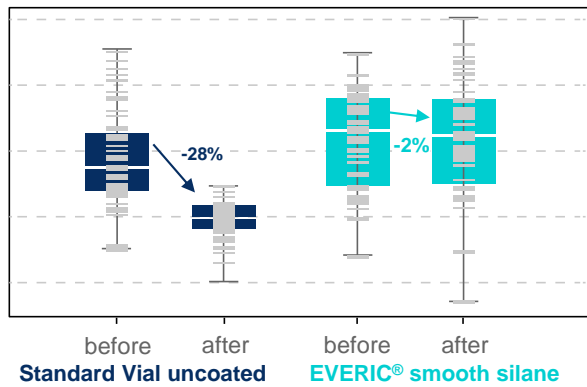
Set-up

- Standard vials (TopLine) vs. EVERIC® smooth silane vials.
- Processing on conventional bulk fill-and-finish line.
- Analysis of cosmetic and mechanical properties, particle count in fill medium, wash medium, noise level, line performance (e.g. downtime, operator interactions), qualitative experience of line technicians.

General observations

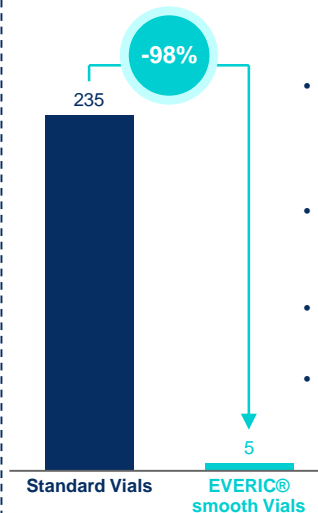
- Washing: Pushing into machine easier/ better gliding, especially downward.
- Belts: Less wiggle/ 'tremble'.
- Tunnel: Smoother transport on tunnel belt/ no sticking/ climbing.
- Rotary table: Standing vials are carried away/ smoother by moving vials.
- Buffer: Less noise/ no climbing.
- Easier packing: Vials "glide" into tray/ no sorting/ pushing necessary.
- No breakage.
- No traces of outer coating found in wash medium.
- No coating particles in filled medium.

Strength: EVERIC® smooth clearly shows higher strength throughout the entire process



- Strength comparison of uncoated vs. EVERIC® smooth silane vials before and after bulk process via burst pressure tests.
- Different, high initial strengths for two vial sets.
- No significant reduction in strength for EVERIC® smooth vials.

Cosmetic defects: 98 % reduction



- 100 % visual optical inspection according to internal Hoffmann-La Roche guidelines.
- Subsequent to the line trial, including all vials that had been processed.
- Number of cosmetic defects reduced by 98 %.
- Reduced final reject rate highly improves yield.

General ordering information

Quality level	TopLine with additional release test									
Packaging	Tray with optional divider									
Possible combinations	EVERIC® smooth can be combined with EVERIC® strong and EVERIC® pure									
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
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