



- 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



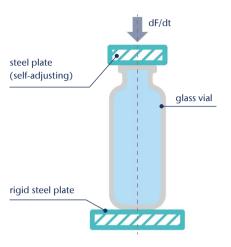
Bottom thickness homogeneity and footprint defined as additional parameters in dimensional specification

Optimized strength

Within existing ISO tolerances with unchanged glass matrix

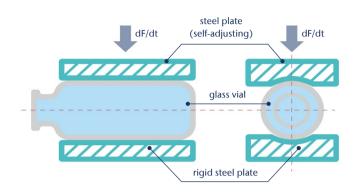


Axial load strength (minimum 2000 N)*



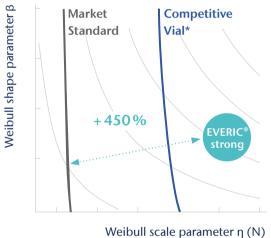
*Statistical in-process testing; AQL 4.0

Side compression strength (minimum 1000 N)*

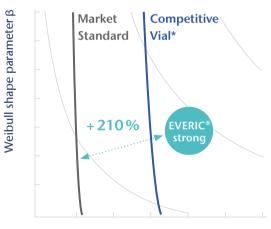


Verifications: Competitive sample testing – superior strength in all aspects

Axial load strength



Side compression



Weibull scale parameter η (N)

*Borosilicate vials, ur	ntoughened.	proposed in	the market.	competitor to	EVERIC®	strong

General ordering information										
Quality level	TopL	TopLine with additional release tests								
Packaging	Tray	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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- 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 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 1 h)



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



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

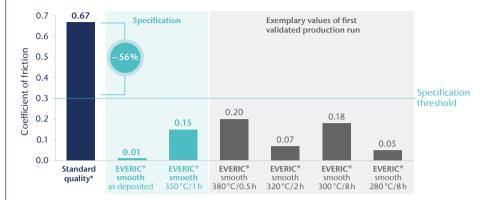




Not in specification In specification

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

- Comparison of coefficient of friction of standard vials vs. EVERIC® smooth 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 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.

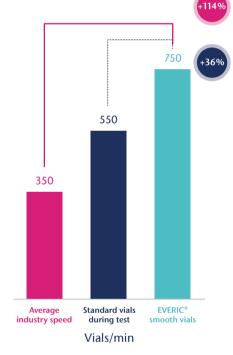
Results

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	TopL	TopLine with additional release test								
Packaging	Tray	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

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