Стеклянные фармацевтические флаконы Velocity Vials

Технические характеристики

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Россия +7(495)268-04-70
Киргизия +996(312)-96-26-47
Казахстан +7(7172)727-132

cga@nt-rt.ru || https://corning.nt-rt.ru/

Corning Velocity® Vials’

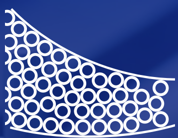
Low Coefficient of Friction Coating

has consistently enabled a 20 – 50% improvement in fill-finish efficiency

Corning’s patented low coefficient of friction (COF) external coating can overcome many of the fill/finish issues common with conventional vials. Velocity® Vials can reduce bottlenecks and the likelihood of damage, including cracks, glass particulates, or other defects generated during the fill/finish process, leading to better throughput and higher yield.

Designed to improve filling line performance

Corning's low COF coating reduces glass-to-glass & glass-to-metal friction, enabling:



Reduced Vial Jams

Reduced Damage

Reduced Tipovers

Click below to see Corning Coated Vials in action

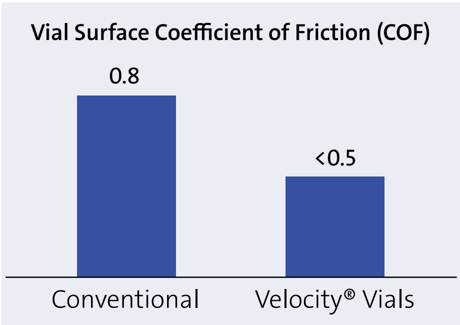
USP Type I Packaging Designed for Speed and Efficiency

One of the fundamental concerns in fill-finish manufacturing is friction created by glass-to-glass and glass-to-metal contact. This resistance can limit filling line efficiency and speed, ultimately constraining throughput and slowing down the delivery of essential medications and treatments. The glass friction from conventional vials can also generate damage that leads to high particle counts, glass breakage, and cracks. These quality issues not only impact throughput, but can also impact to the sterility assurance of medicinal packaging, creating an increased risk of container closure integrity issues, ultimately leading to recalls or contaminated medications reaching the patient.

The COVID-19 pandemic intensified pharmaceutical supply chain constraints and fill-finish capacity shortages that have existed for many years, due in part to the limitations of conventional glass vials. Many have come to accept these limitations as a standard cost of doing business, but innovations in glass packaging are enabling a step-change in performance that shatters these old assumptions.

To meet the immediate need for a primary packaging solution that can improve yield and overcome quality issues as a drop-in solution, Corning introduced Velocity® Vials, a USP Type I borosilicate vial externally coated with Corning's proprietary low coefficient of friction (COF) technology.

Velocity Vials are engineered to deliver better economics, better quality, and a more environmentally sustainable design compared to conventional vials. Velocity Vials can improve filling line efficiency from 20% to 50% while lowering packaging production costs, and can be implemented with a seamless regulatory process for marketed drugs. Compared to conventional vials, Corning's new coated vials can also reduce damage that leads to particles, breaks, and cracks.



The increased efficiency and throughput of Velocity Vials can help drive faster manufacturing of essential medications to meet rising global demand. Pharmaceutical companies and fill-finish contract manufacturers (CMOs/CDMOs) can leverage the improved efficiency as a drop-in solution to increase throughput, thereby producing more vaccines and other drug products in less time.

In a capacity constrained environment, Velocity Vials create immediate fill-finish capacity, allowing pharma's to potentially delay capital investment for new capacity and reduce costs. When adopted broadly across an entire pharmaceutical filling system, Velocity Vials could significantly improve productivity and quality, thus lowering manufacturing cost for pharmaceutical companies and CMOs/CDMOs.

Case Study

Corning Velocity® Vials showed superior performance on customer filling line

In hopes of improving fill finish efficiency and lowering total cost of ownership, a leading pharmaceutical company reached out to Corning to learn more about Velocity Vials. Needing to quickly increase yield without implementing expensive capital projects, the pharma company was looking for a drop-in solution.

The company and its CMO filling partner knew that even well-designed filling lines encounter throughput constraints with vial handling due to the physical interactions between the machines and conventional glass vials. Stress and friction generated on turn tables, depyro tunnels, tracks, and trays, can lead to jams, tip overs, glass breakage, and human line interventions (which risks greater contamination of sterile environments). In addition, the pharmaceutical company and CMO wished to avoid direct lubrication of the filling equipment due to the potential for sterility and line maintenance issues.

Collaborating with the CMO, Corning collected batch data for over 60 conventional vial runs and 30 Velocity Vial runs. Each batch run consisted of approximately 130,000 vials. As shown in Figure 1, Velocity Vials reduced the average number of glass-related downtime events, average glass-related downtime minutes, and average number of vial breakage events per lot. In this trial, Velocity Vials demonstrated 35% higher efficiency* when compared to conventional glass vials.

The CMO line operator found that Velocity Vials ran so well that they decided to end the tiral after 30 runs and move forward with broad adoption of the new technology.

Velocity Vials demonstrated significant improvements over conventional vials on Customer's filling line.

81%
reduction in glass related downtime events per lot

99%
reduction in glass related downtime minutes per lot

No glass breakage events

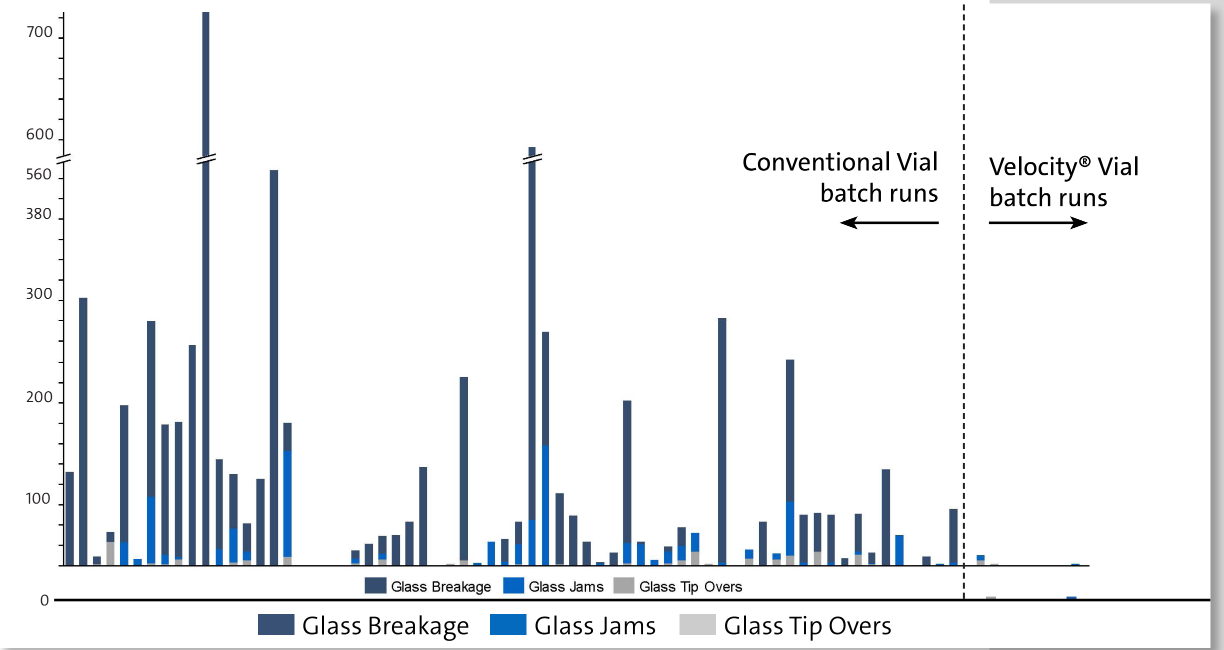
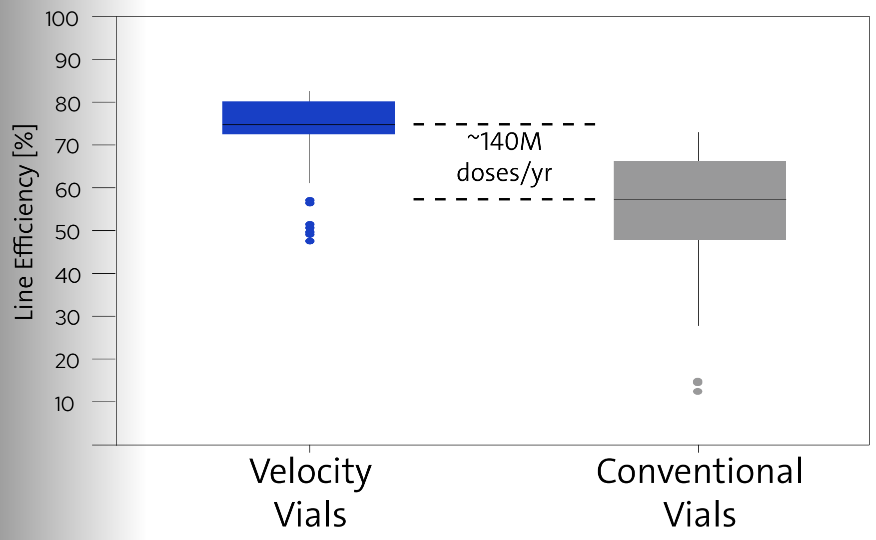


Figure 1 - Per-batch glass-related downtime (minutes) for conventional uncoated vials versus when using Velocity Vials. Batches were run sequentially over time. 60 conventional vial batches were run first and then 30 Velocity Vial batches were run. CMO decided to stop at 30 Velocity runs believing they had seen the value prop confirmed. Average batch size was approximately 130,000 vials.

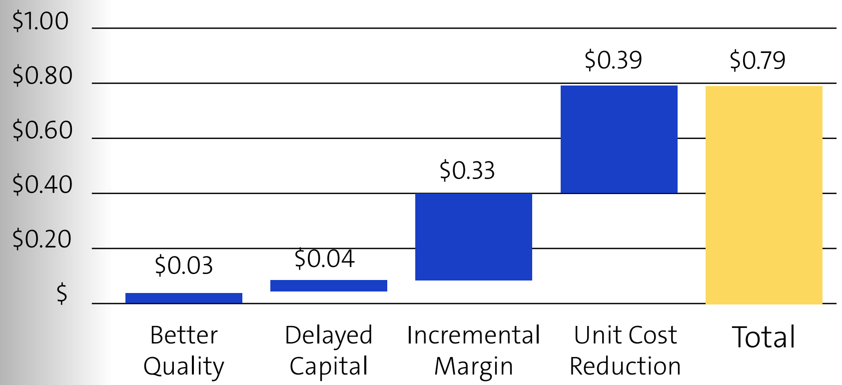
**Run time efficiency is calculated as the (Effective Line Speed/ Line Set Speed)×100.*
39 Velocity vial runs and 66 Conventional borosilicate runs; data was found to be statistically significant through two-sample t-test (t(102)=7.33, p=0)

Velocity Vials demonstrated a 35% improvement in efficiency

	Conventional Borosilicate Vials (n = 66)	Velocity Vials (n = 39)	Percent Improvement
Average Line Efficiency [%]	54.0	72.8	34.8%
$\bar{X}_{Boro} \neq \bar{X}_{Velocity}$: p-value $\ll 0.001$			



Efficiency gain could translate to value of $0.79 per vial for customer A



For a line capable of running 40 million vials, this equates to 14 million more vials and an added value of $11 million

"Ensuring consistent production, high quality, and less downtime is essential as we work to keep pharmaceutical supply chains moving, and to this extent, Corning's Velocity Vials have already shown very promising results. Corning's Velocity Vials demonstrated a significant improvement in efficiency when compared with traditional borosilicate vials on our fill-finish lines."

- CMO Vice President & General Manager

Corning Velocity® Vials

Glass Packaging Designed for Speed and Efficiency

Velocity Vials can deliver better economics, better quality, and a more environmentally sustainable design compared with traditional pharmaceutical packaging.

Our coated borosilicate vials boost efficiency from manufacturing to delivery—increasing the production of life-saving drugs without sacrificing quality or value.

Product Specifications

Working with Corning means working directly with some of the world’s top glass scientists and engineers. Velocity Vials are made with Corning’s high-quality tubing and held to rigid specifications to ensure consistent quality standards.

In addition to a wide range of ISO standard formats, custom formats are available upon request.

Product availability and detailed specifications available upon request.

<table>
<tr><th>SKU</th><th>2R</th><th>3R</th><th>4R</th><th>6R</th><th>8R</th><th>10R</th><th>15R</th><th>20R</th><th>25R</th><th>30R</th></tr>
<tr><td>Outer Diameter (mm)</td><td colspan="3">16</td><td colspan="2">22</td><td colspan="2">24</td><td colspan="3">30</td></tr>
<tr><td>Wall Thickness (mm)</td><td colspan="7">1.0</td><td colspan="3">1.2</td></tr>
<tr><td>Overall Height (mm)</td><td>35</td><td>40</td><td>45</td><td>40</td><td colspan="2">45</td><td>60</td><td>55</td><td>65</td><td>75</td></tr>
<tr><td>Inner Diameter (mm)</td><td colspan="3">7</td><td colspan="7">12.6</td></tr>
<tr><td>Finish (mm)</td><td colspan="3">13</td><td colspan="7">20</td></tr>
<tr><td>Flange Height (mm)</td><td colspan="10">3.6</td></tr>
<tr><td>Brimful Capacity (mL)</td><td>4</td><td>5</td><td>6</td><td>10</td><td>11.5</td><td>13.5</td><td>19</td><td>26</td><td>32.5</td><td>37.5</td></tr>
<tr><td>Weight (g)</td><td>4.4</td><td>5.5</td><td>5.7</td><td>7.9</td><td>8.7</td><td>9.5</td><td>12</td><td>16.2</td><td>18.9</td><td>21.9</td></tr>
</table>

Velocity Vials are Type I borosilicate vials with a low coefficient of friction external coating.

Glass Composition (approximate oxide weight(%))

Oxide Component	Symbol	Corning® 51-V Tubing	Corning® 51-D Tubing
Silicon Dioxide	SiO_2	72.0	73.0
Boron Oxide	B_2O_3	11.5	11.2
Aluminium Oxide	Al_2O_3	6.8	6.8
Calcium & Magnesium Oxide	CaO + MgO	0.7	1.0
Sodium Oxide	Na_2O	6.5	6.8
Potassium Oxide	K_2O	2.4	1.2
Iron Oxide (*)	Fe_2O_3	< 600 ppm	< 400 ppm
Barium Oxide (*)	BaO	< 400 ppm	< 400 ppm
Titanium Dioxide (*)	TiO_2	< 400 ppm	< 300 ppm

(*) Not introduced in the batch composition

Chemical Resistance Classifications

		Corning® 51-V Tubing	Corning® 51-D Tubing
Hydrolytic Resistance (Glass Grain)	Ph. Eur. (3.2.1B) / USP <660>	Type 1	Type 1
Hydrolytic Resistance (Glass Grain)	ISO 720	HGA1	HGA1
Soluble Alkali Test	JP 7.01	Complies	Complies
Acid Resistance Class	DIN 12116	Class S1	Class S1
Alkali Resistance Class	ISO 695	Class A2	Class A2
ASTM Laboratory Glass Class	ASTM E 438	Class B	-

Physical Properties

Name	Unit	Corning® 51-V Tubing	Corning® 51-D Tubing
Average Linear T.E.C.	10^{-7} K^{-1}	54	51
Density	g cm^{-3}	2.33	2.34
Relative Refractive Index	(number) (*)	1.49	1.49

(*) λ at 587.6nm

Viscosity Curve — Characteristic Temperatures

Name	Unit	Corning® 51-V Tubing	Corning® 51-D Tubing
Working Point	$10^{4.0}$	1130 °C	1155 °C
Softening Point	$10^{7.6}$	785 °C	777 °C
Annealing Point	$10^{13.0}$	570 °C	555 °C
Strain Point	$10^{14.5}$	525 °C	515 °C

Heavy Metals / Arsenic / Antimony

Heavy Metals

Contents of Pb, Cd, Hg, CrVI is below the 100 ppm limit value stated by the US Toxics in Packaging Clearing House (TPCH) and European Parliament and Council Directive Article 11 of 94/62/ EC of 10. Dec. 1994 on packaging and packaging waste with updates 2001/171/EC and 2006/340/EC.

Arsenic and Antimony

Corning Pharmaceutical Glass does not introduce any arsenic nor antimony in the batch composition of its glasses. Tests performed as per U.S. and European Pharmacopoeia prescriptions on containers made from Corning clear glass tubes give the following results:
As = Not detectable; Sb = Not detectable

Coating Chemical Characteristics and Physical Properties

Biological Reactivity / Toxicity (*)	Meets Class V for Plastics	Appearancce	Visibly Transparent, Colorless
Solubility - Aqueous or Organic Solvents	Below MDQ (<0.8 µg/g)	Thickness	< 100 nm as single layer
Volatile Organic Compounds	Below LOQ (<0.5 µg/g)	Coefficient of Friction under 10N load	< 0.5

(*) (USP <87> & <88>)

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