CORNING

Valor® Glass

Valor® Glass helps protect patients and improve pharmaceutical manufacturing.

Product Information

Benefits of Valor Glass

- Eliminates glass delamination

  Chemically-durable drug contacting surface with uniform surface chemistry

- Reduces glass particulate generation

  Valor Glass has a low coefficient of friction surface that reduces particulate generation and enhances machinability

- Resists damage and breakage

  Exceptional damage resistance and retained strength throughout processing

- Enables higher throughput through smoother filling line operations

  Valor Glass containers reduce line interventions, enabling lines to run at higher efficiency and higher speeds with improved yields.

- Prevents cracks

  In laboratory testing, Valor Glass vials provide at least 30x protection against cracks than conventional borosilicate glass vials

Valor Glass is compatible with:

- Parenteral product types including container closure systems: liquid, powder, and lyophilized
- Challenging and routine lyophilization cycles
- Existing sterilization techniques
- Dimensions and product specifications: ISO and custom formats available upon request
- Quality Assurance: 100% automated inspection
- Regulatory Compliance: Valor Glass vials meet USP and Ph. Eur. Type I hydrolytic criteria

Eliminates glass delamination

The composition and homogenous interior surface of Valor® Glass containers make them ideal for the protection of drug products.

Glass Components		Valor Glass (Approximate Weight %)
Glass Formers	SiO_2	72 – 75
	Al_2O_3	9 – 12
	B_2O_3	< 0.01
Fluxes	Na_2O	10 – 13
	K_2O	
Property Modifiers	MgO	3 – 4.5
	CaO	
Fining Agents	SnO_2	0.1 – 1
	As_2O_5	< 0.01
	Cl	< 0.01

Intentionally added
< 0.01%

Chemical Resistance

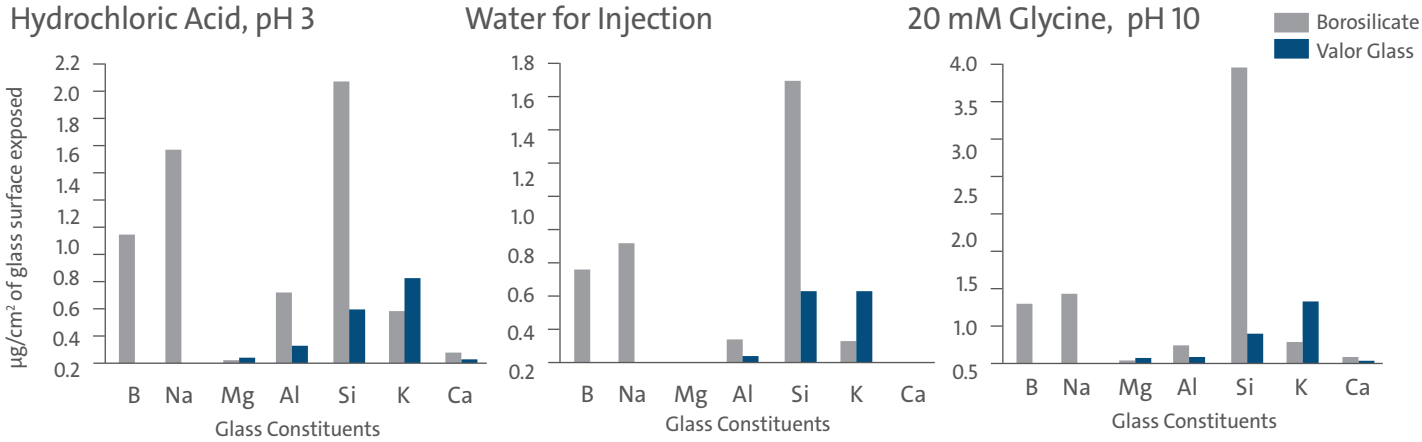
Hydrolytic Resistance	ISO 719	Meets HGB 1 Criteria
Hydrolytic Resistance	Ph. Eur. 3.2.1/USP <660>	Meets Type I Hydrolytic Criteria
Soluble Alkali Test	JP 7.01	Meets Criteria
Acid Resistance Class	DIN 12116	Class S1
Alkali Resistance Class	ISO 695	Class A2

Extractable concentrations by ICP-MS

Valor Glass exhibits lower extractable concentrations against a wide range of pHs.

3 ml containers used during extractable testing underwent a two minute hot water rinse followed by depyrogenation at 320 °C for 60 minute prior to test execution. The containers were then filled with appropriate solutions to a fill volume of 3.5 ml, stoppered and autoclaved for 1 hour at 121 °C, then stored at 50 °C for 30 days.

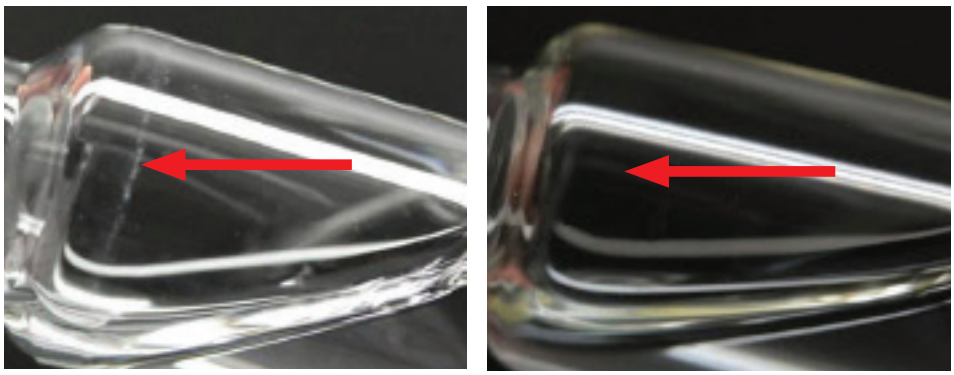
Test conditions above are approximately equivalent to 639 days at room temperature (25 °C) or 121 days at accelerated (40 °C)



* ICH Q3D Class 1 (Cd, Pb, As, Hg), Class 2A (Co, V, Ni), Class 2B (Ti, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt), Class 3 (Li, Sb, Ba, Mo, Cu, Cr) elements are not added to the glass composition and were below analytical evaluation thresholds.

Reduces glass particulate generation

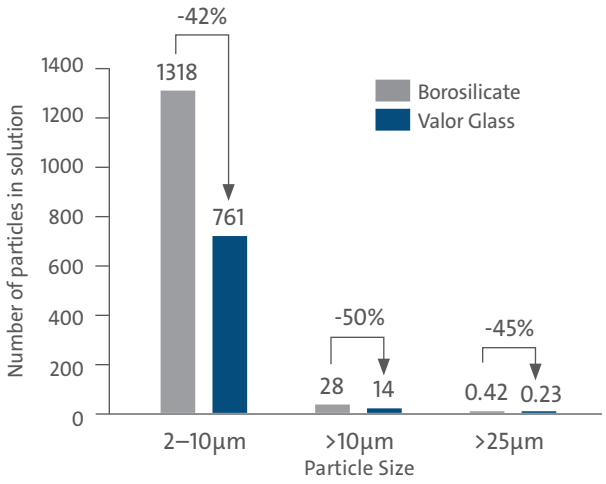
Valor® Glass is inherently strong, making it able to withstand extreme events during the pharmaceutical processing and field applications.



Visible scratches are less evident after pharmaceutical processing with Valor® Glass vials (right) compared to borosilicate containers (left)

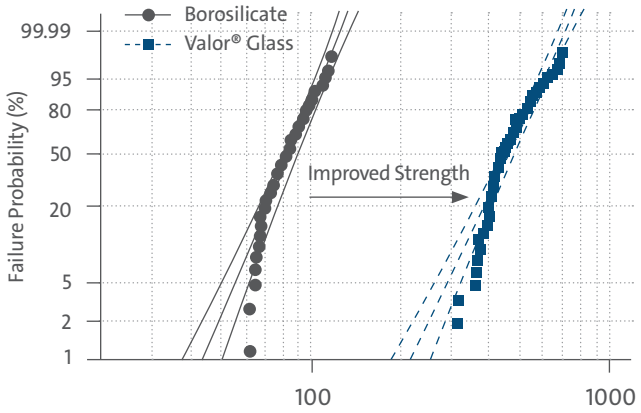
Particles In Solution

In Solution particles measured by USP <788> light obscuration method; samples collected during an engineering trial



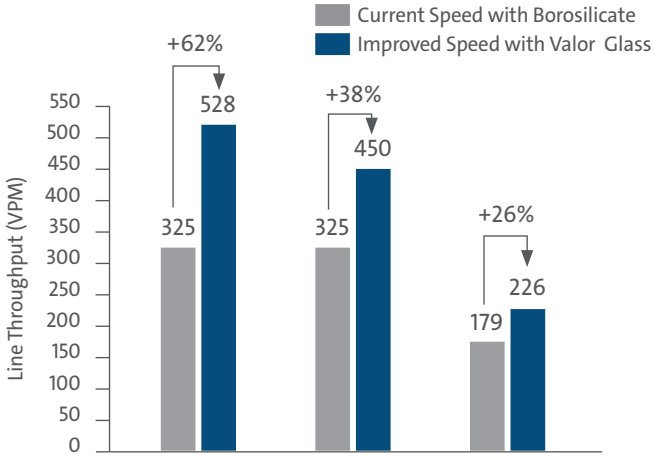
Resists damage and breakage

Valor Glass can show up to 10x improvement in compression testing compared to conventional vials



Throughput Improvement

Valor Glass vials have shown significant improvement in line throughput on various commercial filling lines.



Prevents cracks

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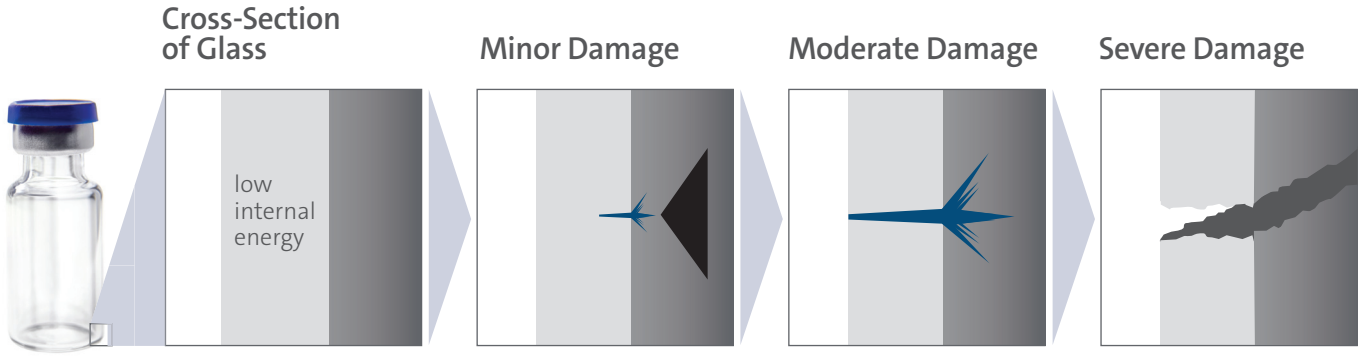
Borosilicate



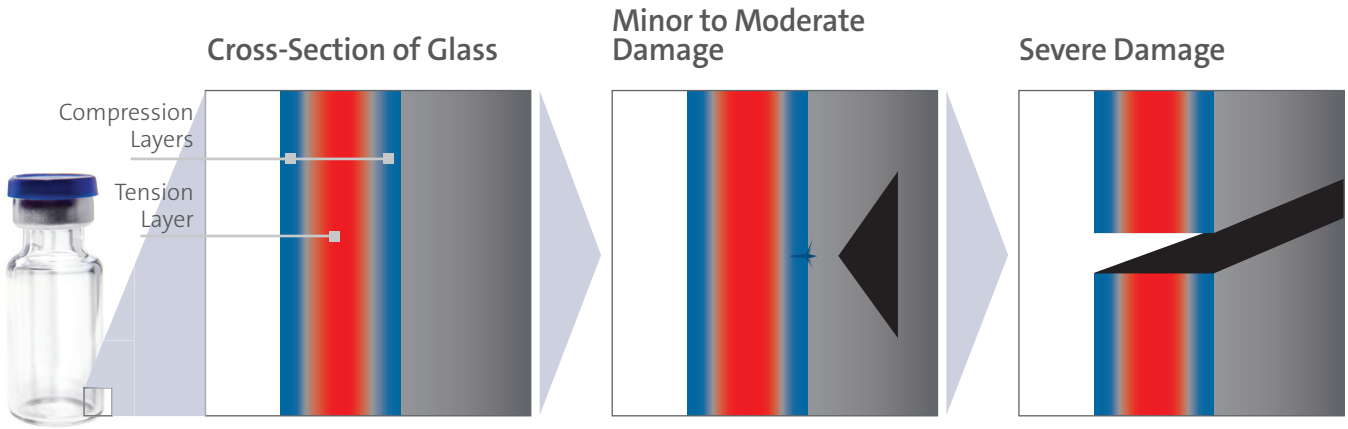
Borosilicate glass has low internal energy

Non-penetrating surface check may grow in to crack with subsequent load

Penetrating crack loss of sterility

Complete break separating into two or more pieces

Corning Valor Glass



Valor Glass is engineered with higher internal energy

Surface flaws contained within compression layer do not propagate

Deep checks propagate and complete break, separating into two or more pieces

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