West®

Exclusive Distributor
of Corning Valor® Glass Vials

VALOR® GLASS PRODUCT INFORMATION

21st Century Drugs Require a 21st Century Glass

THE FUTURE OF GLASS PACKAGING IS HERE

As you look across the pharmaceutical industry's drug pipelines and new drug applications there is a growing need to provide solutions to support increasingly more sensitive and complex molecules as well as combination products. To address these changing needs, West Pharmaceutical Services has entered into a strategic partnership with Corning Incorported to transform containment solutions for injectable medicines.

This partnership combines over 200 years of experience, bring together West's leading innovations in elastomer and primary packaging with Corning's unparalleled glass science expertise, including the innovation of Corning Valor® Glass. West is the exclusive distributor of Valor® Glass, the first and only fundamentally new glass composition to be approved by FDA for use as a primary package for an approved drug product since the advent of conventional borosilicate glass more than 100 years ago.

Not only does this broaden West's capabilities, it makes us the complete solutions provider for injectable drug packaging and delivery systems for the pharmaceutical industry. Through this partnership, West will be better able to provide a first-in-class, end-to-end containment solution with best-in-class performance and product support that we expect will address the regulatory challenges and support gaps that exist with today's fragmented supply chain.

VALOR GLASS PRODUCT BENEFITS

- Eliminates delamination
- Reduces glass particulate generation
- Resists damage and breakage
- Prevents* cracks
- Enables higher throughput through smoother filling line operations
- Decreases total cost of ownership

Important Considerations

- Performs as a drop-in solution
- Displays compatibility with modern manufacturing equipment and processes including depyrogenation, lyophilization, and terminal sterilization
- Compatible with automated visual inspection systems (AVI)
- Compatible with standard labeling technology
- Available in ISO and custom formats upon request

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

QUALITY BY DESIGN

Improved Chemical Durability

Manufacturers invest heavily in quality protection. Valor Glass complies with the highest international quality standards. Valor technology offers equivalent or better overall performance for extractables, leachables, and improved hydrolytic resistance compared to conventional vials.[1]

- Offers a chemically homogeneous drug-contacting surface
- Meets USP and Ph. Eur. Type I hydrolytic performance criteria
- Demonstrates lower extractable concentrations against a wide range of pHs

Eliminates Delamination

Delamination can result in costly issues and potential FDA recalls. Corning identified the root cause of delamination. During the process of converting conventional borosilicate glass, evaporation and condensation of boron rich vapor creates a heterogenious drug-contacting surface that can increase the likelihood of delamination.

Innovation from the Inside Out

Tube Forming

Raw materials are batched, melted, and formed into tubes. Advanced process controls help ensure consistent high quality.

Converting

Tubing is reformed into containers; annealing removes residual stress. Consistent geometry and flaw management enables product performance.

Ion Exchange

Containers are chemically strengthened through ion exchange. This improves load bearing strength and helps to prevent cracks.

Coating

Low coefficient of friction (COF) coating is applied to the exterior of the containers improving damage resistance and machinability and reducing particulate generation.

Inspection

Containers are 100% inspected to meet dimension and cosmetic quality compliance.

1. R.A. Schaut, J.S. Peanasky, S.E. DeMartino, and S.L. Schiefelbein (2014). A new glass option for parenteral packaging. PDA Journal of Parenteral Science and Technology, vol. 68, no. 5, pp. 527-534.

Valor® Glass' uniform surface chemistry does not form boron-rich heterogeneities during converting. The removal of boron from Valor Glass eliminates the potential for delamination to occur.

The composition and uniform surface chemistry and chemically durable drug contact surface makes this new technology ideally suited for sterile, injectable medicines.

Glass Components		Aluminosilicate Bulk Glass (Weight %)
Glass Formers	SiO_2	73.8
	Al_2O_3	10.4
	B_2O_3	<0.01
Fluxes	Na_2O	11.7
	K_2O	
Property Modifiers	MgO	3.5
	CaO	
Fining Agents	SnO_2	0.5
	As_2O_5	<0.01
	Cl	<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

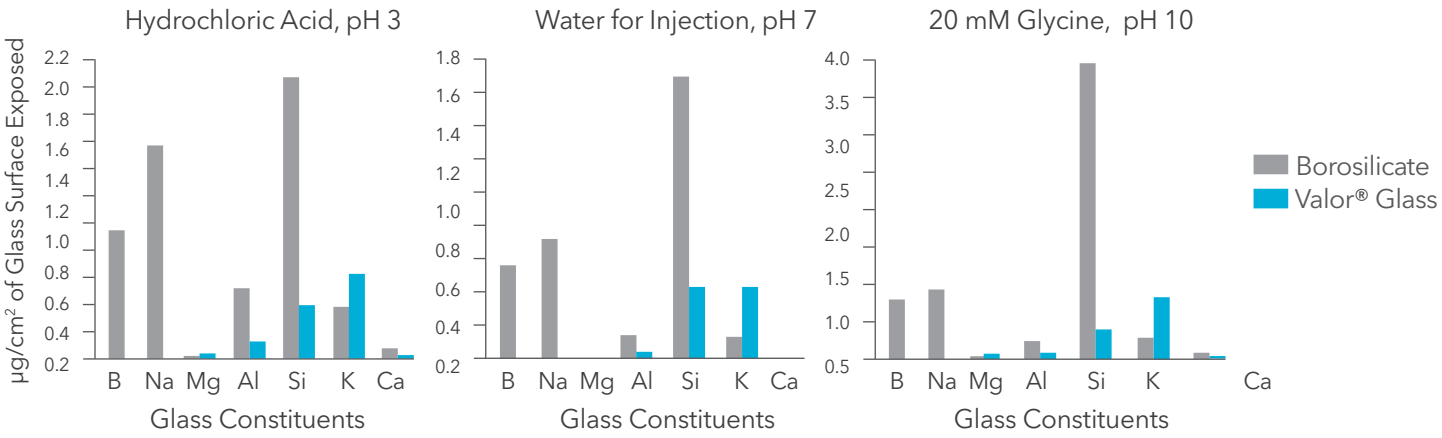
Intentionally added <0.01%

Extractable Concentrations by ICP-MS

Valor Glass exhibits equivalent or better extractable concentrations against a wide range of pHs compared to conventional borosilicate glass.[1]

3 mL containers used during extractable testing underwent a two-minute hot water rinse followed by depyrogenation at 320°C for 60 minutes 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)

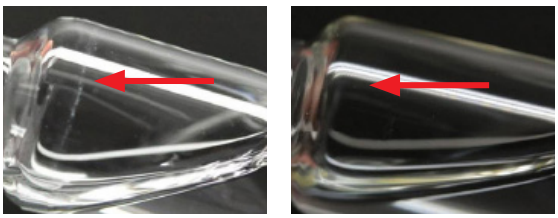


*ICH Q3D Class 1 (Cd, Pb, As, Hg), Class 2A (Co, V, Ni), Class 2B (Ti, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt), Class 3 (Li, Sb, Ba, Mo, Cu, Cr) elements are not added to the glass composition and were below analytical evaluation thresholds.

Internal data on file. https://www.corning.com/media/worldwide/cpt/documents/CPT_Valor_Product_Brochure_V9_102020_FINAL.pdf

Resists Damage

The low COF exterior coating reduces glass particulate generation and enhances machinability. Valor Glass containers have demonstrated up to a 96% reduction in peak particle counts on commercial filling lines, substantially reducing risk of glass particulate contamination. The coating also protects the glass from scratches that lead to cosmetic rejects and strength limiting defects.

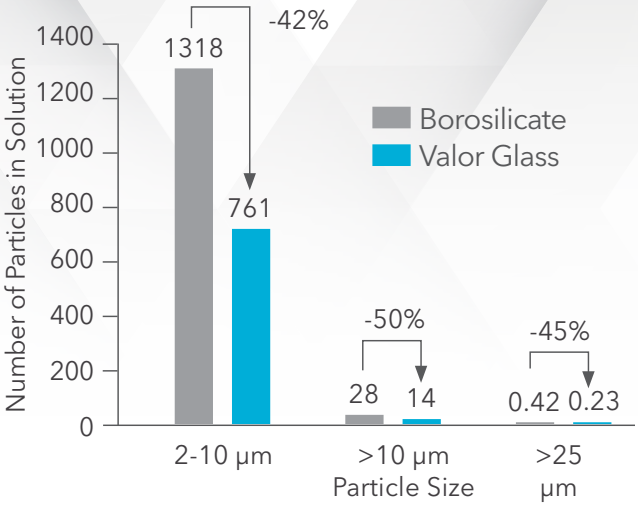


Visible scratches are less evident after pharmaceutical processing with Valor Glass vials (right) compared to conventional borosilicate containers (left)

1. R.A. Schaut, J.S. Peanasky, S.E. DeMartino, and S.L. Schiefelbein (2014). A new glass option for parenteral packaging. PDA Journal of Parenteral Science and Technology, vol. 68, no. 5, pp. 527-534.

Particles in Solution

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

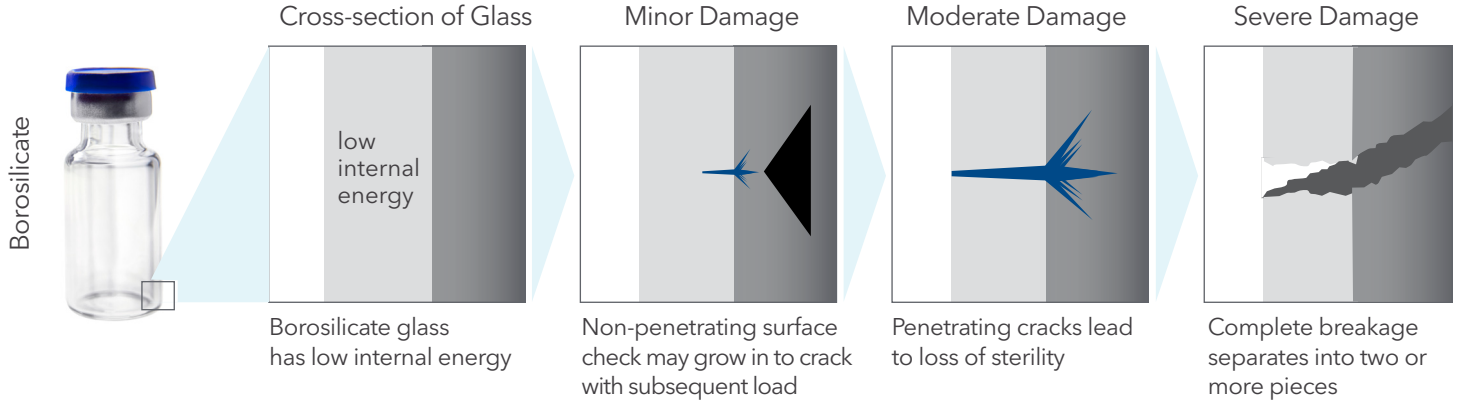


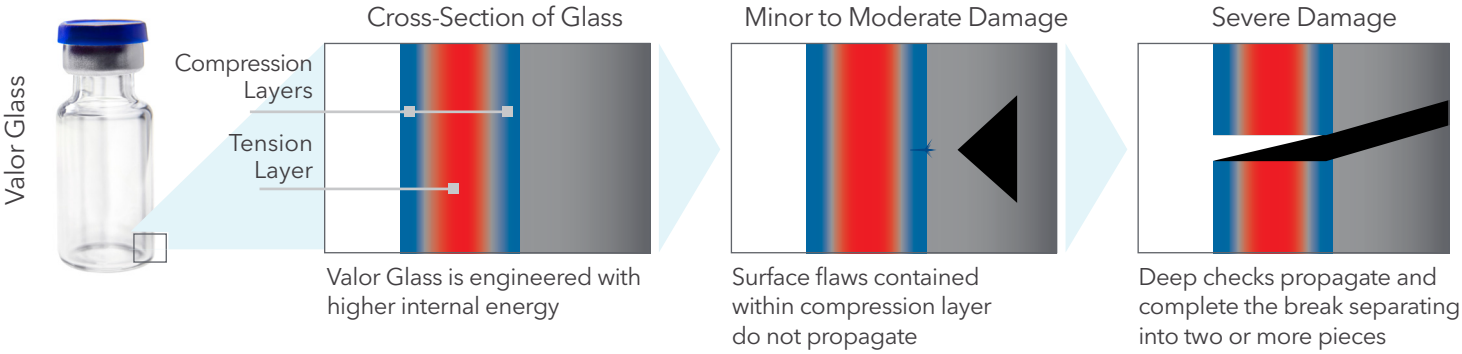
C.L. Timmons, C.Y. Liu, and S. Merkle (2017). Particulate Generation Mechanisms during Bulk Filling and Mitigation via New Glass Vial. PDA Journal of Parenteral Science and Technology, vol. 71, no. 5, pp. 379-392.

Prevents* Cracks

Valor® Glass is engineered with higher internal energy than conventional borosilicate packaging. Damage introduced on filling lines or during shipping can create sub-visible flaws and cracks that can potentially compromise drug product sterility that may result in serious contamination. Valor Glass is uniquely designed to prevent cracks and improve the quality of pharmaceutical packaging bringing a higher level of protection to parenteral drugs and reduces the likelihood of global drug product recalls, supply interruptions, and drug shortages.

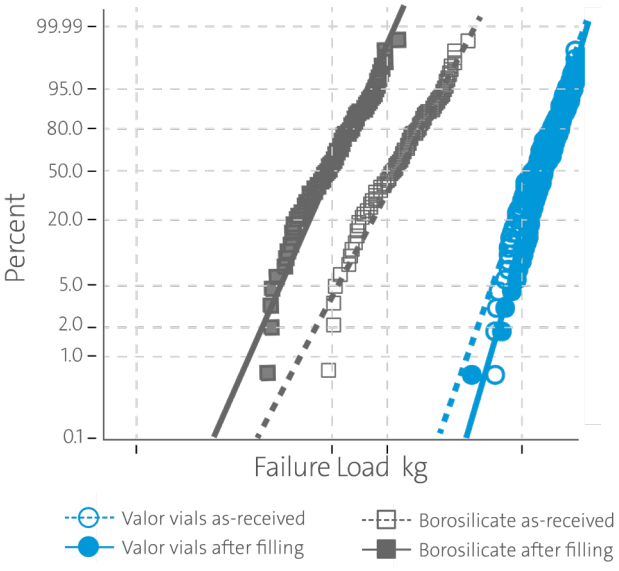
*In laboratory testing, Valor Glass vials provided at least 30x protection against cracks than conventional borosilicate glass vials.





Resists Breakage

Valor packaging is inherently strong and better able to withstand extreme events during pharmaceutical processing and field applications. These robust containers reduce downtime due to glass-related interventions and provide enhanced protection for medicines in the hands of end users. Valor Glass demonstrates strength up to 10 times stronger than conventional borosilicate vials.

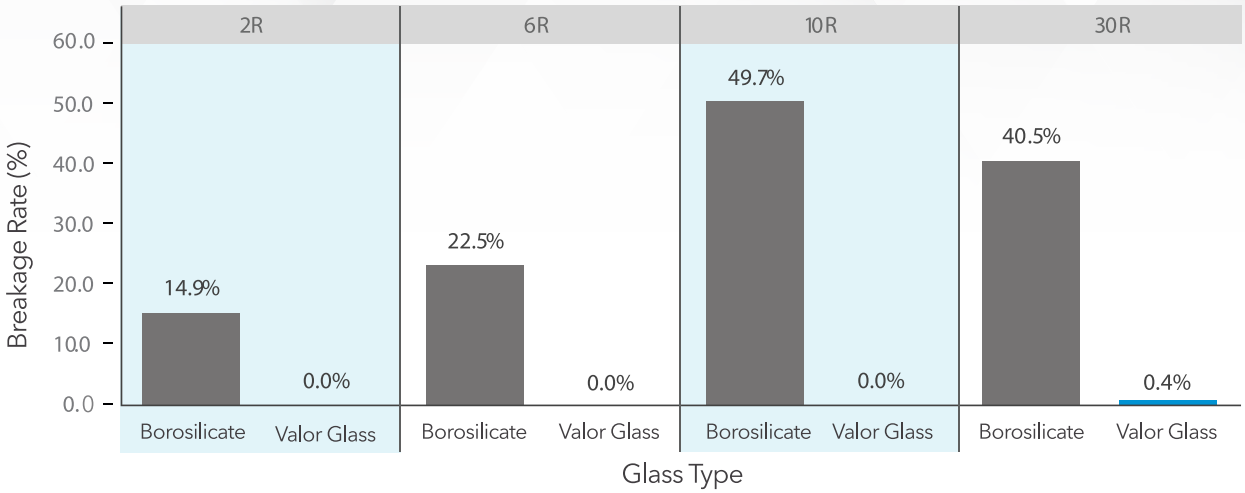


A Robust Container for Challenging Applications

Compared to conventional vials, Valor Vials significantly reduce damage and breakage during low temperature processes such as lyophilization. The chemical strengthening process for Valor Vials imparts compressive stress on the glass surface that typically exceeds the tensile stresses generated in freeze-thaw processes dramatically reducing the potential for breakage.

The advanced parenteral glass packaging technology and low COF exterior surface of Valor® Glass enables the potential for reduced start-to-finish times and improves yields. This may reduce total cost of quality as well as overall manufacturing cost.

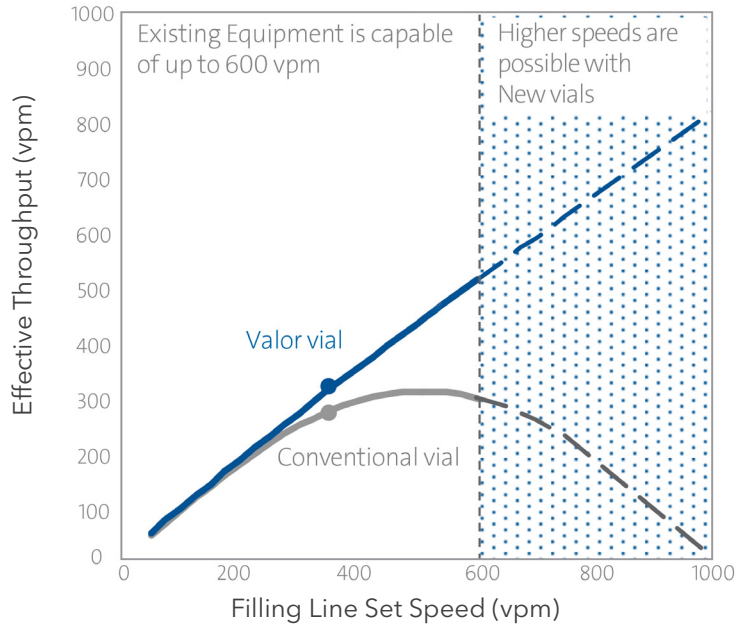
Lab Freeze-thaw Glass Breakage Rate



Freeze-thaw glass breakage rates using aggressive 15% mannitol with 50% fill volumes of 2R, 6R, 10R, 30R borosilicate vials compared to matching Valor containers. Study was conducted at -100°C to room temperature utilizing 1,000 vials/ pedigree.

INCREASED THROUGHPUT POTENTIAL CAN LOWER UNIT FILL COST

Valor Glass' high dimensional consistency, low COF exterior coating, and chemical strengthening enables smoother filling operations on old and new filling lines by reducing glass-related interventions, enabling lines to run at much higher speeds with improved yields.



This immediate increase in efficiency helps maximize the utilization of capital-intensive manufacturing equipment.

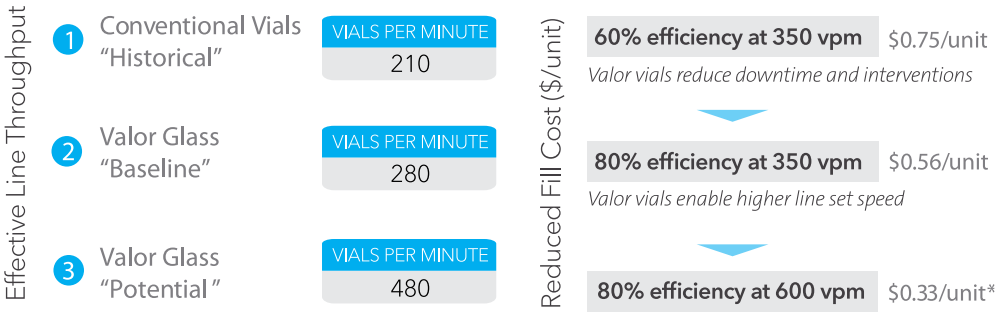
- Reduction or elimination of filling line lubrication
- Less micro-stops and line interventions
- Less rejects

Valor Vials Increase Filling Throughput

Vial friction is a bottleneck when running conventional vials.

The high dimensional consistency and low COF exterior coating of Valor Vials improve bulk filling line efficiency and throughput. Valor Vials can maintain high efficiency (>80%) at higher filling line set speeds.

Valor Vials Can Lower Manufacturing Filling Cost



*Equivalent to $0.42/unit of value.

DIMENSIONAL QUALITY AND SPECIFICATIONS

SKU	2R	6R	10R	20R
Outer Diameter (mm)	16	22	24	30
Wall Thickness (mm)	1	1	1	1.2
Overall Height (mm)	35	40	45	55
Blowback Type	EU	EU	EU	EU
Inner Diameter (mm)	7	12.6	12.6	12.6
Finish (mm)	13	20	20	20
Flange Height (mm)	3.6	3.6	3.6	3.6
Brimful Capacity (mL)	4	10	13.5	26
Weight (g)	4.7	8.5	10	16.5

*Custom formats available upon request.

BEST IN GLASS QUALITY

Fully Controlled and Automated Production Process

Innovative process control monitors the entire state-of-the-art production flow for Valor® Glass through built-in feedback loops and dedicated in-line and in-process inspections.

- Rigorous process control to ensure compliance with specified vial dimensions, cosmetic quality, and functionality
- Valor Vials are manufactured according to ISO 9001 and ISO 15378
- Optimized production process leveraging Six Sigma principles

Visual Quality Inspection

Dimensions

All customer defined critical to quality dimensions are measured on 100% of Valor Vials through industry-leading automated inspection equipment with advanced algorithms determining accept/reject criteria.

Cosmetics

Valor Vials receive 100% automated cosmetic inspection and rejection for converting and coating defects resulting in significantly lower defect rates than sampling-based acceptable quality limits.

Finishing and Packaging

- Fully automated packaging station
- Labeling for traceability

SUSTAINABILITY: ON THE SIDE OF RIGHT

Corning continues to evolve its sustainability programs and policies to demonstrate commitment to positive environmental, social, and governance-related business practices. We are committed to making the world a better place, not only with our innovations, but also with our actions.

We see a future state of pharmaceutical manufacturing that is locally sourced and fully supportive of products that improve patient safety, lower cost, minimize regulatory hurdles and help increase global capacity and access to life saving drugs. By doing so, we're helping to create a sustainable future for the company, the communities where we operate, and the planet we all share.

West READY PACK™
Ready-to-Use Sterile Packaging Solution

ONE PACKAGE, ONE SOURCE, ONE DECISION

Proven vial containment that scales from R&D to Commercial

SEALS

- Maintain CCI with Flip-Off® CCS seals (Clean, Certified, Sterilized)
- Specified low particle level
- Specified low bioburden level before sterilization to meet EMA GMP Annex1 requirements
- Developed for aseptic crimping inside grade A environment
- Available in 13mm and 20mm in red, blue or white

STOPPERS

- NovaPure® stoppers are West's premium line of stoppers, offering the tightest particulate specification for West elastomer products
- FluroTec™ barrier film protects against drug-closure interactions
- Full vision verification to provide consistent high-quality components
- Available in 13mm and 20mm in serum and lyophilization designs

VIALS

- Valor® Glass vials are high-quality, ready-to-use vials for pharmaceutical and biotech drugs.
- Available in a SG EZ-fill® Technology Tray and Nest & Tub formats.
- Available in 2R, 6R, 10R & 20R ISO vial sizes.

For Development & Small-Scale Manufacturing Valor® Glass Ready Pack Offering

Vial Size	Vial Finish	Ready-To-Use Tray Format (Vials/Carton)	Ready-To-Use Nest & Tub Format (Vials/Carton)
2R	13mm	2,280	1,800
6R	20mm	960	720
10R	20mm	960	720
20R	20mm	600	216

For Line Trials & Commercial Manufacturing Valor® Glass Pallet Offering

Vial Size	Vial Finish	Non-Sterile Bulk Tray Format (Vials/Pallet)	Ready-To-Use Tray Format (Vials/Pallet)	Ready-To-Use Nest & Tub Format (Vials/Pallet)
2R	13mm	86,000	45,600	36,000
6R	20mm	54,250	19,200	14,400
10R	20mm	38,280	19,200	14,400
20R	20mm	23,000	12,000	4,320

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