



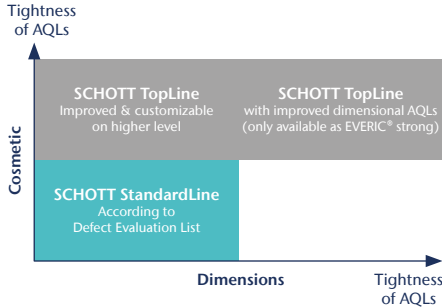
# Core Vials in StandardLine quality – setting the industry standard











To secure patient safety, the requirements for pharmaceutical glass vials are high, especially for parenteral applications:

- Dimensional inaccuracies can lead to difficulties during filling or even put container closure integrity at risk
- Cosmetic properties are highly relevant for inspectability and imperfections may result in high reject rates during fill-and-finish
- Chemical resistance is crucial to keep drug-container interaction at a minimum

**SCHOTT Pharma Core Vials in StandardLine quality** offer cosmetic AQLs\* that, at their minimum, match the requirements of the current Defect Evaluation List as the most relevant industry standard. Defects are also aligned with the relevant PDA Technical Reports.



 Type I Borosilicate Glass with high chemical resistance according to ISO 8362-2	 Manufactured according to cGMP regulations	 Unlimited shelf life for glass**
 Compliant with all current standards such as Ph. Eur., USP and CP	 Tight dimensional control	 SCHOTT FIOLAX® clear or amber glass tubing
 Formats according to current version of ISO 8362-1	 Tight cosmetic control	

✓  
**High chemical resistance**  
due to excellent raw material and converting expertise

✓  
**Efficient fill-and-finish and secure CCI** thanks to accurate dimensions

✓  
**Low reject rate and excellent inspectability** due to high cosmetic quality

\* AQL = Acceptable Quality Level. Indicates how high the maximum proportion of a defective subset can be that is considered acceptable quality in a sample.  
\*\* limitations may come from secondary packaging.

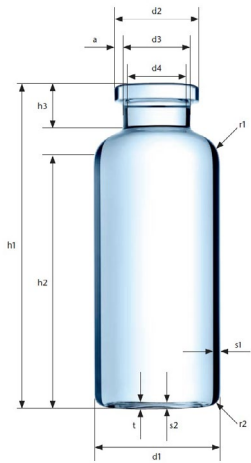


## Release tests

### Dimensions

Defined parameters in drawing determine testing

- In-line inspection
  - 100% by camera/sensor
  - Defined standard parameters: neck outer diameter, collar outer diameter, collar height, neck and collar height, total height, bottom depth, inner neck diameter
  - Plus additional optional parameters (e.g. collar radius, shoulder angle)
- Statistical off-line inspection
  - Minimum inspection level S-4 (according to ISO 2859-1)
  - Standardized global test methods based on off-line camera, profile projector, caliper, etc.
  - Defined standard parameters (e.g. outer diameter, bottom thickness, outer heel radius)
  - Additional optional parameters



**ISO 8362-1**  
Dimensions,  
brimful capacity  
and mass

Size designation of injection vial	Overflow capacity ml	a mm	d1 mm	d2 mm	d3 mm	d4 mm	h1 mm		h2 mm	h3 mm	r1 mm	r2 mm	s1 mm		s2 mm	t mm	Mass g	
							Tol	min.					Tol	min.				
2R	4						35		22								4.4	
3R	5		16	±0.15	13	10.5	7	40	27	8	2.5	1.5			0.6		5.5	
4R	6	±0.5						45	32								5.7	
6R	10			22				40	±0.5	26		±0.5				0.7	7.9	
8R	11.5			±0.2		16.5		45		31			2				8.7	
10R	13.5		24					45		30							9.5	
15R	19	±1						60		45					0.7		12.0	
20R	26				20		12.6	55		35							16.2	
25R	32.5	±1.5	1.5	30	±0.25			65	±0.7	45			5.5	2.5	1.2	±0.05	1	18.9
30R	37.5					17.5		75		55	10	±0.75					21.9	
50R	62	±4	2.5	40	±0.4			73		49			6	4	1.5		34.5	
100R	123	±7	3.5	47	±0.5			100	±0.75	75			6.5	1.7	±0.07	0.9	1.5	60

### Chemical

- Hydrolytic resistance surface testing according to Pharmacopoeias (USP, Ph. Eur.) and ISO 4802-2

## A global manufacturing network paired with outstanding hot forming experience and continuous strive for innovation

- Advancing the industry with groundbreaking glass innovations such as borosilicate glass for over 130 years
- Fueling science and inspiring progress in hot forming with dedicated experts
- Providing customers with state-of-the-art quality and inspection technologies
- Offering supply security for the entire value chain due to vertical integration with the leading borosilicate tubing manufacturer



General ordering information												
Quality level	StandardLine											
Neck finish	Crimp*											
Packaging	Tray with optional divider											
Blowbacks	Non-blowback, European blowback*											
Palletizing	A standard Euro Pallet (1200 x 800 mm) contains 15–27 layers of 9 trays each											
Formats	2R	3R	4R	6R	8R	10R	15R	20R	25R	30R	50R	100R
Pieces per tray	344	344	344	186	186	154	154	95	95	95	40	35

\* other finishes available upon request

[schott-pharma.com/vials](http://schott-pharma.com/vials)

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