



# 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

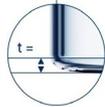
- In-line inspection
  - 100 % by camera/sensor
  - Defined standard parameters: neck outer diameter, collar outer diameter, collar height, neck and collar height, total height, bottom depth, inner neck diameter
  - Plus additional optional parameters (e.g. collar radius, shoulder angle)
- Statistical 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

## Chemical

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



Size designation of injection vial	Overflow capacity ml		a mm	d1 mm		d2 mm +0.2 -0.3	d3 mm max.	d4 mm ±0.2	h1 mm		h2 mm min.	h3 mm		r1 mm ≈	r2 mm ≈	s1 mm		s2 mm min.	t mm max.	Mass g ≈	
		Tol			Tol					Tol			Tol				Tol				
2R	4								35		22										4.4
3R	5		1	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	8.5	±0.5	3.5		1	±0.04		0.7		7.9
8R	11.5		1.2		±0.2		16.5		45		31				2						8.7
10R	13.5			24					45		30			4							9.5
15R	19	±1							60		45	9						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	±0.07	0.9	1.5		34.5
100R	123	±7	3.5	47	±0.5				100	±0.75	75			6.5	4	1.7					60



### ISO 8362-1

Dimensions, brimful capacity and mass

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



Providing customers with state-of-the-art quality and inspection technologies



Fueling science and inspiring progress in hot forming with dedicated experts



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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