



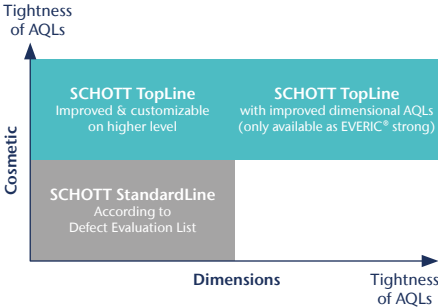
Core Vials in TopLine quality – beyond the industry standard



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 TopLine quality offer tighter cosmetic and dimensional AQLs* than regular vials. Further customization is possible upon request.



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 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

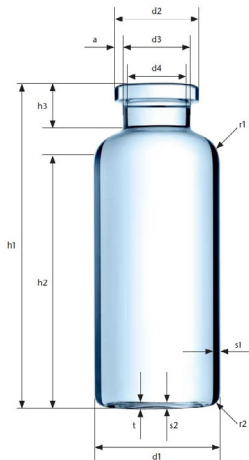
Cosmetics

- 100% inline inspection



Chemical

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



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.	min.	min.	Tol	min.	Tol	min.	Tol	min.	Tol	min.				
2R	4						35		22													4.4
3R	5						40		27	8			2.5	1.5						0.6		5.5
4R	6	±0.5					45		32													5.7
6R	10						40	±0.5	26		8.5	±0.5	3.5				1	±0.04			0.7	7.9
8R	11.5		22				45		31						2							8.7
10R	13.5			±0.2		16.5	45		30													9.5
15R	19	±1	24				60		45		9		4							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

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	TopLine												
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

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