



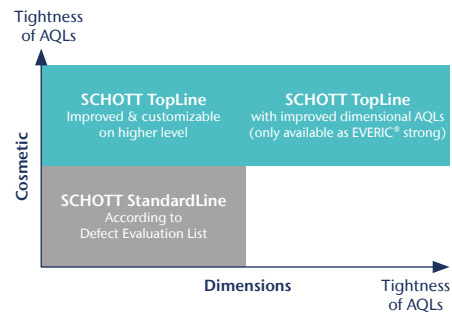
TopLine vials – beyond the industry standard



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 **TopLine vials** 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



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
2R	4						35	22							4.4
3R	5	1	16	±0.15	13	10.5	7	40	27	8				0.6	5.5
4R	6	±0.5					45	32							5.7
6R	10		22				40	±0.5	26					0.7	7.9
8R	11.5	1.2		±0.2	16.5		45		31	8.5					8.7
10R	13.5		24				45		30		2				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					1	18.9
30R	37.5					17.5	75		55	10					21.9
50R	62	±4	2.5	40	±0.4		73		49						34.5
100R	123	±7	3.5	47	±0.5		100	±0.75	75					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 competence centers

- 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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PHARMA

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