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 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.

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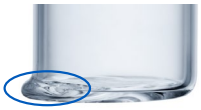
Release tests

Dimensions
Defined parameters in drawing determine testing

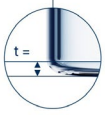
- In-line inspection
  - 100 % by camera/sensor
  - Defined standard parameters: neck outer diameter, collar outer diameter, collar height, neck and collar height, total height, bottom depth, inner neck diameter
  - Plus additional optional parameters (e.g. collar radius, shoulder angle)
- Statistical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

Size designation of injection vial	Overflow capacity ml	Tol	a mm	d1 mm	Tol	d2 mm +0.2 −0.3	d3 mm max.	d4 mm ±0.2	h1 mm	Tol	h2 mm min.	h3 mm	Tol	r1 mm ≈	r2 mm ≈	s1 mm	Tol	s2 mm min.	t mm max.	Mass g ≈
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	±1		24					45		30	9		4						9.5
15R	19								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	±0.75	49			6	4	1.5	±0.07	0.9	1.5	34.5
100R	123	±7	3.5	47	±0.5				100		75			6.5		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 technologiesologies

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	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

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