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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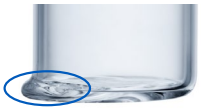
Release tests

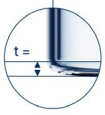
Dimensions
Defined parameters in drawing determine testing

- 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				0.7		9.5
15R	19								60		45									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
- Fueling science and inspiring progress in hot forming with dedicated experts
- Providing customers with state-of-the-art quality and inspection technologiesologies
- 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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