

# StandardLine cartridges – setting the industry standard



## To secure patient safety, the requirements for pharmaceutical glass cartridges 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 **StandardLine cartridges** 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.



Tightnes of AQLs



Type I borosilicate glass with high chemical resistance according to pen ISO 13926-1 and dental ISO 11040-1



Compliant with all current standards such as Ph. Eur.,



Formats according to pen ISO 13926-1 and dental ISO 11040-1

USP and CP



Manufactured according to cGMP regulations



Tight dimensional control



Tight cosmetic control



Unlimited shelf life for glass\*\*

SCHOTT FIOLAX® clear glass tubing

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

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\* 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.

### SCHOTT PHARMA

#### **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



Lengths I1 and I2 shall be agreed upon between manufacturer and customer.

Application & filling volumes: ISO and customizable format		Tubing OD d1 mm		Tubing ID d2 mm		d3 d4 nin nm mm		d5 mm		d6 mm		h1 mm		h2 mm	
		Tol		Tol			Tol		Tol		Tol		Tol		Tol
Pen: 0.6-1.5 ml (ISO)/Dent: 1.8-2.2 ml (ISO)	8.65		6.85		6.55										
Double-Chamber 0.1–1.0 ml/Pen. (ISO)	10.75		8.65		8.3										
Pen/Autoinj. Typ: 3.0 ml (ISO)	10.85	±0.1	8.65	±0.09	8.35	7.15		5.5	±0.25	3.15					±0.1
Pen/Autoinj. Typ: 1.6 ml (ISO)	10.95		9.25		8.95							5.0		2.9	
Pen/Autoinj. Typ: 3.0 ml (ISO)	11.6		9.7		9.35		±0.2				+0.2	3.0	±0.2	2.9	
Pen/Autoinj. Typ: 3.0-5.0 ml	14.0	+0.11	12.0	.0.1	11.65		±0.2	7.2			±0.2				
Pen/Autoinj. Typ: 3.0-5.0 ml	14.45		11.85 ±0.1	11.5	9.5		7.75	±0.35	4.5					±0.15	
Pen/Autoinj. Typ: 3.0-10.0 ml	17.05	±0.17	14.25		13.9			1.75							
Pen/Autoinj. Typ: 3.0–10.0 ml	18.25	±0.13	16.05	±0.15	15.5	12.0	0	11.0		7.0		8.0		2.6	±0.2
Wearable Device 3.0-10.0 ml	22.05	±0.17	19.05		18.55	13.0			max.				±0.5	3.6	

## SCHOTT Pharma offers a global manufacturing network paired with outstanding hot forming experience and a continuous drive for innovation

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- 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

HARM

General ordering information							
Quality level	StandardLine						
Neck finish	Crimp						
Packaging	Тгау						
Blowbacks	Non-blowback						
Palletizing	A standard Euro Pallet (1200 x 800 mm) contains 17–18 layers of 18 trays each						
Formats	1.5 ml	1.8 ml	3.0 ml				
Pieces per tray	344	344	344				

schott-pharma.com/cartridges

carbon neutral