

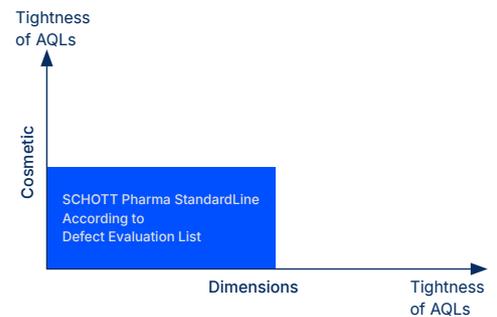


Core Ampoules in StandardLine quality

Pharmaceutical ampoules always in line with evolving industry standards



- Dimensional inaccuracies can lead to difficulties during filling or put container closure integrity at risk.
- Cosmetic properties are highly relevant to inspectability and may lead to high reject rates during fill-and-finish.
- Chemical resistance is crucial to keep drug-container interactions at a minimum.
- To deal with high pharmaceutical requirements and to secure patient safety, SCHOTT Pharma Core Ampoules offer cosmetic AQLs* according to the current Defect Evaluation List (the most relevant industry standard) and are aligned with the PDA technical report.



Type I Borosilicate Glass with high chemical resistance acc. to ISO 9187-1 standard



Manufactured according to cGMP



Unlimited shelf life for glass**



Compliant with all current standards, such as Ph. Eur., USP, and CP



Tight dimensional control



Uses SCHOTT FIOLAX® clear or amber*** glass tubing



Formats according to current version of ISO 9187-1, including forms B, C and D



Tight cosmetic control



Break-systems: One-point-cut (OPC), easyOPC, or Score-ring (SCR) recommended

High chemical resistance

Made with SCHOTT FIOLAX® Type I Borosilicate Glass to keep drug-container interaction to a minimum.

Efficient fill-and-finish

Tight tolerances ensure high container closure integrity for fill-and-finish.

Low reject rate

High cosmetic quality provides a low reject rate and high inspectability.

* Acceptance quality level: Statistical measurement of the maximum acceptable number of defective goods in a particular sample size.

** Limitations may come from secondary packaging

*** For further details on SCHOTT FIOLAX®, see tubing data sheet

Release tests

Dimensions

Defined parameters in drawing determine testing

In-line inspection

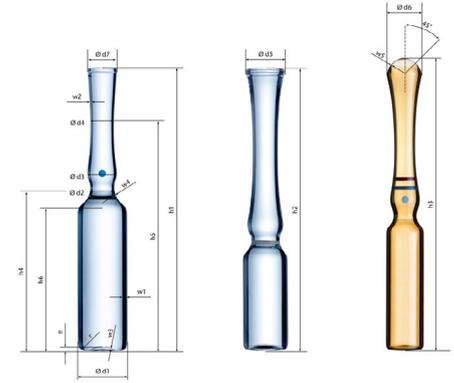
- 100 % by camera/sensor
- Defined standard parameters: total length, stem eccentricity, bulb diameter, stem diameter, stem diameter at sealing point, constriction diameter
- Other parameters include: bottom, OPC dot diameter, color break ring width, coding ring width

Statistical off-line inspection

- Minimum inspection level S-4, according to ISO 9178-1 standard
- Standardized global test methods based on different quality aspects, such as off-line camera, profile projector, caliper
- Defined standard parameters, such as breakforce, bottom radius, head wall thickness, constriction wall thickness

ISO 9187-1

Dimensions, brimful



OPC One Point Cut	OPC & easyOPC – ISO 9187-2		
	1 ml – 3 ml	24–65 N	24–45 N
	5 ml	30–70 N	30–60 N
	10 ml – 30 ml	30–80 N	30–65 N*

SCO Scoring	Breakforce SCO & CBR – ISO 9187-1		CBR Color Break Ring
	1 ml – 5 ml	30–80 N	
	10 ml	30–90 N	
	20 ml – 30 ml	30–100 N	

* available from 1–20 ml

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

Verifications: A global manufacturing network paired with outstanding hot forming experience and a continuous drive for innovation

For 130 years we have advanced the world of glass with groundbreaking innovations such as Borosilicate Glass

We fuel science and inspire progress in hot forming with dedicated competence centers

We offer supply security along the entire value chain thanks to vertical integration with the leading borosilicate tubing manufacturer

Our global manufacturing footprint with 16 production sites shares equivalent quality standards and ensures global supply chain resilience

More than 250 production patents prove our continuous innovation and improvement

We provide our customers with state-of-the-art quality and inspection technologies

General ordering information								
Quality level	StandardLine							
Form	B, C and D*							
Break-system	OPC or easyOPC, SCO**							
Optional painting	More than 10 colors available for ID rings, OPC dot, text or logos							
Packaging	Tray, optionally ETO treated (for D-Ampoules out of Mexico)							
Palletizing*	A standard Euro pallet (1,200 x 800 mm) contains 7–17 layers of 12 trays each							
Formats	1 ml	2 ml	3 ml	5 ml	10 ml	20 ml	25 ml	30 ml
Pieces per tray*	525	525	377	275	189	144	116	224

* Contact us for more information regarding ISO dimensions

** CBR available upon request

Many standard ampoules configurations are available.

Contact your local sales representative for more information.

schott-pharma.com/ampoules

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