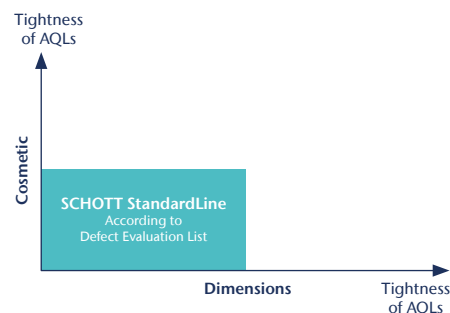


StandardLine Ampoules

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 standards and to secure patient safety, SCHOTT StandardLine Ampoules offer the minimum cosmetic AQLs* according to the current Defect Evaluation List (the most relevant industry standard) and are aligned with the current 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-cust (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

**SCHOTT
PHARMA**

Release tests

Dimensions

Defined parameters in drawing determine testing

In-line inspection

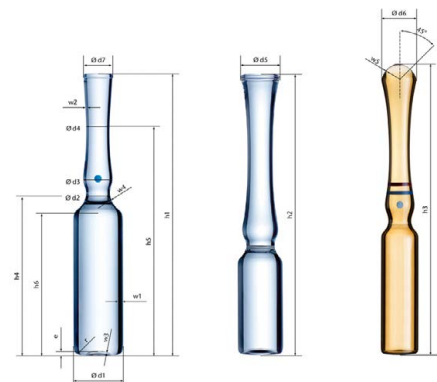
- 100% by camera/sensor
- Defined standard parameters: total length, stem eccentricity bulb diameter, stem diameter, stem diameter at sealing point, constriction diameter
- Other parameters include: bottom, OPC dot diameter, color break ring width, coding ring width

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 break-force, bottom radius, head wall thickness, constriction wall thickness

ISO 9187-1

Dimensions, brimful



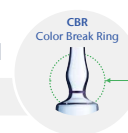
OPC and easyOPC – ISO 9187-2

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*




Breakforce SCO & CBR – ISO 9187-1

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 sterilized (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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