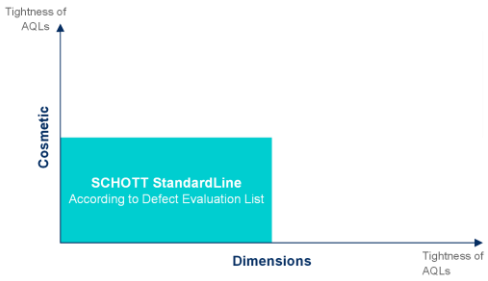
StandardLine Ampoules

Datasheet

StandardLine Ampoules – Always in line with evolving industry standard

- dimensional inaccuracies can lead to difficulties during filing or put container closure integrity at risk
- cosmetic properties are of high relevance for inspectability and might lead to high reject rates during fill-and-finish
- chemical resistance is crucial to keep the drug-container interactions at a minimum
- To deal with the high pharmaceutical standards, and to secure patient safety, SCHOTT StandardLine Ampoules offer cosmetic AQLs* at minimum according to current Defect Evaluation List as most relevant industry standard, also aligned with current PDA Technical Report



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

Manufactured acc. to cGMP

Unlimited shelf life for glass**

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

Tight dimensional control

SCHOTT FIOLAX® clear or amber*** glass tubing

Formats according to current version of ISO 9187-1 (incl. form B, C and D

Tight cosmetic control

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

High chemical resistance

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

Efficient fill-and-finish

Tight tolerances ensure an fill-and-finish process with high container closure integrity

Low reject rate

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

SCHOTT PHARMA

Release Tests:

Dimensions:
Defined parameters in drawing determine testing

In-line inspection:

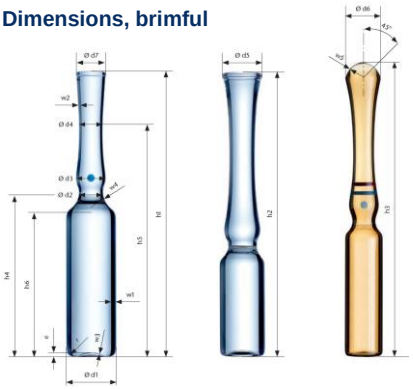
- 100% by camera/ sensor
- Defined standard parameters: total length, stem eccentricity bulb diameter, steam diameter, steam diameter at sealing point, constriction diameter
- Other parameters possible: bottom, OPC dot diameter, color break ring width, coding ring width

Statistical off-line inspection:

- Inspection level S-4 is minimum (according ISO 9178-1)
- Standardized global test methods based with different quality aspects e.g. off-line camera, profile projector, caliper
- Defined standard parameters (e.g. break-force, bottom radius, head wall thickness, constriction wall thickness)

ISO 9187-1

Dimensions, brimful



OPC and easyOPC - ISO 9187-2

1ml – 3ml	24 – 65N	24 – 45N
5ml	30 – 70N	30 – 60N
10ml – 30ml	30 – 80N	30 – 65N*

Breakforce SCO & CBR - ISO 9187-1

1ml – 5ml	30 – 80N
10ml	30 – 90N
20ml – 30ml	30 – 100N

*available from 1-20ml

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 continuous strive for innovation

- Since 130 years we advance the world with groundbreaking glass innovations like Borosilicate Glass
- We fuel science and inspire progress in hot forming with dedicated competence centers
- We offer supply security along entire value chain due 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 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 (1200 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

Many Standard Ampoules configurations are available.

Contact your sales representative for more information.

*Contact us for more information regarding ISO dimensions
**CBR available upon request

FIND OUT MORE:
www.schott-pharma.com/ampoules

SCHOTT PHARMA