

Стеклянные ампулы StandardLine, easyOPC, AC

Технические характеристики

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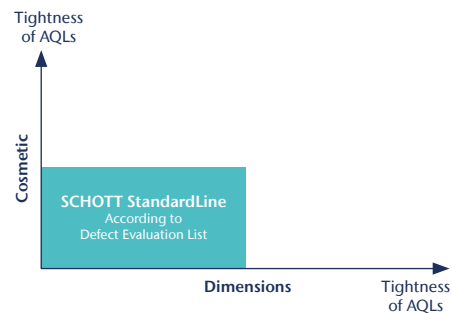


Ampoules easyOPC

Pharmaceutical glass ampoules for safe and easy opening



- 89% of health care professionals have difficulties in opening ampoules, which could generate more than €1 bn in costs for the pharmaceutical industry.
- SCHOTT Pharma's Ampoules easyOPC use StandardLine Ampoules, which undergo a further production process that adds a reduced break force range (from 2–65 N, depending on format) while eliminating deviations.
- Ampoules easyOPC have an AQL* of 0.01 for pharmaceutical companies and 50 ppm** in the product lot as an addition to the StandardLine specification for break-force defect.



Particle loss can be reduced up to 60% when combined with the correct opening technique



Reduction in unbreakable ampoules resulting in less market complaints



Even tighter and more consistent break force than OPC



Safe and easy opening reduces the risk of injury at point of use



Decreased time to market since no requirement to change registration files



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



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



Tight dimensional control



Tight cosmetic control

Improved Total Cost of Ownership

Decreased quality costs due to reduced broken glass ampoules and complaints from the end user

Safe and easy administration

Protects the medicine inside while lowering the risk of injury to nurses and doctors

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

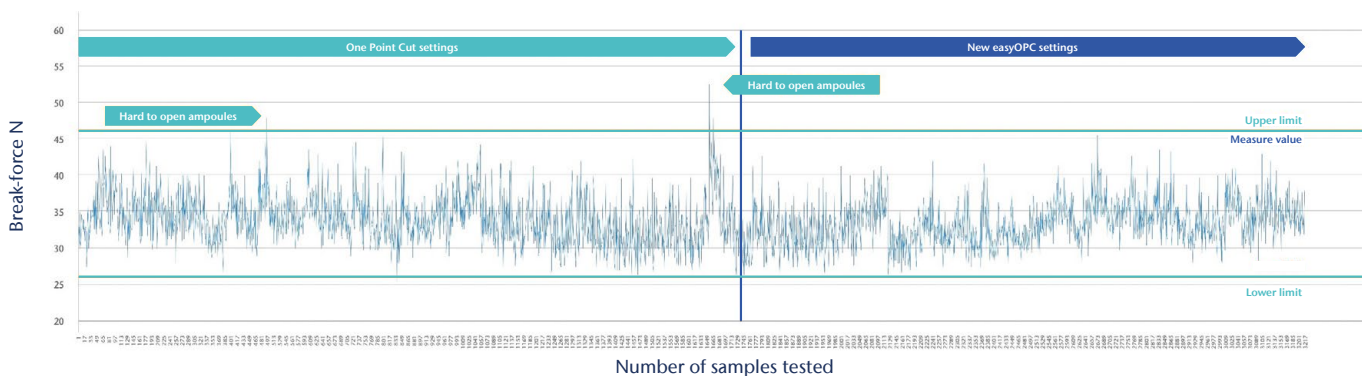
** Pieces per million

*** For further details on SCHOTT Fiolax®, see Tubing data sheet

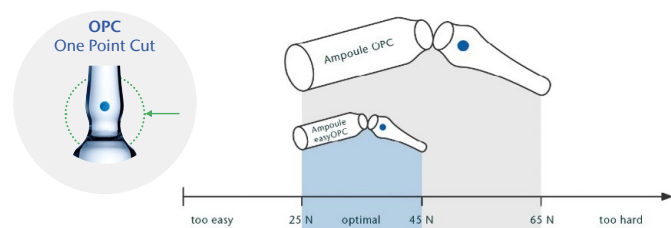
Break-force measurements

Comparison between Ampoules easyOPC and standard OPC ampoules

Reference range: 26–46 N/Ampoule 1 ml Form C



Improved ISO 9187-2



| Ampoules size | OPC ISO 9187-2 | easyOPC |
|---------------|----------------|----------|
| 1 ml – 3 ml | 24–65 N | 24–45 N |
| 5 ml | 30–70 N | 30–60 N |
| 10 ml – 20 ml | 30–80 N | 30–65 N |
| Quality | | |
| | | AQL: 0.4 |
| | | 50 ppm |

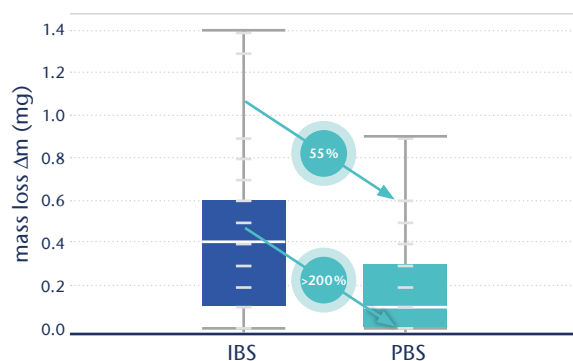
Particle reduction

Comparison between state-of-the-art and incorrect opening with OPC break-force system. Best break system combined with state-of-the-art opening technique reduces mean load of particles up to 60%.

Mass loss for 2 ml ampoules

IBS* max. particles 1.4 mg > PBS** max particles 0.9 mg
 IBS mean particles ~ 0.4 mg > PBS mean particles 0.17 mg

* IBS: Improper break system
 ** PBS: Proper break system



General ordering information

| | | | | | | |
|-------------------|---|------|------|------|-------|-------|
| Quality level | StandardLine | | | | | |
| Form | B, C and D | | | | | |
| Break-system | easyOPC | | | | | |
| Optional painting | More than 10 colors available for OPC dot, text or logos | | | | | |
| Packaging | Tray | | | | | |
| 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 |
| Pieces per tray* | 525 | 525 | 377 | 275 | 189 | 144 |

* Configuration of packaging and/or palletizing can deviate based on local conditions

Many standard ampoules configurations are available.

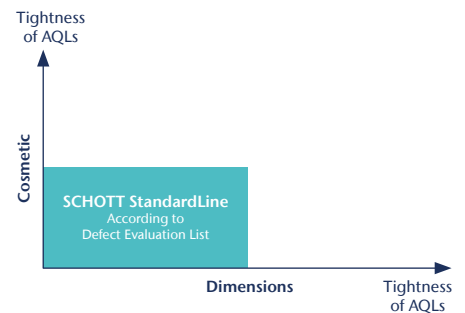
Contact your local sales representative for more information.

Ampoules Anti-Counterfeiting (AC)

Pharmaceutical glass ampoules for effective protection against drug counterfeiting



- Reports from the World Health Organization (WHO) state that 10% of all drugs sold worldwide could be counterfeits.
- SCHOTT Pharma's Ampoules Anti-Counterfeiting (AC) provide pharmaceutical companies with a powerful tool against counterfeiting, as well as protection for patient health.
- Ampoules AC are printed with an ink containing light-emitting particles in the shape of identification rings, OPC dots, and/or printed text. Only visible with a special reader, these markings ensure the drug's authenticity.
- To deal with the 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.



Ensures the legitimacy and correct dosage of active ingredients



Secure the protection of intellectual property



Safeguards your reputation with tamper-proof containers



Decreased time to market since no requirement to change registration files



Uses SCHOTT FIOLAX® clear or amber** glass tubing



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



Tight cosmetic control



Tight dimensional control



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

Improved Total Cost of Ownership

Guarantee the protection of reputation and revenue by preventing drug tainting

Protection of intellectual property

Create a unique proof of authenticity with the special ink used in identification rings, OPC dots, and labelled text

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

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

General ordering information

| | | | | | | | | | |
|--------------------|---|------|------|------|-------|-------|-------|-------|--|
| Quality level | StandardLine | | | | | | | | |
| Form | B, C and D* | | | | | | | | |
| Format | 1–30 ml | | | | | | | | |
| Break-system | OPC or easyOPC, SCO** | | | | | | | | |
| Optional painting | More than 10 colors available for ID rings, OPC dot, text or logos | | | | | | | | |
| Packaging | Tray | | | | | | | | |
| 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

*** Configuration of packaging and/or palletizing can deviate based on local conditions

Many standard ampoules configurations are available.

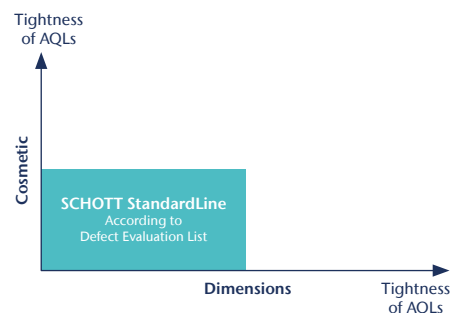
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StandardLine Ampoules

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

Release tests

Dimensions

Defined parameters in drawing determine testing

In-line inspection

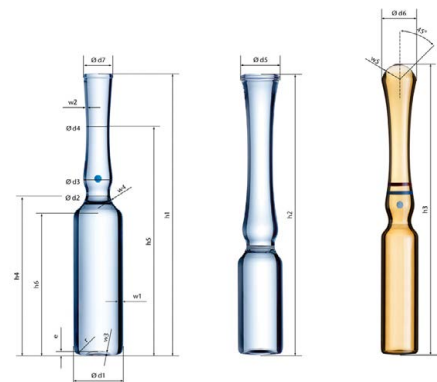
- 100% by camera/sensor
- Defined standard parameters: total length, stem eccentricity bulb diameter, stem diameter, stem diameter at sealing point, constriction diameter
- Other parameters include: bottom, OPC dot diameter, color break ring width, coding ring width

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 to 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
-  Our global manufacturing footprint with 16 production sites shares equivalent quality standards and ensures global supply chain resilience
-  We fuel science and inspire progress in hot forming with dedicated competence centers
-  More than 250 production patents prove our continuous innovation and improvement
-  We offer supply security along the entire value chain thanks to vertical integration with the leading borosilicate tubing manufacturer
-  We provide our customers with state-of-the-art quality and inspection technologies

General ordering information

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|-------------------|---|------|------|------|-------|-------|-------|-------|
| 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 |

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** CBR available upon request

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