

Фармацевтические лиофилизированные флаконы TopLyо, EVERIC, Type I plus Технические характеристики

По вопросам продаж и поддержки обращайтесь:

Алматы (727)345-47-04
Ангарск (3955)60-70-56
Архангельск (8182)63-90-72
Астрахань (8512)99-46-04
Барнаул (3852)73-04-60
Белгород (4722)40-23-64
Благовещенск (4162)22-76-07
Брянск (4832)59-03-52
Владивосток (423)249-28-31
Владикавказ (8672)28-90-48
Владимир (4922)49-43-18
Волгоград (844)278-03-48
Вологда (8172)26-41-59
Воронеж (473)204-51-73
Екатеринбург (343)384-55-89

Иваново (4932)77-34-06
Ижевск (3412)26-03-58
Иркутск (395)279-98-46
Казань (843)206-01-48
Калининград (4012)72-03-81
Калуга (4842)92-23-67
Кемерово (3842)65-04-62
Киров (8332)68-02-04
Коломна (4966)23-41-49
Кострома (4942)77-07-48
Краснодар (861)203-40-90
Красноярск (391)204-63-61
Курск (4712)77-13-04
Курган (3522)50-90-47
Липецк (4742)52-20-81

Магнитогорск (3519)55-03-13
Москва (495)268-04-70
Мурманск (8152)59-64-93
Набережные Челны (8552)20-53-41
Нижний Новгород (831)429-08-12
Новокузнецк (3843)20-46-81
Ноябрьск (3496)41-32-12
Новосибирск (383)227-86-73
Омск (3812)21-46-40
Орел (4862)44-53-42
Оренбург (3532)37-68-04
Пенза (8412)22-31-16
Петрозаводск (8142)55-98-37
Псков (8112)59-10-37
Пермь (342)205-81-47

Ростов-на-Дону (863)308-18-15
Рязань (4912)46-61-64
Самара (846)206-03-16
Санкт-Петербург (812)309-46-40
Саратов (845)249-38-78
Севастополь (8692)22-31-93
Саранск (8342)22-96-24
Симферополь (3652)67-13-56
Смоленск (4812)29-41-54
Сочи (862)225-72-31
Ставрополь (8652)20-65-13
Сургут (3462)77-98-35
Сыктывкар (8212)25-95-17
Тамбов (4752)50-40-97
Тверь (4822)63-31-35

Тольятти (8482)63-91-07
Томск (3822)98-41-53
Тула (4872)33-79-87
Тюмень (3452)66-21-18
Ульяновск (8422)24-23-59
Улан-Удэ (3012)59-97-51
Уфа (347)229-48-12
Хабаровск (4212)92-98-04
Чебоксары (8352)28-53-07
Челябинск (351)202-03-61
Череповец (8202)49-02-64
Чита (3022)38-34-83
Якутск (4112)23-90-97
Ярославль (4852)69-52-93

Россия +7(495)268-04-70

Казахстан +(727)345-47-04

Беларусь +(375)257-127-884

Узбекистан +998(71)205-18-59

Киргизия +996(312)96-26-47

эл.почта: sqh@nt-rt.ru || сайт: <https://schott.nt-rt.ru/>

SCHOTT TopLyo®

Pharmaceutical glass vial with hydrophobic coating to avoid fogging



- For stability reasons, more than 50% of all biologic drugs are lyophilized.
- Fogging is a widely known undesirable phenomenon that occurs during lyophilization, which results in elevated levels of rejects.
- Overfilling vials to compensate for drug loss through unsatisfactory residual emptying after reconstitution leads to higher costs.
- SCHOTT TopLyo® is unique in combining hydrophobic behavior and the avoidance of free silicone.
- Inner coating is applied using patented and proven plasma impulse chemical vapor deposition (PICVD) technology.
- An additional “release criterion” has been specifically developed.



Si-O-C-H layer applied via PICVD



Layer thickness of ~ 40 nm



Long-term layer stability



Coating bonds covalently to the glass substrate



Suitable for depyrogenation



Dense coating (i. e. non-porous)



Contact angle for water > 90° (hydrophobic surface without silicone)



Stable after washing process



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

No fogging

Particularly suitable for antibody drug conjugates (ADCs) thanks to hydrophobic inner surface

Elegant lyo cake

Reduced rejects due to improved lyo cake aesthetics

Improved emptying

Less residual volume so no overfilling necessary

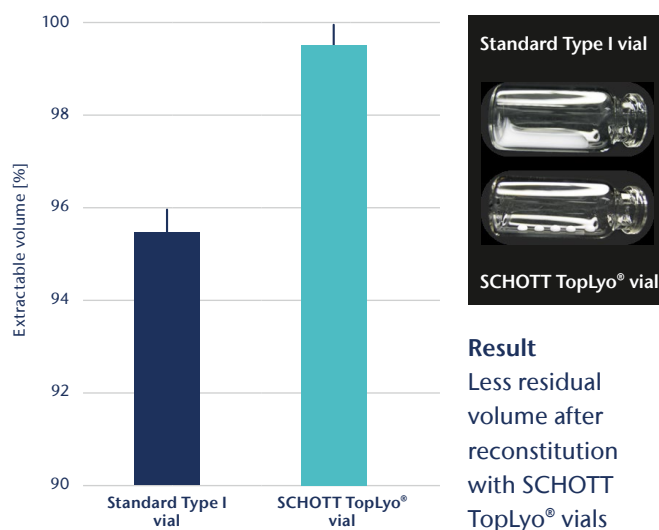
Drug stability

No free silicone thanks to residual free technology

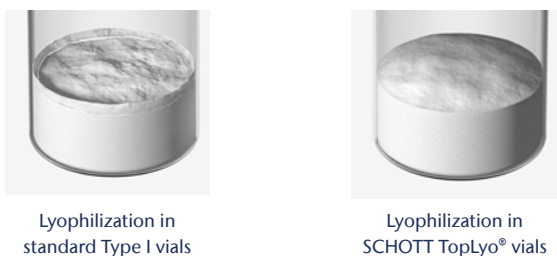
Release test: Drain-off test for hydrophobicity



Verifications: Improved emptying



Verifications: No fogging and elegant lyo cake



Method

10R vials Type I glass and SCHOTT TopLyto vials.
5.0 ml formulation dried in 10R vials with different surfaces.
0.15 mg/ml human growth hormone, 40 mg/ml mannitol, and 10 mg/ml sucrose. Phosphate/glycine buffer (pH 7.0).
Sterilization using 0.2 µm PES Filter, 25 °C, 30 min.

Result

Less cake disruption and dry material pulling from the edge with SCHOTT TopLyto vials.

Verifications: Stress tests have proven stability

		TopLyto [®] 10R	TopLyto [®] 15R	TopLyto [®] 10R, depyrogenated	TopLyto [®] 15R, depyrogenated
ca.	average	103	102	99	101
5 mm*	stand. dev./range	±2/±4	±2/±4	±2/±5	±2/±4
ca.	average	102	102	98	100
15 mm*	stand. dev./range	±2/±5	±2/±4	±2/±5	±1/±3
ca.	average	106	103	101	101
25 mm*	stand. dev./range	±4/±9	±1/±3	±3/±5	±1/±3

Method

TopLyto vials: 10R (> four years of storage) and 15R (three months storage). Contact angle measurement at three lateral positions (bottom, middle, and neck area)*: Reference vs. depyrogenated (30 min at 330 °C). 15 vials measured per sample type.

Result

All analyzed vials show hydrophobic behavior with stable contact angle > 90°. No significant differences were observed for different storage times.

General ordering information

Quality level	TopLine with additional release test										
Packaging	<ul style="list-style-type: none"> • Tray with optional divider • Pre-washed and pre-sterilized: adaptiQ[®] (tray, cup nest) 										
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15–27 layers of nine trays each										
Formats	2R	3R	4R	6R	8R	10R	15R	20R	25R	30R	50R
Pieces per tray	344	344	344	186	186	154	154	95	95	95	40

Many configurations are available in small quantities as “Fast Track Articles”.

Visit our online shop or speak to your sales representative for more information.



EVERIC[®] pure

Pharmaceutical glass vial with homogenous inner surface leading to unmatched drug stability



- The conventional vial converting process can lead to a near-bottom region with a changed inner surface, possibly resulting in:
 - proportionately increased leachable level for low-fill volumes
 - increased risk of pH shift
 - increased delamination risk
- This risk is even higher the more risk factors apply (e.g. terminal sterilization, general sensitivity towards leachables, storage at room temperature).
- EVERIC[®] pure vials provide a homogenous inner surface with improved leaching behavior.



FIOLAX[®] CHR glass tubing for improved hydrolytic resistance



Improved forming process due to patented delamination control technology



Unchanged glass composition – Type I borosilicate glass



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

Low leachables level
Especially relevant for low-filled drugs

Delamination under full control
Particularly important for formulations that are terminally sterilized (diluent, WFI) or phosphate buffer-based

Lower pH shift and conductivity
Especially suitable for low-fill volumes

No re-registration necessary

Release test



1) Glass attack

Autoclaving, empty head first.

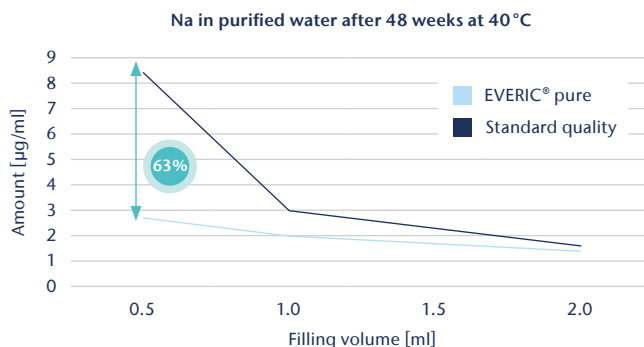
2) Leaching

Autoclaving filled with H₂O.

3) Determination of sodium via AAS

Certified release criterion for Sodium (Na) – limit value defined per format.

Verifications: Unmatched drug stability for low-filling volumes with EVERIC® pure vials



Vials produced with a standard converting process served as benchmark.

Shown here is the amount of sodium leaching (µg/ml) in purified water after 48 weeks at 40°C for different filling volumes (ml).

Result: The unique low leachable level of EVERIC® pure vials becomes more relevant the lower the filling volume.

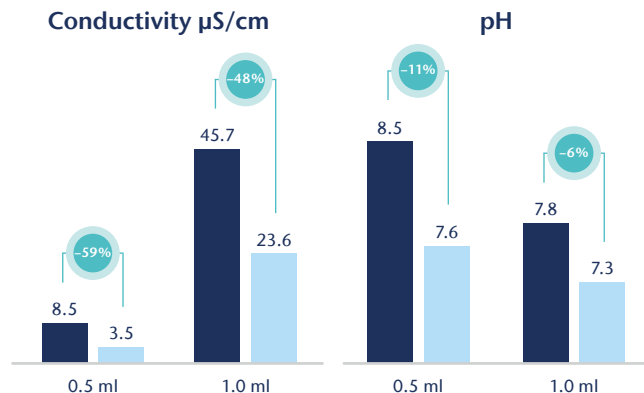
Verifications: Allowed conductivity (based on EP) fulfilled only with EVERIC® pure

Vials produced with a standard converting process served as benchmark.

2R vials were filled with purified water. Terminal sterilization at 121°C for 30 min at worst case has been conducted.

Shown here is conductivity in µS/cm and pH after 48 weeks at 40°C.

Result: EVERIC® pure vials lead to lower pH shift and superior conductivity.



General ordering information

Quality level	TopLine with release test										
Packaging	<ul style="list-style-type: none"> • Tray with optional divider • Pre-washed and pre-sterilized: adaptiQ® (tray, cup nest) 										
Possible combinations	EVERIC® pure can be combined with EVERIC® strong and EVERIC® smooth										
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15–27 layers of nine trays each										
Formats	2R	3R	4R	6R	8R	10R	15R	20R	25R	30R	50R
Pieces per tray	344	344	344	186	186	154	154	95	95	95	40

Many configurations are available in small quantities as “Fast Track Articles”.

Visit our online shop or speak to your sales representative for more information.



EVERIC[®] care

Pharmaceutical glass vial with barrier coating for high pH fillings with hydrophobic surface



- Established primary packaging solutions reach their limit when protecting sensitive drugs from glass leachables in the high alkaline pH range.
- With EVERIC[®] care, SCHOTT offers a vial with an exceptional ion barrier coating that minimizes leachable levels to the highest extent possible, designed for use in a wide range of pH conditions, even highly alkaline solutions.
- Applied using patented and proven plasma impulse chemical vapor (PICVD) coating technology (known from SCHOTT TopLyo[®] and SCHOTT Type I plus[®] coatings).
- Two additional release criteria have been specifically developed.



Si-O-C-H layer applied via PICVD



Contact angle for water > 90° (hydrophobic surface without silicone)



Long-term layer stability



Coating bonds covalently to the glass substrate



Suitable for depyrogenation



Dense coating (i. e. non-porous)



Surface shows excellent barrier properties in reducing ion leaching, also in high pH solutions



Stable after washing process



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

Secured drug stability

The excellent barrier reduces ion leaching, providing drug stability even for extreme conditions such as high pH

Improved dosage accuracy

Improved residual emptying and reduced protein adsorption*

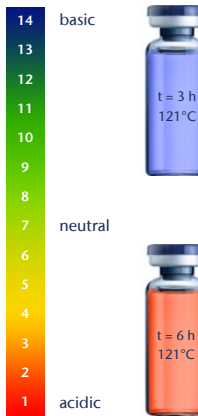
Reduced rejects

For lyophilized products, no fogging occurs and an elegant cake is achieved due to the hydrophobic surface

* adsorption behavior needs to be tested case by case

Release tests

1. Fast performance test



1) Coating attack

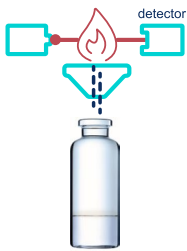


Autoclaving filled with 0.005 M KOH (pH 11.7 at start).

2) Coating attack and leaching



Autoclaving filled with 0.1 M HCl (pH 1 at start).



3) Determination of sodium via AAS

Certified release criterion for solution (Na) – limit value defined per format.

2. Drain-off test for hydrophobicity



Autoclaving filled with H₂O.



Half-filled with white milky test fluid and stoppered. Shaken overhead three times.



In specification



Not in specification

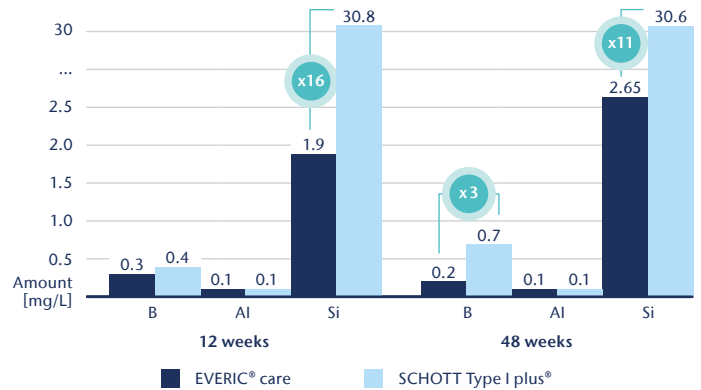
Verifications: Superior leachables results for dissolved glass elements in 10R vial with nominal filling volume*

SCHOTT Type I plus® vials served as benchmark. These vials have an SiO₂ inner coating acting as an ion barrier against glass leachables.

Shown here are glass elements in sodium bicarbonate (pH 8.5) after 12 and 48 weeks at 40 °C.

As shown in the figure, for high pH, the barrier properties of EVERIC® care are superior.

* Multiple tests have been performed with different buffer solutions. Please contact SCHOTT for further information



General ordering information

Quality level	TopLine + additional release tests
Packaging	• Tray, optionally with divider • Pre-washed & pre-sterilized: adaptiQ®*
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15–27 layers of nine trays each
Formats	10R*
Pieces per tray	154

* Discuss the availability of other formats with your local SCHOTT representative and the availability of ready-to-use formats (SCHOTT adaptiQ®) – coming soon

Many configurations are available in small quantities as “Fast Track Articles”.

Visit our online shop or speak to your sales representative for more information.

EVERIC[®] strong

Pharmaceutical glass vial with optimized strength for reduced risk of breakage



- During conventional bulk fill-and-finish processing, vials are continuously subjected to side compression (e.g. during depyrogenation, on rotary table) and axial load (e.g. during crimping).
- In addition, vials used in injection devices have to prove their reliability with regards to strength.
- Breakage rarely occurs, but leads to unwanted interruptions and downtimes, resulting in increased manufacturing costs.
- EVERIC[®] strong provides improved vial strength without changing the glass composition or applying additional chemical treatments.
- An additional “release criterion” has been specifically developed.



FIOLAX[®] OS (“optimized strength”) glass tubing with tighter scratch and fissure specification



Improved forming process (tighter tolerances in critical areas) and specialized inspection (100% bottom inspection via camera and sensor)



Unchanged glass composition – Type I borosilicate glass



“Flawless” processing: No glass-to-glass contact, automated back-end (packaging robot), packaged with separators



Geometry within ISO specification



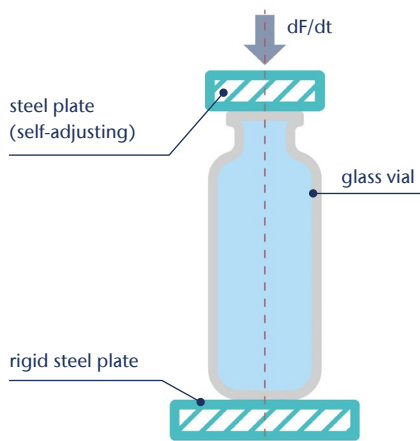
Bottom thickness homogeneity and footprint defined as additional parameters in dimensional specification

Optimized strength

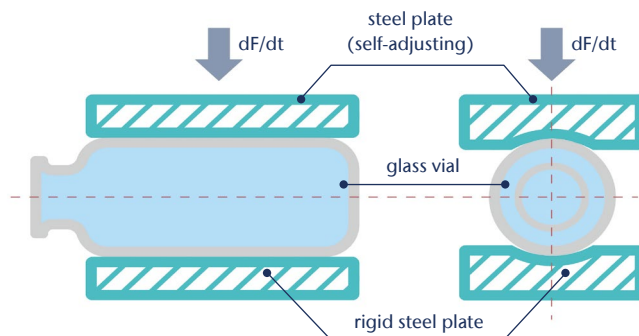
Within existing ISO tolerances with unchanged glass matrix

Release test

Axial load strength (minimum 2000 N)*



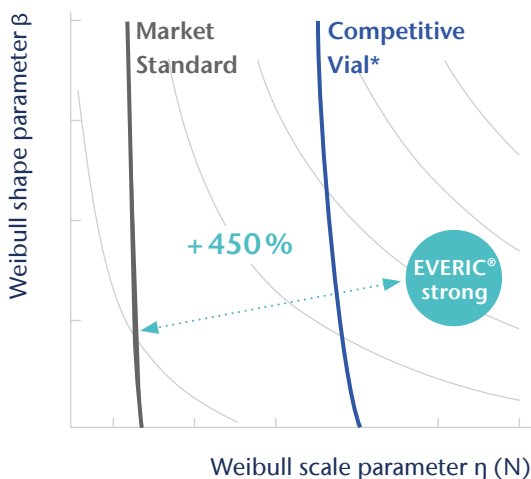
Side compression strength (minimum 1000 N)*



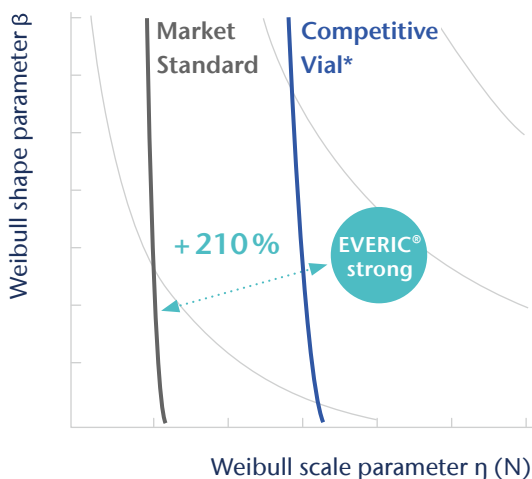
*Statistical in-process testing; AQL 4.0

Verifications: Competitive sample testing – superior strength in all aspects

Axial load strength



Side compression



*Borosilicate vials, untoughened, proposed in the market, competitor to EVERIC® strong

General ordering information

Quality level	TopLine with additional release tests									
Packaging	Tray with divider									
Possible combinations	EVERIC® strong can be combined with EVERIC® pure and EVERIC® smooth									
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15–27 layers of nine trays each									
Formats	2R	3R	4R	6R	8R	10R	15R	20R	25R	30R
Pieces per tray	187	187	187	126	126	104	104	77	77	77

Many configurations are available in small quantities as “Fast Track Articles”.

Visit our online shop or speak to your sales representative for more information.

EVERIC[®] smooth

Pharmaceutical glass vial with low friction outer coating for improved line efficiency



- Conventional bulk fill-and-finish lines don't often operate at maximum efficiency. The main reason for this is continuous glass-to-glass contact, potentially leading to:
 - sticking and climbing in and after the depyrogenation oven
 - increased cosmetic defects, resulting in higher final reject rates and higher risk of breakage
 - reduced line speed
- Consequences are downtimes, interruptions, and increased costs.
- The outer coating of EVERIC[®] smooth vials provides a protected outer surface that smoothly runs through the fill-and-finish process, resulting in improved line performance.
- An additional “release criterion” has been specifically developed.



Coating up to the shoulder



Layer thickness 10–70 nm



High mechanical resistance



Coating applied via dip coating process



Coefficient of friction ≤ 0.3



Fully transparent



Particle-free



Stable after washing process



Stable sterilization:
Autoclaving (121 °C for 1 h)
Depyrogenation
(up to 350 °C for 1 h)



No migration of coating to the vial's inner surface

Increased line speed

Smoother and faster transportation due to optimized gliding behavior

No sticking and climbing

Due to lower coefficient of friction

Lower final reject rate

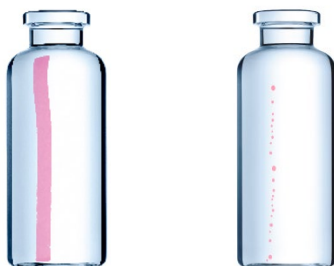
Reduction of cosmetic rejects thanks to protective outer coating

Release test: Presence of outer coating

1) Marking

To determine the surface tension, a test ink with a defined surface energy (28 mN/m) is used. Recommendation: arcotest® test inks.

2) Evaluation of outer surface

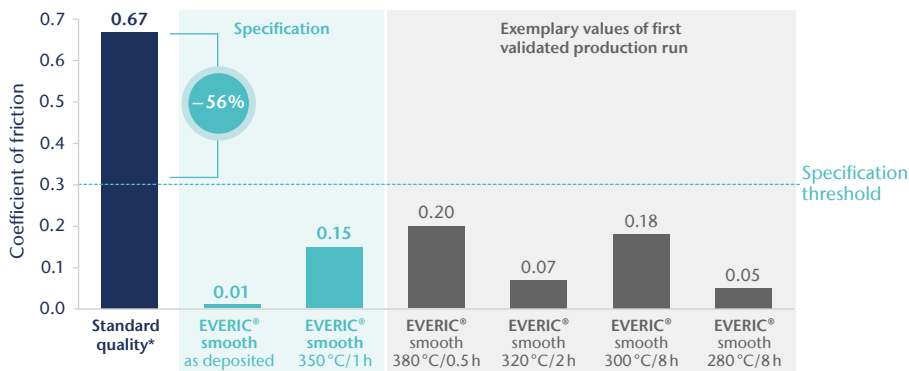


Not in specification

In specification

Verifications: Low coefficient of friction for improved gliding behavior even after depyrogenation

- Comparison of coefficient of friction of standard vials vs. EVERIC® smooth vials after different depyrogenation conditions (1 h for 300 °C/320 °C/350 °C).
- Result: Coefficient of friction stays under specification threshold.



*production average over time, all substrates with comparable surface due to pre-treatment

Verifications: Significant increase of line speed with EVERIC® smooth vials

Set-up

- Place: OPTIMA pharma, in Schwäbisch Hall, Germany.
- Date: 30.07.2020.
- Samples: ~ 34,000 2R EVERIC® strong & smooth vials, standard vials from unknown manufacturer as reference.

Machine

- Test bulk filling machine.
- Round-run throughput, vials were processed multiple times.
- Depyrogenation tunnel, rotary buffering table, star wheel transport (no washing, filling stoppering, crimping).
- Speed was successively increased to 750 vials/min.

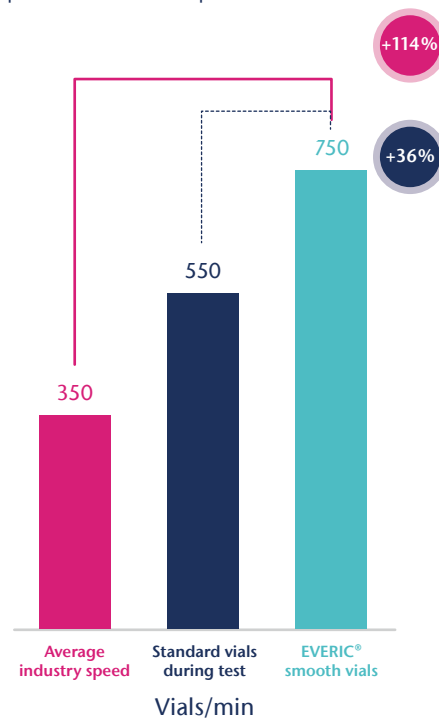
Results

Standard vials

- Abortion of test at 550 vials/min → test machine could not be operated properly anymore.

EVERIC® vials

- Ran smoothly at reached maximum transport speed (750 vials/min).
- Decreased disruptions.
- No breakage.
- Less exerted force → decreased wear and tear on format parts can be assumed.



General ordering information

Quality level	TopLine with additional release test									
Packaging	Tray with optional divider									
Possible combinations	EVERIC® smooth can be combined with EVERIC® strong and EVERIC® pure									
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15–27 layers of nine trays each									
Formats	2R	3R	4R	6R	8R	10R	15R	20R	25R	30R
Pieces per tray	344	344	344	186	186	154	154	95	95	95

Many configurations are available in small quantities as “Fast Track Articles”.

Visit our online shop or speak to your sales representative for more information.

EVERIC[®] freeze

Pharmaceutical glass vials for deep-cold temperature applications



- Applications such as gene therapies or mRNA vaccines require deep-cold storage. In many cases this increases the risk for breakage.
- Influencing factors are filling height, freeze-thaw procedure parameters, and the container itself: its dimensional and cosmetic quality. During freezing, the container must withstand a higher internal pressure, for which it ideally needs to be defect-free and optimized for the greater impact.
- EVERIC[®] freeze combines the highest level of dimensional accuracy and cosmetic quality, as seen with EVERIC[®] strong, with geometrical optimization to improve strength for frozen applications.



FIOLAX[®] OS (Optimized Strength) glass tubing with tighter scratch and fissure specification



Improved forming process (tighter tolerances in critical areas) and specialized inspection (100% bottom inspection via camera and sensor)



Unchanged glass composition – Type I borosilicate glass



Higher wall thickness improves resistance to internal pressure



Outer geometry and CCI-relevant parameters 100% within ISO specification



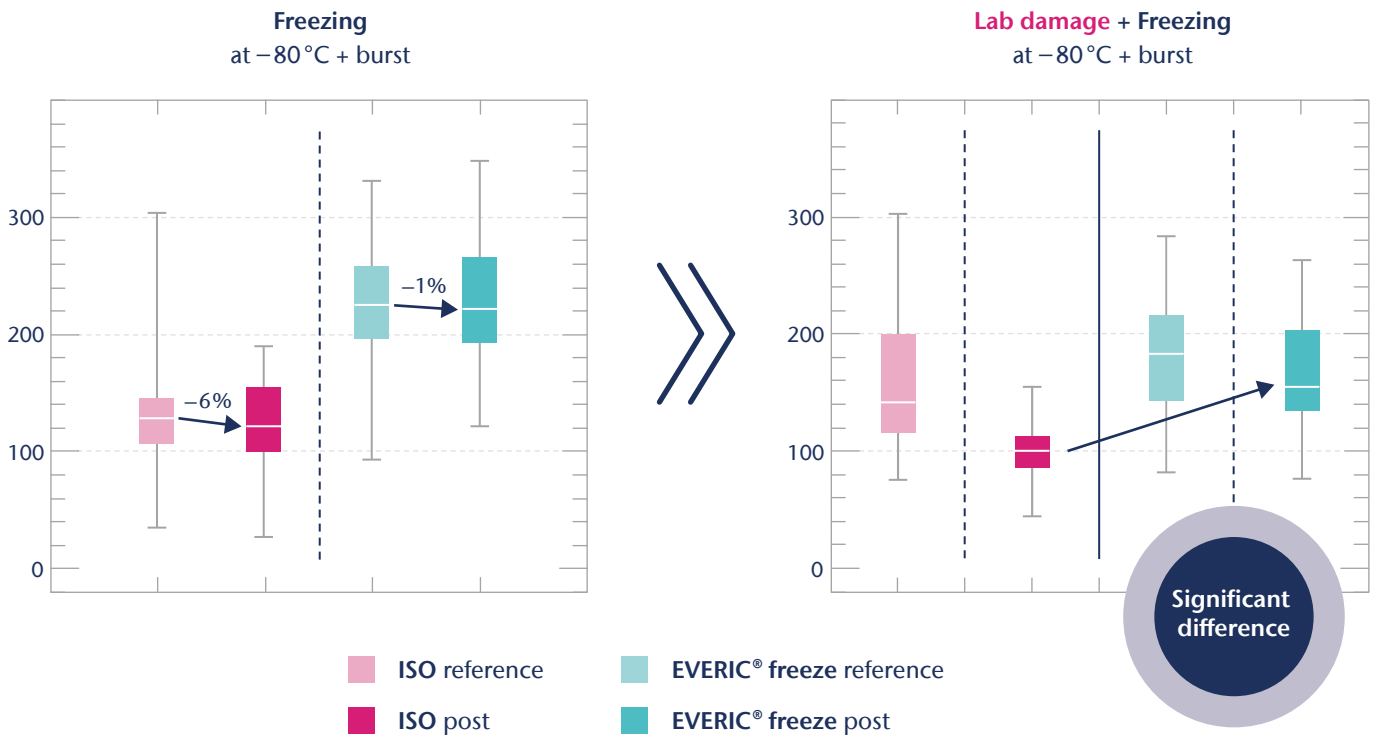
“Flawless” processing: no glass-to-glass contact, automated back-end (packaging robot), packaged with separator

Optimized strength within existing outer ISO tolerances with unchanged glass matrix

No re-registration necessary

Verification: EVERIC® freeze shows improved burst strength performance after fill-and-finish process and storage at –80 °C

Results burst pressure 2 mL: ISO (TopLine) vs EVERIC® freeze – Box-whisker plot



General ordering information										
Quality level	TopLine									
Packaging	Tray with divider									
Possible combinations	EVERIC® freeze can be combined with EVERIC® smooth									
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15–27 layers of 12 trays each									
Formats	2 mL	3 mL	4 mL	6 mL	8 mL	10 mL	15 mL	20 mL	25 mL	30 mL
Pieces per tray	187	187	187	126	126	104	104	77	77	77

Many formats are available as **“Fast Track Articles”**.

Visit our online shop or speak to your sales representative for more information.

SCHOTT Type I plus[®]

Pharmaceutical glass vial with barrier coating against leachables for sensitive formulations



- For highly sensitive drugs, leachables of the primary packaging into the drug product need to be minimized in order to protect their stability.
- The adsorption of proteins to the glass surface can result in conformational changes, denaturation, aggregation, and loss of effectiveness.
- SCHOTT Type I plus[®] vials have an ion barrier coating that can reduce adsorption and ensures low leachable levels for pharmaceutical products in the neutral and acidic pH ranges.
- Inner coating is applied using patented and proven plasma impulse chemical vapor deposition (PICVD) technology.
- An additional “release criterion” has been specifically developed.



SiO₂ layer applied via PICVD



Layer thickness of ~ 100–200 nm



Long-term layer stability



Coating bonds covalently to the glass substrate



Suitable for depyrogenation



Dense coating (i. e. non-porous)



Surface shows excellent barrier properties in reducing ion leaching: Na, Ca, B, Si, Al



Stable after washing process



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

Secured drug stability

Ion barrier provides stability for leachable sensitive drugs (e.g. radiopharmaceuticals and aluminum-sensitive drugs)

Reduced adsorption

For certain proteins, adsorption can be reduced thanks to a specialized inner surface*

Avoidance of pH-shift

Particularly relevant to WFI

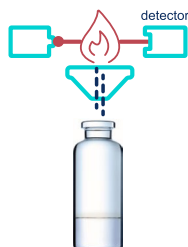
* adsorption behavior needs to be tested case by case

Release test



1) Leaching

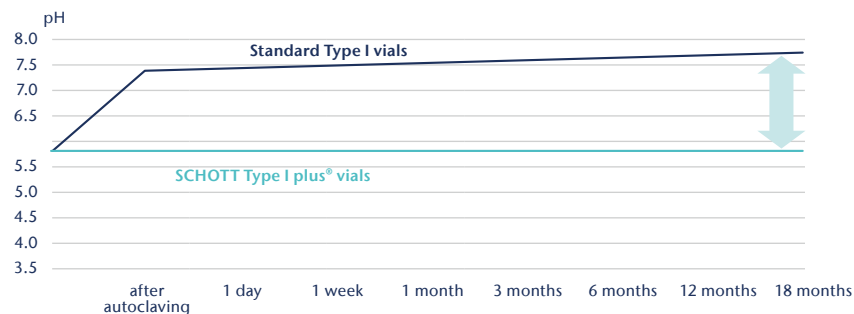
Autoclaving filled with 0.1 M HCl (pH 1 at start).



2) Determination of sodium via AAS

Certified release criterion for sodium (Na) – defined limit value.

Verifications: Avoidance of pH shift



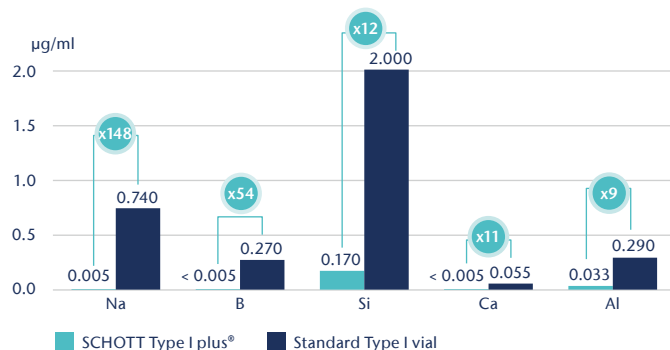
Method

10 ml vials, washed in accordance with ISO 4802. Autoclaving 1 h at 121 °C. Storage at room temperature. Measurement of pH value prior to and after autoclaving (directly after, one day, one week, one/six/12/18 months).

Result

After autoclaving, standard Type I vials show pH shifts from 5.5 up to 7.5. SCHOTT Type I plus vials fully prevent pH shift.

Verifications: Secured drug stability



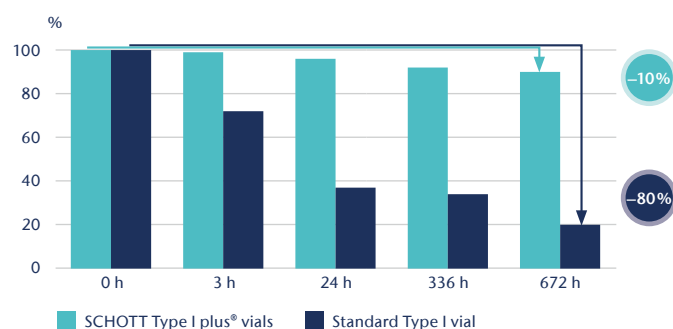
Method

10R vials, filled with purified water, 1 h autoclaving at 121 °C. Leached ions in µg/ml by ICP-MS (ICP-OES for Si).

Result

The ion barrier is effective for all other elements of the glass matrix.

Verifications: Reduced adsorption



Method

Nicotinic acetylcholine receptor, concentration: 150 µg/ml, see: "A. Schratzenholz: Drug loss through adsorption of a nicotinic acetylcholine receptor in SCHOTT Type I plus vials and standard vials".

Result

Tested protein shows less tendency to adsorb to SCHOTT Type I plus vials.

General ordering information

Quality level	TopLine with additional release test										
Packaging	<ul style="list-style-type: none"> Tray with optional divider Pre-washed and pre-sterilized: adaptiQ® (tray, cup nest) 										
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15–27 layers of nine trays each										
Formats	2R	3R	4R	6R	8R	10R	15R	20R	25R	30R	50R
Pieces per tray	344	344	344	186	186	154	154	95	95	95	40

Many configurations are available in small quantities as "Fast Track Articles".

Visit our online shop or speak to your sales representative for more information.



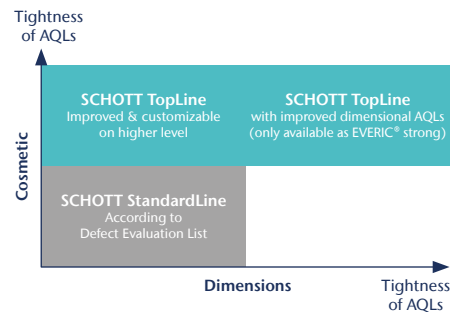
Core Vials in TopLine quality – beyond the industry standard



To secure patient safety, the requirements for pharmaceutical glass vials 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 Pharma Core Vials in TopLine quality offer tighter cosmetic and dimensional AQLs* than regular vials. Further customization is possible upon request.



Type I Borosilicate Glass with high chemical resistance according to ISO 8362-2



Manufactured according to cGMP regulations



Unlimited shelf life for glass**



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



Tight dimensional control



SCHOTT FIOLAX® clear glass tubing



Formats according to current version of ISO 8362-1



Tight cosmetic control



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

* 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.

A global manufacturing network paired with outstanding hot forming experience and continuous strive for innovation

- 

Advancing the industry with groundbreaking glass innovations such as borosilicate glass for over 130 years
- 

Providing customers with state-of-the-art quality and inspection technologies
- 

Fueling science and inspiring progress in hot forming with dedicated experts
- 

Offering supply security for the entire value chain due to vertical integration with the leading borosilicate tubing manufacturer



General ordering information

Quality level	TopLine												
Neck finish	Crimp*												
Packaging	Tray with optional divider												
Blowbacks	Non-blowback, European blowback												
Palletizing	A standard Euro Pallet (1200 x 800 mm) contains 15–27 layers of 9 trays each												
Formats	2R	3R	4R	6R	8R	10R	15R	20R	25R	30R	50R	100R	
Pieces per tray	344	344	344	186	186	154	154	95	95	95	40	35	

* other finishes available upon request

adaptiQ[®] cup nest

Ready-to-use pharmaceutical vials for nested processing



- adaptiQ[®] cup nest provides pre-washed, depyrogenated and pre-sterilized vials in a highly standardized nest configuration
- Easily use these vials on your ready-to-use filling line
- The cup nest eliminates glass-to-glass contact of the vials while allowing easy denesting
- The adaptiQ[®] cup nest has equal lateral dimensions for all vial sizes (199 mm width x 230 mm length) in a standard 3" tub
- Compliant with ISO 21882 standard "Sterile packaged ready for filling glass vials" with packaging dimensions harmonized to ISO 11040-7 "Prefilled Syringes"



Minimized particle load



Compatible with all SCHOTT Pharma ISO vials, including speciality vials



Harmonized documentation for all product combinations



Vials according to ISO 8362-1



Compatible with all major filling line vendors



Standardized processing and continuous monitoring facilitates EU GMP Annex I compliance

Material data

Tubing	SCHOTT FIOLAX [®] clear Highly resistant Borosilicate Glass tubing (Type I)	First hydrolytic class according to EP, USP, and JP in its current version
Vial	SCHOTT FIOLAX [®] clear TopLine vials EVERIC [®] pure SCHOTT Type I plus [®] coating SCHOTT TopLy [®] coating	Glass container: USP 660; EP 3.2.1; JP 7.01; and dedicated release test limit values for EVERIC [®] pure, SCHOTT Type I plus [®] and SCHOTT TopLy [®]
Nest	Polymer suitable for EtO sterilization	
Tub	Polymer suitable for EtO sterilization	
Seal & Inlay	Tyvek [®] – High-density polyethylene (HDPE)	Polymers according to USP <88> class VI (current version)
Bag	Industry-standard polymer foil with Tyvek [®] window (HDPE)	
Transport box	Akylux [®] – Corrugated polypropylene (PP)	

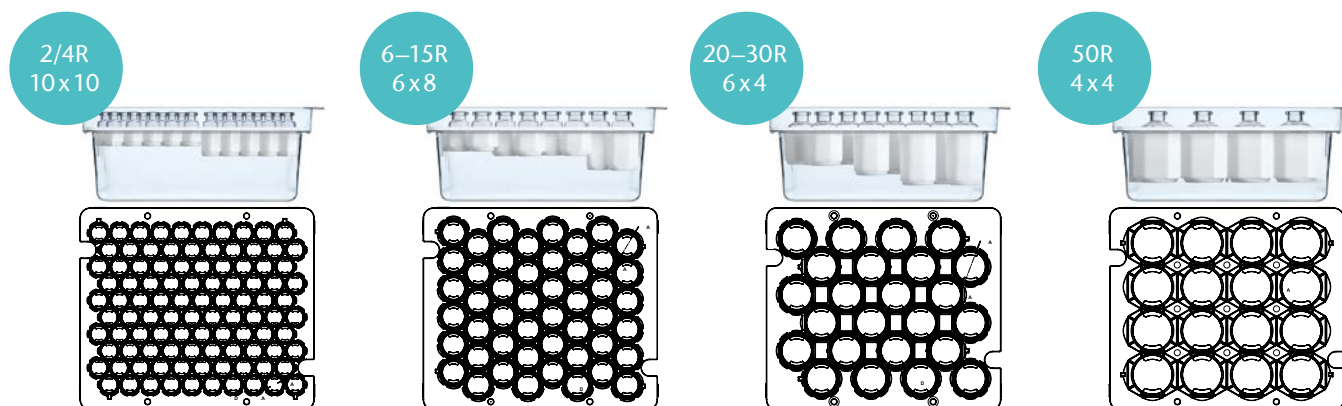
Sterilization and residuals

Sterilization method	ETO (Ethylene Oxide)	ISO 11135 “Sterilization of health-care products”
Sterility assurance level	< 10 ⁻⁶ ; Overkill approach Biological Indicators (EPCD) tested for every run	ISO 11135 “Sterilization of health-care products”
Endotoxines	< 0.25 EU/ml	Limit values according to ISO 11040-4, USP 1231, USP 85
Ethylene oxide	≤ 1 µg/ml	Limit values according to ISO 10993-7
Ethylene chlorohydrin	≤ 50 µg/ml	Limit values according to ISO 10993-7
Documentation creation	Certificate of processing review – parametric review	ISO 11135 “Sterilization of health-care products”
Documentation verification	Certificate of analysis (BI) – microbiological release	ISO 11135 “Sterilization of health-care products”

Storage and transport recommendations

- Temperature range for long-term storage (more than 60 days) is defined between 15–30°C
- During transport, it is allowed to deviate from this requirement
- Storage should always be above the dew point
- Longer-term storage with exposure to sunlight is not allowed
- The goods should be stored in a normal warehouse environment (no contaminants in the atmosphere) with pest control in place
- Shelf life is five years from the date of production and certified in CoC
- Avoid mechanical stress throughout all process steps

Pitch pattern



General ordering information

Quality level	TopLine									
Neck finish	Crimp									
Packaging	Akylux® boxes with 15 nests per box Six nests are available for human-use applications									
Blowbacks	Non-blowback, European blowback									
Palletizing	A standard Euro Pallet (1,200 x 800 mm) contains 15 boxes of 15 nests each									
Formats	2R	4R	6R	8R	10R	15R	20R	25R	30R	50R
Pieces per nest	100	100	48	48	48	48	24	24	24	16

Many standard vial configurations are available in small quantities in our **Online Shop**. Speak to your local sales representative for more information.

schott-pharma.com/adaptiq

SCHOTT Pharma AG & Co. KGaA, Hattenbergstrasse 10, 55122 Mainz, Germany
pharma@schott.com

carbon neutral
natureplus.com | 04-07/2023/10
print production

MIX
FSC
FSC® C008855
recycled



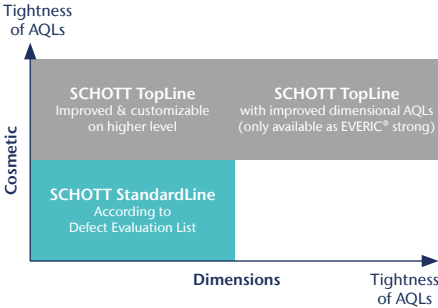
Core Vials in StandardLine quality – setting the industry standard



To secure patient safety, the requirements for pharmaceutical glass vials 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 Pharma Core Vials in StandardLine quality 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.



Type I Borosilicate Glass with high chemical resistance according to ISO 8362-2



Manufactured according to cGMP regulations



Unlimited shelf life for glass**



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



Tight dimensional control



SCHOTT FIOLAX® clear or amber glass tubing



Formats according to current version of ISO 8362-1



Tight cosmetic control



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

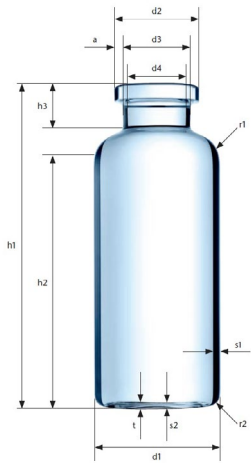
* AQL = Acceptable Quality Level. Indicates how high the maximum proportion of a defective subset can be that is considered acceptable quality in a sample.
** limitations may come from secondary packaging.

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



ISO 8362-1
Dimensions,
brimful capacity
and mass

Size designation of injection vial	Overflow capacity ml	a mm	d1 mm	d2 mm	d3 mm	d4 mm	h1 mm		h2 mm		h3 mm		r1 mm		r2 mm		s1 mm		s2 mm		t mm	Mass g
							Tol	min.	min.	Tol	min.	Tol	min.	min.	Tol	min.	min.	max.	min.	max.		
2R	4						35		22													4.4
3R	5		16	±0.15	13	10.5	7	40	27	8			2.5	1.5						0.6		5.5
4R	6	±0.5						45	32													5.7
6R	10			22				40	±0.5	26		±0.5					1	±0.04			0.7	7.9
8R	11.5			±0.2		16.5		45		31					2							8.7
10R	13.5		24					45		30												9.5
15R	19	±1						60		45										0.7		12.0
20R	26				20		12.6	55		35												16.2
25R	32.5	±1.5	1.5	30	±0.25			65	±0.7	45			5.5	2.5	1.2	±0.05				1		18.9
30R	37.5					17.5		75		55	10	±0.75										21.9
50R	62	±4	2.5	40	±0.4			73		49			6		1.5							34.5
100R	123	±7	3.5	47	±0.5			100	±0.75	75			6.5	4	1.7	±0.07	0.9			1.5		60

Chemical

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

A global manufacturing network paired with outstanding hot forming experience and continuous strive for innovation

- Advancing the industry with groundbreaking glass innovations such as borosilicate glass for over 130 years
- Providing customers with state-of-the-art quality and inspection technologies
- Fueling science and inspiring progress in hot forming with dedicated experts
- Offering supply security for the entire value chain due to vertical integration with the leading borosilicate tubing manufacturer

General ordering information												
Quality level	StandardLine											
Neck finish	Crimp*											
Packaging	Tray with optional divider											
Blowbacks	Non-blowback, European blowback*											
Palletizing	A standard Euro Pallet (1200 x 800 mm) contains 15–27 layers of 9 trays each											
Formats	2R	3R	4R	6R	8R	10R	15R	20R	25R	30R	50R	100R
Pieces per tray	344	344	344	186	186	154	154	95	95	95	40	35

* other finishes available upon request

По вопросам продаж и поддержки обращайтесь:

Алматы (727)345-47-04
Ангарск (3955)60-70-56
Архангельск (8182)63-90-72
Астрахань (8512)99-46-04
Барнаул (3852)73-04-60
Белгород (4722)40-23-64
Благовещенск (4162)22-76-07
Брянск (4832)59-03-52
Владивосток (423)249-28-31
Владикавказ (8672)28-90-48
Владимир (4922)49-43-18
Волгоград (844)278-03-48
Вологда (8172)26-41-59
Воронеж (473)204-51-73
Екатеринбург (343)384-55-89

Иваново (4932)77-34-06
Ижевск (3412)26-03-58
Иркутск (395)279-98-46
Казань (843)206-01-48
Калининград (4012)72-03-81
Калуга (4842)92-23-67
Кемерово (3842)65-04-62
Киров (8332)68-02-04
Коломна (4966)23-41-49
Кострома (4942)77-07-48
Краснодар (861)203-40-90
Красноярск (391)204-63-61
Курск (4712)77-13-04
Курган (3522)50-90-47
Липецк (4742)52-20-81

Магнитогорск (3519)55-03-13
Москва (495)268-04-70
Мурманск (8152)59-64-93
Набережные Челны (8552)20-53-41
Нижний Новгород (831)429-08-12
Новокузнецк (3843)20-46-81
Ноябрьск (3496)41-32-12
Новосибирск (383)227-86-73
Омск (3812)21-46-40
Орел (4862)44-53-42
Оренбург (3532)37-68-04
Пенза (8412)22-31-16
Петрозаводск (8142)55-98-37
Псков (8112)59-10-37
Пермь (342)205-81-47

Ростов-на-Дону (863)308-18-15
Рязань (4912)46-61-64
Самара (846)206-03-16
Санкт-Петербург (812)309-46-40
Саратов (845)249-38-78
Севастополь (8692)22-31-93
Саранск (8342)22-96-24
Симферополь (3652)67-13-56
Смоленск (4812)29-41-54
Сочи (862)225-72-31
Ставрополь (8652)20-65-13
Сургут (3462)77-98-35
Сыктывкар (8212)25-95-17
Тамбов (4752)50-40-97
Тверь (4822)63-31-35

Тольятти (8482)63-91-07
Томск (3822)98-41-53
Тула (4872)33-79-87
Тюмень (3452)66-21-18
Ульяновск (8422)24-23-59
Улан-Удэ (3012)59-97-51
Уфа (347)229-48-12
Хабаровск (4212)92-98-04
Чебоксары (8352)28-53-07
Челябинск (351)202-03-61
Череповец (8202)49-02-64
Чита (3022)38-34-83
Якутск (4112)23-90-97
Ярославль (4852)69-52-93

Россия +7(495)268-04-70

Казахстан +(727)345-47-04

Беларусь +(375)257-127-884

Узбекистан +998(71)205-18-59

Киргизия +996(312)96-26-47

эл.почта: sqh@nt-rt.ru || сайт: <https://schott.nt-rt.ru/>