SCHOTT FIOLAX®

Special Glass Tubes for the Production
of Pharmaceutical Primary Packaging

SCHOTT
glass made of ideas

Glass Tubing – Reliable Supplies around the World

Innovative Solutions for the Future

While proudly looking back on more than 100 years of experience and excellence in glass technology, we at SCHOTT have set our sights on the future: our Business Segment Tubing has been a decisive factor in setting market trends thanks to continuous process innovation, combined with sophisticated technologies and SCHOTT'S own long-time know-how.

In-house chemical and physical laboratories where pharmaceutical containers such as ampoules and vials can be produced in realistic conditions present an ideal background for the research and development of successful solutions for the future.

A production capacity of more than 110,000 metric tons and production sites on three continents have made the SCHOTT Group's Business Segment Tubing one of the world's leading suppliers of glass tubing. Some 60 different glass types, manufactured in a seemingly endless variety of sizes, can be supplied to customers in nearly every country around the world, thanks to SCHOTT's extensive distribution network and logistics.

All SCHOTT's sites have a common single strategy for research & development, production, quality assurance, and logistics. Ongoing technology transfer processes ensure world leadership in technical expertise. And this is just one of the reasons why identical products comply with the same high quality requirements all over the world.

Glass: The First Choice for Pharmaceutical Packaging

Glass has many advantages over other packaging materials used for pharmaceutical primary packaging: it has only a few components, hence allowing reliable information on the chemical resistance and protection of the medicines. In this manner, reliable recommendations can be given to the user on the shelf life of the contents.

This is of great significance in the pharmaceutical field: glass can be very easily sterilized, it is absolutely impervious to gas, has good temperature resistance and withstands high inner pressure; especially when tubing glass is used for packaging. Last but not least, the ecological aspects of this recyclable material are significant.

Glass Tubing – More than Just Glass

Not all glass is the same. Special glass tubing from SCHOTT has properties which make it the first choice for pharmaceutical primary packaging. Pharmaceutical packaging made from glass tubing is generally lighter than ordinary glass containers manufactured by other methods, thanks to the evenly distributed wall thicknesses. Add to that the exceptional clarity and transparency of glass tubing, which is especially advantageous for highly automated processes where optical control is standard.

Outstanding material quality with narrow tolerances - for smooth excellent machine operation and superior product quality.

Contents

SCHOTT FIOLAX®
Proven Quality Credentials on the Pharmaceuticals Market

Due to its low alkali content, FIOLAX® is a premium glass of the first hydrolytic class. Therefore FIOLAX® stands for outstanding chemical resistance, neutrality, impermeability, and strength. Apart from being the perfect neutral-glass container for injectable solutions, FIOLAX® also makes a particularly safe packaging medium for biotechnological products.

FIOLAX®-amber additionally offers effective protection against ultra-violet rays and short-wave visible light. FIOLAX® therefore fulfils the most stringent packaging requirements for the degree of permanent protection demanded for parenteral medicines.

Uncompromising Quality

100% quality control from the receipt of the raw materials throughout automated production all the way to the warehouse, guarantees reliable compliance with the strictest quality assurance measures.

Our production facilities with their state-of-the-art safety, control and documentation system are in accordance with the relevant GMP Guidelines. There is 100% control of all important product parameters. An opto-electronic testing system is employed for statistical process control of all quality characteristics. Extensive control systems ensure compliance with the strict production standards.

Coating Made to Measure

Upon request, the tubes can also be coated to protect them from scratches, using FDA registered coating materials. FIOLAX® perfectly meets all our customers' requirements for manufacturing in accordance with the GMP Guidelines.

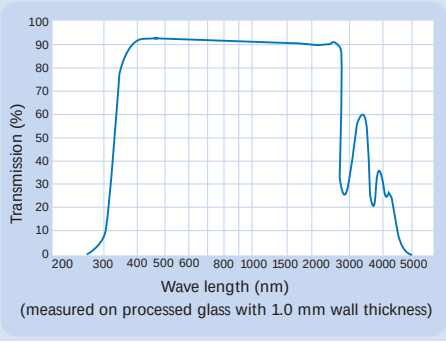
Tubing Ends for All Applications

FIOLAX® is available in a vast range of end executions to meet any requirements. For vials and ampoules, closed ends manufactured in accordance with SCHOTT's own DENSOCAN® system are a safe and reliable way to avoid contamination in the process chain, both before and during processing.

For syringes and cartridges, open tubing ends have stood the test of time as the standard solution most preferred by our customers. It goes without saying that other types of tubing ends are also available on request.

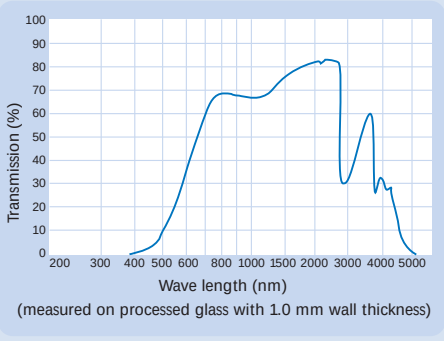
Technical Data

SCHOTT FIOLAX®-clear



(measured on processed glass with 1.0 mm wall thickness)

SCHOTT FIOLAX®-amber



(measured on processed glass with 1.0 mm wall thickness)

Physical Data

Coefficient of mean linear thermal expansion α (20 °C; 300 °C) according to DIN ISO 7991	4.9 · $10^{-6}K^{-1}$	5.4 · $10^{-6}K^{-1}$
Transformation temperature *T*g:	565 °C	560 °C
Glass Temperature at viscosity η in dPa · s:		
10^{13} (annealing point)	565 °C	560 °C
$10^{7,6}$ (softening point)	785 °C	770 °C
10^{4} (working point)	1,160 °C	1,165 °C
Density ρ at: 25 °C	2.34 g · cm^{-3}	2.42 g · cm^{-3}

Chemical Resistance

Hydrolytic Class (DIN ISO 719)	HGB 1	HGB 1
to Ph. Eur.	Type I	Type I
to USP	Type I	Type I
Acid Class (DIN 12 116)	Class S 1	Class S 2
Alkali Class (DIN ISO 695)	Class A 2	Class A 2

Chemical Composition

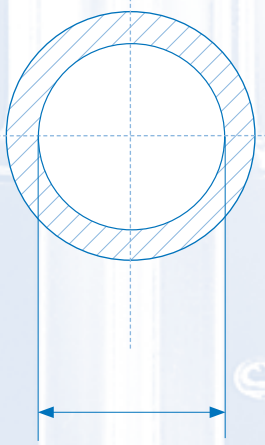
main components in approx. weight %

SiO_2	75 %	70 %
B_2O_3	10.5 %	7 %
Al_2O_3	5 %	6 %
Na_2O	7 %	7 %
K_2O	-	1 %
BaO	-	2 %
CaO	1.5 %	< 1 %
TiO_2	-	5 %
Fe_2O_3	-	1 %

SCHOTT FIOLAX® for Syringes

The Innovation: Inside Diameter Tolerances up to ± 0.05 mm

The precise inside diameters of FIOLAX® improves the operational reliability of the syringe plunger. Depending on the tube size, we manufacture inside diameter tolerances of up to +/- 0.05 mm upon request. It is these extremely narrow inside diameter tolerances which ensure the precisely defined activation forces and even sliding forces of the plunger plug inside the syringe body.



The narrow geometric tolerances typical of FIOLAX® are extremely important for prefillable syringes.

On the one hand, FIOLAX® with its precise dimensions optimizes machine operation throughout the manufacturing process, especially during the shaping of the syringe head. On the other hand the narrow inside diameter tolerances ensure very exact filling quantities, especially in syringe systems with scales.

The standard tubing end execution for FIOLAX® for syringes has both ends open. In this manner, the open end can be used to form the first mouth thus guaranteeing consistently high yields.
Other dimensions and end executions are also available on request.

Outside Diameter	DIN standard	Inside Diameter	DIN standard	Bundle Weight	Pallet Weight
mm		mm		approx. kg	approx. kg
FIOLAX®-clear Selected Dimensions for syringes according to DIN ISO 11040-4					
6.85 ±0.09	±0.10	**4.65** ±0.08	±0.10	16.1	1,014.3
8.15 ±0.10	±0.10	**6.35** ±0.09	±0.10	17.8	996.8
10.85 ±0.10	±0.10	**8.65** ±0.09	±0.20	20.0	1,120.0
14.45 ±0.10	±0.10	**11.85** ±0.10	±0.20	20.7	1,014.3
17.05 ±0.17	±0.20	**14.25** ±0.15	±0.20	19.3	1,080.8
22.05 ±0.17	±0.20	**19.05** ±0.15	±0.20	16.3	1,141.0

SCHOTT FIOLAX®
for Cartridges and Pen Systems

More than anything else, it is the resistance of FIOLAX® to compressive stress which makes this glass type the first choice for manufacturing cartridges and pen systems.

The extremely narrow geometric tolerances are not only advantageous for processing and formation but also permit maximum dosing accuracy. This prevents so-called “overfill losses“ to the greatest possible extent while increasing dosing accuracy for the user. Inside diameter tolerances of up to +/- 0.05 mm are available on request.

A 100% optical control integrated in the manufacturing process guarantee the exceptional quality of FIOLAX®.

The standard tubing end execution for FIOLAX® for cartridges and pen systems has both ends open. It goes without saying that other dimensions and types of tubing ends are also available on request.

Outside Diameter	DIN standard	Inside Diameter	DIN standard	Bundle Weight	Pallet Weight
mm		mm		approx. kg	approx. kg
FIOLAX®-clear Standard dimensions for Cartridges and Pen Systems according to ISO 13926-1					
8.65 ±0.10	±0.10	**6.85** ±0.09	±0.10	20.3	1,136.8
10.85 ±0.10	±0.10	**8.65** ±0.09	±0.10	20.0	1,120.0
10.95 ±0.10	±0.15	**9.25** ±0.09	±0.10	19.7	1,103.2
11.60 ±0.10	±0.15	**9.65** ±0.09	±0.10	19.3	1,080.8
14.00 ±0.11	±0.15	**12.00** ±0.10	±0.15	20.6	1,112.4
14.45 ±0.11	±0.15	**11.85** ±0.10	±0.15	20.7	1,014.3
18.25 ±0.13	±0.15	**16.05** ±0.13	±0.15	20.6	988.8
FIOLAX®-clear Standard dimensions for dental Cartridge Ampoules according to DIN ISO 11040-1					
8.65 ±0.15	±0.15	**6.85** ±0.15	±0.15	20.3	1,136.8

SCHOTT FIOLAX® for Ampoules

Maximum Cleanliness: DENSOCAN®

DENSOCAN® is a tubing end execution specifically developed and patented by SCHOTT. The tubes are separated with a low particle content and then sealed on the production line by flame. Only a pressure compensation vent remains.
There is no possibility of contamination of the closed tubes during storage, transport or processing.

In this way, the lowest possible particle content is guaranteed.

FIOLAX® for ampoules makes sure that medicines remain safely packed at all times. Its excellent surface properties provide permanent protection of the contents, ensuring long-term effectiveness of the packed pharmaceuticals.

A 100% optical control of all FIOLAX® glass tubes involves the examination of every single glass tube for contamination or surface flaws. This is the only way to produce high-transparency glass which safely preserves the contents.

The standard tubing end execution for FIOLAX® for ampoules is DENSOCAN®. It goes without saying that other dimensions and types of tubing ends are also available on request.

Outside Diameter	DIN standard	Wall Thickness	DIN standard	Bundle Weight	Pallet Weight
mm		mm		approx. kg	approx. kg
FIOLAX®-clear Standard dimensions for Ampoules according to DIN ISO 9187-1					
10.75 ±0.12	±0.15	**0.50** ±0.02	±0.03	19.0	1,026.0
12.75 ±0.12	±0.15	**0.50** ±0.02	±0.03	17.0	918.0
14.75 ±0.12	±0.15	**0.55** ±0.02	±0.03	15.5	837.0
17.75 ±0.14	±0.20	**0.60** ±0.03	±0.04	13.6	734.4
22.50 ±0.19	±0.25	**0.70** ±0.04	±0.04	12.6	680.4
FIOLAX®-amber Standard dimensions for Ampoules according to DIN ISO 9187-1					
10.75 ±0.12	±0.15	**0.50** ±0.02	±0.03	19.7	1,063.8
12.75 ±0.12	±0.15	**0.50** ±0.02	±0.03	17.6	950.4
14.75 ±0.12	±0.15	**0.55** ±0.02	±0.03	16.1	869.4
17.75 ±0.14	±0.20	**0.60** ±0.03	±0.04	14.1	761.4
22.50 ±0.19	±0.25	**0.70** ±0.04	±0.04	13.1	707.4

SCHOTT FIOLAX® for Vials

Whether or not the properties of medicines remain unchanged over long periods of time literally depends on the containers they are kept in. The outstanding chemical resistance, neutrality and impermeability of FIOLAX®-clear and FIOLAX®-amber ensures optimum protection of the contents against premature ageing and loss of effectiveness.

FIOLAX®-amber additionally offers effective protection from ultra-violet rays and short-wave visible light.

And to top everything, all FIOLAX® glass tubes are subjected to 100% optical control throughout the entire production process.

The standard tubing end execution for FIOLAX® for vials is DENSOCAN®. It goes without saying that other dimensions and types of tubing ends are also available on request.

Outside Diameter	DIN standard	Wall Thickness	DIN standard	Bundle Weight	Pallet Weight
mm		mm		approx. kg	approx. kg
FIOLAX®-clear Standard dimensions for Vials according to DIN ISO 8362-1					
16 ±0.14	±0.15	**1.0** ±0.04	±0.04	20.0	1,080.0
22 ±0.19	±0.20	**1.0** ±0.04	±0.04	16.7	1,002.0
24 ±0.19	±0.20	**1.0** ±0.04	±0.04	16.0	864.0
30 ±0.20	±0.25	**1.2** ±0.05	±0.05	14.9	804.6
FIOLAX®-amber Standard dimensions for Vials according to DIN ISO 8362-1					
16 ±0.14	±0.15	**1.0** ±0.04	±0.04	20.7	1,117.8
22 ±0.19	±0.20	**1.0** ±0.04	±0.04	11.5	885.1
24 ±0.19	±0.20	**1.0** ±0.04	±0.04	16.5	891.0
30 ±0.20	±0.25	**1.2** ±0.05	±0.05	15.4	831.6

SCHOTT Service & Logistik

The department Scientific Services provides expert assistance on all issues concerning the properties of our glass tubing, further processing and the great variety of applications of our FIOLAX® glass tubes.

Our Scientific Services advisors offer a wide range of services, from preventive product analysis to independent surveys and customized analyses.

Problem Solutions throughout the Entire Process Chain

Our team of qualified experts is optimally equipped with its own chemical and physical laboratories.
Therefore, in addition to developing new, innovative packaging solutions made of glass, our department Scientific Services also provides valuable help and inspiration for the solution of problems in existing processes. Give us a try!

Scientific Services

Our range of activities at a glance:
- Fault analysis and recommended on the manufacturing process
- Advice on specific regulations and standards
- Know-how transfer by training and lectures

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Ordering Round the Clock

FIOLAX® is easy to order over the Internet around the clock. The extensive, login-protected functions under www.schott.com/tubing/ecom make ordering all the easier. Lists of favourites and online order confirmations indicating delivery dates are just a few of the practical options available.

Further information and personalized login data are available either by e-mail under kundenservice.rohrglas@schott.com, by phone under +49 (0) 9633/80-100, or by fax under +49 (0) 9633/80-233.

A safe Thing

The high quality of our products also requires corresponding handling during transport. To guarantee safety and the lowest possible amount of particles, SCHOTT has developed DENSOPACK®.

Each bundle of tubes is shrink-wrapped with foil at both ends which stops the tubes moving, hence avoiding scratches. This procedure not only means better stability and safety during transport but also reduces the customer's packaging waste. The shrink wrapping round the whole pallet offers supplementary protection during transport.

DENSOPACK®:
Tightest packing method + shrink foil
= optimum protection during transport

All Round Protection

In addition to packaging in accordance with the DENSOPACK® system, corner protection is affixed to the pallet. This can be an effective way of preventing broken glass and lateral shifting of separate bundles. Even more effective transportation protection can be achieved by then also wrapping the entire pallet with SCHOTT DENSOPACK® shrinking foil. This packing ensures that the FIOLAX® special glass tubing reaches the customer in the same quality as it has left the production at SCHOTT-Rohrglas.

Corner protection for pallets reduces the risk of breakage and of the individual bundles moving sideways.

Certified Supplies

SCHOTT supplies on special pallets specifically adapted to the products. The pallets fit perfectly into standard containers and are ideally suited for storage.

Each pallet is provided with a pallet certificate containing the relevant product information specially classifying the glass tubes from a particular pallet: production date, dimensions, production and specification numbers.

In connection with the labeling of the DENSOPACK® units, pallet certification simplifies the customer's incoming goods control and internal documentation. In addition, this information simplifies the machinery set-up as the necessary data can be entered directly in the customer's own system. This provides extra security and saves time.

A service from SCHOTT:
each pallet comes with a pallet certificate containing important production data.

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