FIOLAX® clear with Controlled Hydrolytic Resistance (CHR)

General Product Information

The increasing demand of a reduced sodium release from glass led to the development of a FIOLAX® clear tubing with controlled hydrolytic resistance (CHR) of the inner surface. This quality feature enables the converting process based on a known and defined low sodium release from the starting material. For the first time, not only the hydrolytic resistance of the glass grains, but also from the inner surface is monitored and specified for the glass tubing – therefore: The best quality right from the start! The composition, chemical as well as physical properties of Type I borosilicate FIOLAX® clear glass remain fully untouched, hence FIOLAX® clear CHR can be used without any need to change registration files.

Value-adding Product Benefits

Guaranteed quality right from the start
The specification of a limit for the hydrolytic resistance of the inner surface of the tubing sheds light into this so far unknown aspect – always guaranteed by a certificate.

Applicable to registered products
FIOLAX® clear tubing can be replaced by FIOLAX® clear CHR tubing without the need of a new registration of the pharmaceutical product.

Superior product quality especially for sensitive formulations
FIOLAX® clear CHR is especially beneficial for highly demanding formulations, which are sensitive towards extractables such as sodium, e.g. biotech drugs or pH sensitive / unbuffered formulations.

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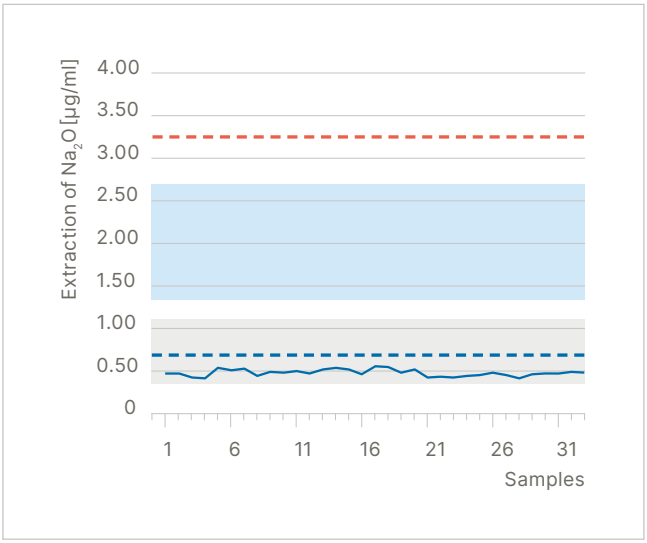
FIOLAX® clear CHR

Facts at a Glance

Verification

The hydrolytic resistance of the inner surface of a container is composed by two different aspects – the initial level of the tubing as well as the influence of the converting process. Whereas many efforts were made optimizing the production process of a container, the level of the glass tubing at the beginning mostly remains an unknown aspect.
By implementing a tighter process control during tube production as well as the introduction of the inner surface test parallel to the tubing production, it is now possible to guarantee a tubing with a specified, low sodium release of the inner surface. Exemplarily, measurement data of tube sections acc. to ISO 4802-2:2016 of FIOLAX® clear CHR are shown in the graph (referring to 2R vial dimensions: outside diameter 16.00 mm, wall thickness 1.00 mm). The data reveals that it is possible to specify a limit of 0.70 µg/ml for this tubing dimension, which is below 25 % of the ISO 4802-2 limit for a 2R vial.



Availability

FIOLAX® clear CHR tubing is produced according to the current Technical Performance Specification (TPS) for pharmaceutical Type I glass tubing including SCHOTT perfeXion® technology. It is available within our Best value ❗ customizing options for FIOLAX® clear CHR for an outside diameter range of 6.85 mm up to 50.00 mm.

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Test and Specification

For FIOLAX® clear CHR a limit for the sodium extraction from the inner surface acc. to ISO 4802-2:2016 is specified. Since the release depends on the tubing diameter, the limit is specific for each dimension and is adapted to tubing. The limits of standard sizes are displayed in the table below, customized dimensions are also available upon request. After autoclaving with purified water for 1 h at 121 °C the amount of sodium oxide in the extraction solution is determined by means of flame spectrometry and expressed as micrograms of Na_2O per milliliter of extraction solution [µg/ml], which is equivalent to parts per million [ppm].

CHR certifed

For each delivery of FIOLAX® clear CHR tubing a Certificate of Conformity (CoC) will be supplied.

	Container Size [ml]*	Outside Diameter [mm]	Inside Diameter [mm]	Wall Thickness [mm]	Limit Value for HC_F 1 acc. to ISO 4802-2 [µg/ml]	Limit Value for FIOLAX® clear CHR Tubing [µg/ml]
Syringe 	0.50	6.85	4.65	1.10	5.00	2.20
	1.00	8.15	6.35	0.90	4.50	1.60
	1.00 / 2.00 / 2.25 / 3.00	10.85	8.65	1.10	4.50 / 4.10 / 4.10 / 3.20	1.20
	5.00	14.45	11.85	1.30	2.50	0.90
	10.00	17.05	14.25	1.40	2.00	0.80
	20.00	22.05	19.05	1.50	1.50	0.60
Cartridge 	1.50	8.65	6.85	0.90	4.50	1.40
	3.00	11.60	9.70	0.95	3.20	1.00
	10.00	22.05	19.05	1.50	2.00	0.60
Vial 	2R / 3R / 4R	16.00	14.00	1.00	3.20 / 3.20 / 2.50	0.70
	6R / 8R	22.00	20.00	1.00	2.50 / 2.00	0.50
	10R / 15R	24.00	22.00	1.00	2.00 / 2.00	0.50
	20R / 25R / 30R	30.00	27.60	1.20	1.50 / 1.50 / 1.50	0.50
	50R	40.00	37.00	1.50	1.50	0.50
	100R	47.00	43.60	1.70	1.20	0.50
Ampoule 	1.00	10.75	9.75	0.50	4.50	1.00
	2.00	10.75	9.75	0.50	4.10	1.00
	5.00	14.75	13.65	0.55	2.50	0.80
	20.00	22.50	21.10	0.70	1.50	0.50

* acc. to ISO 11040-4 (syringes), 8362-1 (vials), 9187-1 (ampoules)

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SCHOTT AG, Erich-Schott-Strasse 14, 95666 Mitterteich, Germany

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