

cartriQ[®]

Sterile pharmaceutical cartridges for peptide and protein-based injectables



- Pre-washed, depyrogenated, siliconized, pre-crimped, and steam sterilized cartridges
- Ideal for a broad range of hand-held injection devices such as pens and autoinjectors
- Highly standardized, nested tub configuration to eliminate glass-to-glass contact
- Advanced baked-on siliconization process to reduce the amount of free silicone
- 3" tub and nest according to the global ISO standard 11040-7 "Prefilled syringes" and compliant with ISO 21881 "Sterile packaged ready for filling glass cartridges"

Material data

Tubing	SCHOTT FIOLAX [®] CHR clear Improved Borosilicate tubing glass (Type I) with Controlled Hydrolytic Resistance (CHR)	First hydrolytic class according to EP, USP and JP in its current version
Cartridge	<ul style="list-style-type: none"> • 1.5 ml pen cartridge OD 8.65 mm; ID* 6.85 mm; L 56.95 mm; for 8 mm crimp • 3.0 ml pen cartridge OD 11.60 mm; ID* 9.7 mm; L 62.3 mm; for 8 mm crimp • 5.0 ml pen cartridge OD 14.00 mm; ID* 12 mm; L 65 mm for 8 mm crimp • 5.0 ml wearable cartridge OD 17.05 mm; ID* 14.25 mm; L 70 mm; for 13 mm crimp • 10.0 ml wearable cartridge OD 22.05 mm; ID* 19.05 mm; L 68.70 mm; for 13 mm crimp OD = outer dimension; ID = inner dimension; L = length	Glass Container: 80% of USP 660; EP 3.2.1; JP 7.01
Break-Loose Force**	Pen ≤ 10 N; Test speed 100 mm/min Wearable ≤ 15 N; Test speed 100 mm/min	acc. to ISO 21881 empty cartridge, dry, de-crimped state
Gliding Force**	Pen ≤ 3 ml ≤ 5.5 N; Test speed 100 mm/min Pen ≤ 5 ml ≤ 6 N; Test speed 100 mm/min Wearable ≤ 10 N; Test speed 100 mm/min	
Recommend stopper & plunger combinations	<ul style="list-style-type: none"> • Dätwyler drug contact rubber with corresponding plunger: FM457/0 grey FirstLine™ (WEST on demand) • Dätwyler Al cap: clear lacquer (WEST on demand) 	Tightness acc. to ISO 21881 Self-sealing acc. to ISO 21881 Fragmentation/coring derived from ISO 11608-3

* Best Value ID optionally available custom

** acc. To recommended plungers

SCHOTT
PHARMA

Nest	Polymer suitable for steam sterilization	Polymers according to USP <88> class VI and ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity Design acc. ISO 21881 and ISO 11407 (syringes)
Tub	Polymer suitable for steam sterilization	
Seal & Inlay	Tyvek® – High-density polyethylene (HDPE)	
Bag	Tyvek® – High-density polyethylene (HDPE)	
Transport box	Akylux® – Corrugated polypropylene (PP)	

Sterilization

Sterilization method	Moist heat	ISO 17665 “Sterilization of health-care products – moist heat”
Sterility assurance level	< 10 ⁻⁶ ; Overkill approach using biological indicators	ISO 17665 “Sterilization of health-care products – moist heat”
Endotoxines	< 0.25 EU/ml	Limit values according to ISO 11040-4, USP 1231, USP 85
Documentation creation	Certificate of processing	ISO 17665 “Sterilization of health-care products – moist heat”
Documentation verification	Parametric release	ISO 17665 “Sterilization of health-care products – moist heat”

Storage and transport recommendations

- Temperature range for long term storage (more than 60 days) is defined within > 15 °C and < 30 °C
- During transport it is allowed to deviate from this requirement
- Storage shall be always above the dew point
- Avoid long term storage with exposure to sunlight
- The goods shall be stored in normal warehouse environment (no contaminants in the atmosphere) with pest control in place
- Shelf life is initially two years from date of production and certified in CoC
- Avoid mechanical stress throughout all process steps

Pitch pattern



General ordering information

Quality level	TopLine				
Packaging	Akylux® boxes with 15 nests per box Online-shop 3.0 ml Dätwyler: 6 nests for human-use applications (FHU)				
Palletizing	Standard Euro pallet (1200 x 800 mm) contains 15 boxes of 15 nests each				
Formats	1.5 ml	3.0 ml	5.0 ml	5.0 ml	10.0 ml
Pieces per pallet	36,000	22,500	18,000	10,800	9,000

3.0 ml configuration with combi-seal & plunger is available in small quantities as “Fast Track Article”.

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

schott-pharma.com/cartriq

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carbon neutral
natureplac.com | 04-07/2023/010
print production

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FSC C008855
www.fsc.org

ENGLISH 07/2023 km/nino Printed in Germany