

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)	

SCHOTT
PHARMA

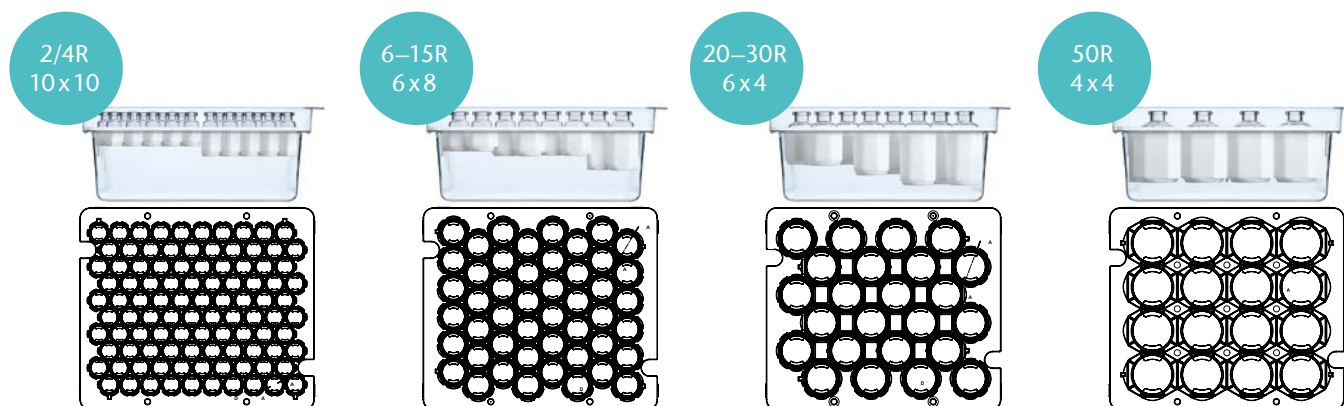
Sterilization and residuals

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

**SCHOTT
PHARMA**

carbon neutral
natureplac.com | 04-47/2022/10
print production

MIX
FSC
FSC® C008855
recycled