QUALIKAP QKP-F

Hydrophilic PVDF capsule filters

- Testable in situ
- Autoclave sterilizable
- Sanitizable
- Thermowelded assembly
- EC-listed materials for food contact
- FDA-listed materials per CFR21
- Extractables as per USP for plastic materials
- Validation Guide available
- Low extractables

QUALIKAP QKP-F capsules are especially designed to be used as sterilizing final filter for small batches in pharma and food applications. QUALIKAP QKP-F are fitted with a pleated hydrophilic PVDF membrane filter element, which guarantees enhanced microbiologic retention.
Typical applications are alcoholic solutions , ultra pure water, vaccines, physiological solutions, ophthalmic liquids and lab batches purification process, etc.
The manufacturing is done in a controlled environment; each filter element is tested to verify the integrity.
Each capsule is supplied with conformity test certificate showing the lot.

MATERIALS OF CONSTRUCTION

Membrane	hydrophilic PVDF membrane
Upstream drainage layers	polypropylene
Downstream drainage layers	polypropylene
Core and Cage	polypropylene
Outer Shell	polypropylene
Terminals	polypropylene

FOOD-SAFETY

The materials used for QUALIKAP-QKP-F are in compliance with EU regulation 10/2011 and its amendments, and with regulations (EC) 1935/2004 and 1895/2005.

BIO-SAFETY AND EXTRACTABLES

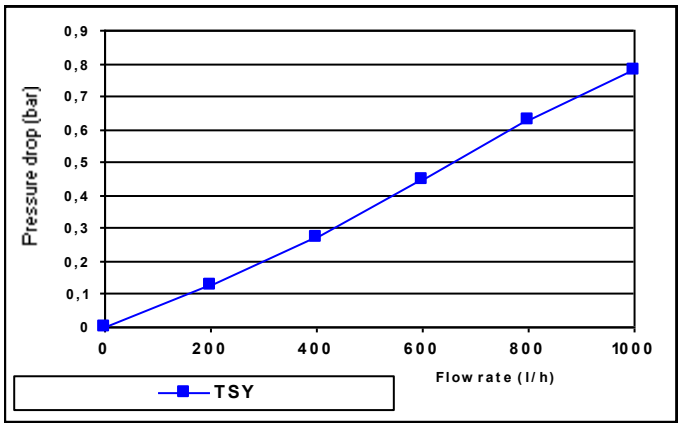
- Materials are compliant to USP-VI CLASS toxicological requirements and USP-Plastic Materials chemical and physical requirements.
- Capsule filters meet USP "Water for injection" requirements for endotoxin particle release; the bacterial endotoxin are determined using LAL Test.
- Extractable NVR (gravimetric) after autoclave ≤ 2 mg.
- TOC and conductibility according USP "Purified water" and "Water for Injection" requirements.

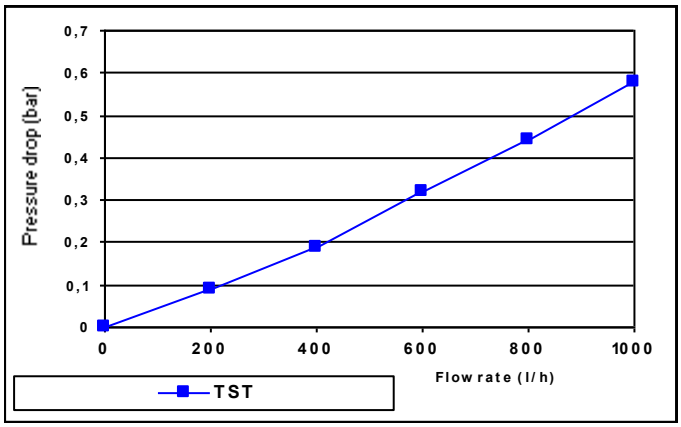
RECOMMENDED OPERATING CONDITIONS

- max. continuous temperature	40 °C
- max. cumulative time of steam sterilization (no in line sterilization available)	16 hours at 125 °C or 8 hours at 135 °C (30' cycle)
- max. pressure	5 bar at 40 °C
- chemical sanitization	compatible with a wide range of sanitizers
- forward flow max. differential pressure	4,5 bar at 40 °C
- reverse flow max. differential pressure	1,0 bar at 40 °C
- recommended pressure drop for changeover	2,0 bar at 40 °C
- in situ recommended flushing volume	1 liter

CODE	ABSOLUTE FILTRATION GRADE IN LIQUIDS	BACTERIAL REDUCTION CHARGE >10^7 CFU/cm^2 *	ACCEPTANCE LIMIT FOR DIFFUSION TEST (ml/min)
TSY	0,2 µm	Brevundimonas diminuta	≤ 13.0 @ 2,3 bar
TST	0,45 µm	Serratia marcescens	≤ 8.0 @ 1,5 bar
* according ASTM F838			

WATER FLOW RATE CHARTS





QUALIKAP QKP-F ORDERING INFORMATION

QKP - F - 2 S - X P TSY - PH

OUTER SHELL	CODE
polypropylene	**P**

MEMBRANE FILTER	CODE
PVDF	**F**

NOMINAL LENGHT	CODE
175 mm	**2**

Vent-Draining valve—O Rings	CODE
Silicone	**S**

FILTER ELEMENT ASSEMBLY	CODE
Thermowelded	**X**

TERMINALS FILTER ELEMENT	CODE
polypropylene	**P**

FILTRATION GRADE micron	CODE
0,2	**TSY**
0,45	**TST**

CODE	PRODUCT GRADE
PH	Fluxed and tested with apirogen water , Quality certificate in the box

- Max diameter (valves included): 117 mm
- Tri-clamp connections 1 1/2”

DS-QKP-635-EN-25

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