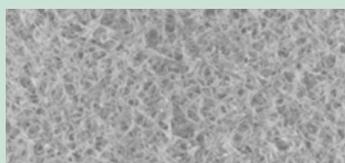
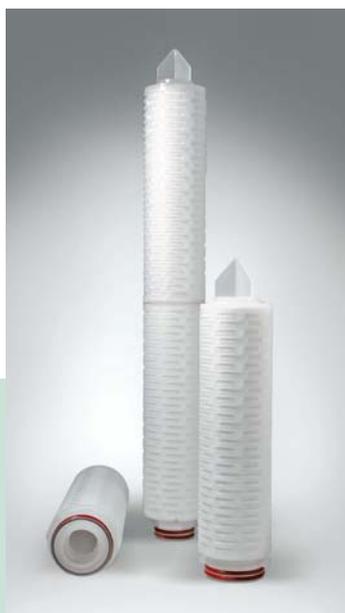


EPM.K (KFM.K)

0.2 µm and 0.45 µm Polyamide membrane two-layers Filter Cartridges and Capsules

For clarifying and sterilizing filtration of pharmaceutical preparations



Description

EPM.K membrane filter cartridges are produced by the proprietary technology of Technofilter on the basis of two layers of hydrophilic polyamide membrane with the micron rating of 0.2 µm and 0.45 µm. Filter cartridges have high throughput and high chemical resistance to organic solvents and alkali.

A polyamide hydrophilic membrane makes EPM.K the best option for application in the processes of large volume filtration of parenteral preparations, antibiotics, water and alkaline solutions.

Features and advantages

Features	Advantages
Proprietary polyamide hydrophilic membrane Nylon ₆₊₆₆	<ul style="list-style-type: none"> • High lifetime and filtration rates at low differential pressure; • Wide chemical compatibility; • Easy to wet to perform the filtration and tests.
Reliable checked characteristics of the 0.2 µm membrane	<ul style="list-style-type: none"> • Comply with the requirements of the directive of the Association of Manufacturers of Medical Industry on microbiological examination of 0.2 µm filters for sterilizing filtration of liquids; • Confirmation of sterilization capability on the basis of the integrity test results.
High strength of the structure of the cartridge	<ul style="list-style-type: none"> • Reliable maintenance of filter integrity under heavy duty operational conditions; • Able to withstand steam sterilization.
100 % control Apyrogenic	<ul style="list-style-type: none"> • Guaranteed integrity and efficient operation of the product; • Provide full retention of bacteria, bacteriophages and particles in high flow rate processes of liquids filtration; • Passed all necessary tests for biological safety, extractability, pyrogene and fiber emission; • Provided with necessary quality certificates.

Specifications

Micron rating

prefilter/filter

0.2/0.2 µm
0.45/0.2 µm
0.80/0.45 µm

Nominal Dimensions and Filter Areas

Filter Cartridges

H, mm	D, mm	S, m ²
100 (4")	70	0.27
250 (10")	70	0.75
500 (20")	70	1.5
750 (30")	70	2.25
1000 (40")	70	3.0

Capsule filters

H, mm	D, mm	S, m ²
250 (10")	94	0.75
125 (5")	92	0.34
60 (2,5")	92	0.14

H - height
D - diameter
S - filtration surface area

Cartridge materials

Membrane	Nylon ₆₊₆₆ (the second layer)
Prefilter membrane	Nylon ₆₊₆₆ (the first layer)
Draining layer	Polypropylene
Body, end parts, adapter	Polypropylene
Supporting (encapsulated) adapter ring	Stainless steel
O-rings	Silicone (other materials available)

Integrity test

In the course of industrial testing each membrane filter is integrity tested by the non-destructive physical method of determination of the rate of air passing through the water wetted membrane.

Sterilization capability test (Bacterial challenge test)

Bacteria removal test is performed for each series of 0.2 µm sterilizing filter cartridges passing the bacterial suspension of Brevundimonas diminuta in the amount of 10⁷ CFU/cm² through the cartridge. Confirmed test results correlate with the integrity test.*

* According to GOST R ISO Aseptic processing of healthcare products. Part 2. Filtration.

Integrity test values of EPM.K, 250 mm height

Brand	Max. diffusion, ml/min	Test pressure, MPa (bar) at 20 °C
EPM.K-/020	15*	0,25 (2,5)
EPM.K-/045	15	0,16 (1,6)

* This threshold diffusion value ensures 100 % retention of Brevundimonas Diminuta bacteria of the concentration of T_R>10⁷ CFU/cm².

Bacterial endotoxins (pyrogenicity)

Filtrate samples are examined for bacterial endotoxin (BE) content using the LAL test. BE content – 0.05 EU/ml, the allowable value for water intended for preparation of injection solutions is less than 0.25 EU/ml.

Operational parameters

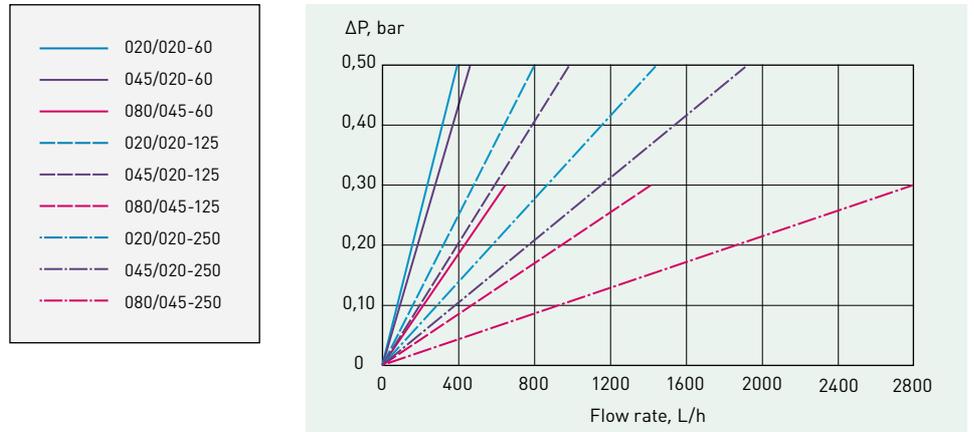
Maximal differential pressure	0.5 MPa at 20 °C, 0.2 MPa at 80 °C (Filter Cartridges) 0.4 at 20 °C, 0.2 MPa at 60 °C (Capsules)
Maximal reverse differential pressure	0.1 MPa at 20 °C
Maximal operational temperature	80 °C (Filter Cartridges), 60 °C (Capsules)

Sterilization and washing

Direct flow wash out	Hot water (up to 80 °C) and chemical agents (pH 3-14)
Autoclaving	121 °C, 0.12 MPa, 30 min, 20 cycles (Filter Cartridges) 121 °C, 0.12 MPa, 30 min, 5 cycles (Capsules)
Steam sterilization*	121 °C, 0.12 MPa, 30 min, 10 cycles

* Only for filter cartridges

Flow Rates of EPM.K



Filter Cartridges ordering information

EPM.K	045/020	D1	250	M
Brand	Micron rating, prefilter/membrane	Adapter code	Cartridge height	Application
	Code	D	100 mm (4")	M - medicine industry and biopharmaceutical industry
	020/020 0.2/0.2 μm	D1	125 mm (5")	
	045/020 0.45/0.2 μm	A1	250 mm (10")	
	080/045 0.8/0.45 μm	A4	500 mm (20")	
		A	750 mm (30") 1000 mm (40")	

Capsules ordering information

KFM.K	045/020	K	60
Brand	Micron rating, prefilter/membrane	Connection type	Cartridge height
	Code	K – sanitary flange connection	60 mm
	020/020 0.2/0.2 μm		125 mm
	045/020 0.45/0.2 μm		250 mm
	080/045 0.8/0.45 μm		