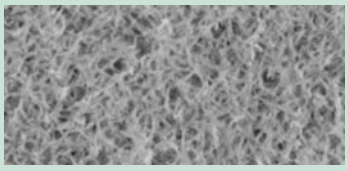
EPM.K⁺ (KFM.K⁺)

Zeta Potential Polyamide membrane Filter Cartridges and Capsules

For sterilizing filtration with pyrogenicity control, removal of viruses from pharmaceutical preparation



Description

An EPM.K⁺ is a membrane cartridge on the basis of positively charged (Zeta potential) polyamide membrane for removal of endotoxins and viruses from pharmaceutical class water systems. Positively charged membrane surface ensures retention of not only particles and microorganisms, but also bacterial endotoxins (pyrogenes), viruses and molecules that are not retained by a standard sterilizing microfilter.

Features and advantages

Features	Advantages
Proprietary hydrophilic polyamide membrane with modified charge ($Nylon_{6+66}$).	• Reliable sterilizing filtration with pyrogenicity control; • Effective removal of negatively charged viruses, molecules, endotoxins, bacteria, particles and biological contaminations; • Wide chemical compatibility; • Easy to wet to perform the filtration and tests.
Reliable checked characteristics of the 0.2 µm membrane	• Comply with the requirements of the directive of the Association of Manufacturers of Medical Industry on microbiological challenge of 0.2 µm filters for sterilizing filtration of liquids; • Confirmation of sterilization capability on the basis of the integrity test results.
Large filtration surface area	• High lifetime and filtration rates at low differential pressure.
High strength of the structure of the cartridge	• Reliable maintenance of filter integrity in arduous conditions; • Withstands multiple sterilization and washing.
100 % integrity control, before and after filtration	• Guaranteed efficient operation of the product.
Developed and adapted for pharmaceutical and bioengineering industries	• Materials used in the filter structure passed tests for biological safety, contain minimal amount of extractable components and are qualified for contact with intravenous preparations and food products.

Specifications

Micron rating

prefilter/filter

0.2/0.2 μm
0.45/0.2 μm
0.45 μm

Nominal Dimentions 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

General applications

- Filtration of injections and infusion solutions with pyrogenicity control;
- Sterilizing filtration of low seminated solutions;
- For removal of mycoplasms, viruses and bacterial endotoxins from water solutions;
- Continuous sterilizing filtration in water treatment systems;
- Production of deionized water / water for injections.

Materials

Membrane	$Nylon_{6+66}$ with positive Zeta potential
Prefilter membrane	$Nylon_{6+66}$ with positive Zeta potential
Draining layer	Polypropylene
Body, end parts	Polypropylene
O-rings	Silicone (other materials are available by request)

Integrity test values of one-layer EPM.K⁺ with the height of 250 mm

Brand	Max. diffusion, ml/min	Test pressure, MPa (bar)
EPM.K⁺-/020	15*	0.25 (2.5) at 20 °C
EPM.K⁺-/045	15	0.16 (1.6) at 20 °C

* This threshold diffusion value ensures 100 % retention of Brevundimonas Diminuta bacteria in the concentration of T_R>10^7 CFU/cm^2.

Bacterial endotoxins (pyrogenicity)

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

Operational parameters

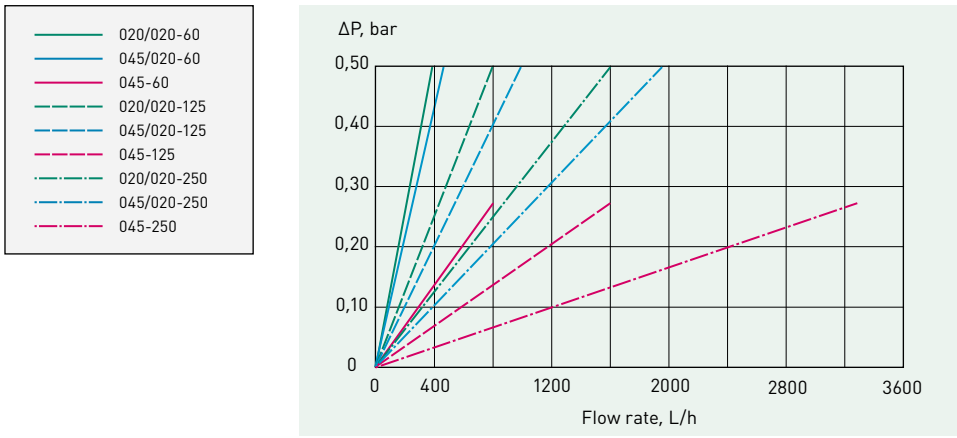
Maximal differential pressure	0.5 MPa at 20 °C, 0.2 MPa at 80 °C (Filter Cartridges) 0.4 MPa at 20 °C, 0.2 MPa at 60 °C (Capsules)
Maximal reverse differential pressure	0.1 MPa at 20 °C
Maximal operational temperature	80 °C (Filter Cartridges), 60 °C (Capsules)

Sterilization and washing

Direct flow wash out	Hot water (up to 80 °C) and chemical agents
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⁺ and KFM.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")	
	045	0.45 µm	A4	500 mm (20")	
				750 mm (30")	
				11000 mm (40")	

Capsules ordering information

KFM.K⁺	045/020		K	60
Brand	Micron rating		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	P – thread tapered connection	250 mm
	045	0.45 µm		