

## BIOKLARIS Evo PHARMA

- PES membrane optimized for pharmaceutical use
- Easy integrity testable in situ
- High effective filtration area
- Repeatedly steamable in situ or in autoclave
- Thermowelded construction (without resins or adhesives)
- Preflushed with pyrogen-free water



BIOKLARIS Evo PHARMA filter element was developed to meet the specific requirements of the pharmaceutical industries .

Designed to guarantee greater mechanical resistance it is indicated for the treatment of WFI water and aqueous solutions for drugs manufacturing.

The asymmetrical polyethersulfone membrane combined with the high effective filtration area is able to guarantee excellent performances and to assure the filtrate sterilization.

The removal of microorganisms is guaranteed by bacterial challenge tests according to ASTM F 838, reported in the "Validation Guide".

BIOKLARIS Evo PHARMA filter elements can be repeatedly sterilized with steam or sanitized with chemical products and can be regenerated with soda solutions .

Manufacturing is realized in a Certified clean room, with constant monitoring of all production parameters.

### MATERIALS OF CONSTRUCTION

<b>Membrane</b>	PES (hydrophilic)
<b>Upstream supports</b>	polypropylene
<b>Downstream supports</b>	polypropylene
<b>Internal Core</b>	polypropylene
<b>External Cage</b>	polypropylene
<b>End caps</b>	polypropylene

### FOOD-SAFETY

The materials used for the BIOKLARIS Evo PHARMA cartridges are in accordance with the D.M. 21/3/73 (S.O. no.104 of 20.04.73) and subsequent updates, to the European regulation (EU) 10/2011 and subsequent updates, to the regulations (EC) 1935/2004 and 1895/2005.

The materials used in the construction of the BIOKLARIS Evo PHARMA comply with the FDA requirements for food contact according to CFR21 170-199.

### RECOMMENDED OPERATING CONDITIONS

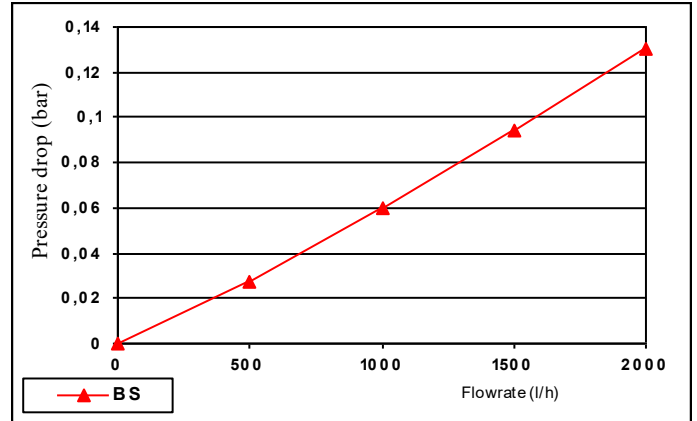
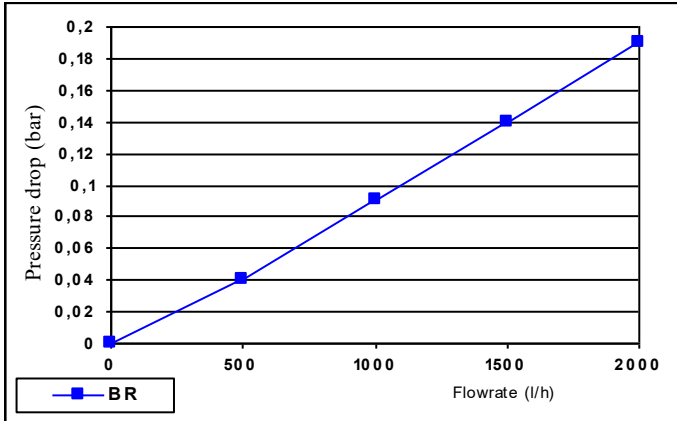
- max. continuous temperature	75 °C
- max. cumulative number of steam sterilization cycles	≥100 hours at 121 °C, ≥80 hours at 125 °C, with max ΔP 0,3 bar (cycles of 60 minutes)
- sanitization with hot water	90 °C max
- sanitization with chemicals	can be sanitized by standard chemical agents
- regeneability	NaOH solution up to 3% at 85 °C
- max. differential pressure	5,0 bar at 25 °C and 1,0 bar at 90 °C
- recommended change out differential pressure	2,0 bar at 25 °C

### INTEGRITY TEST DATA

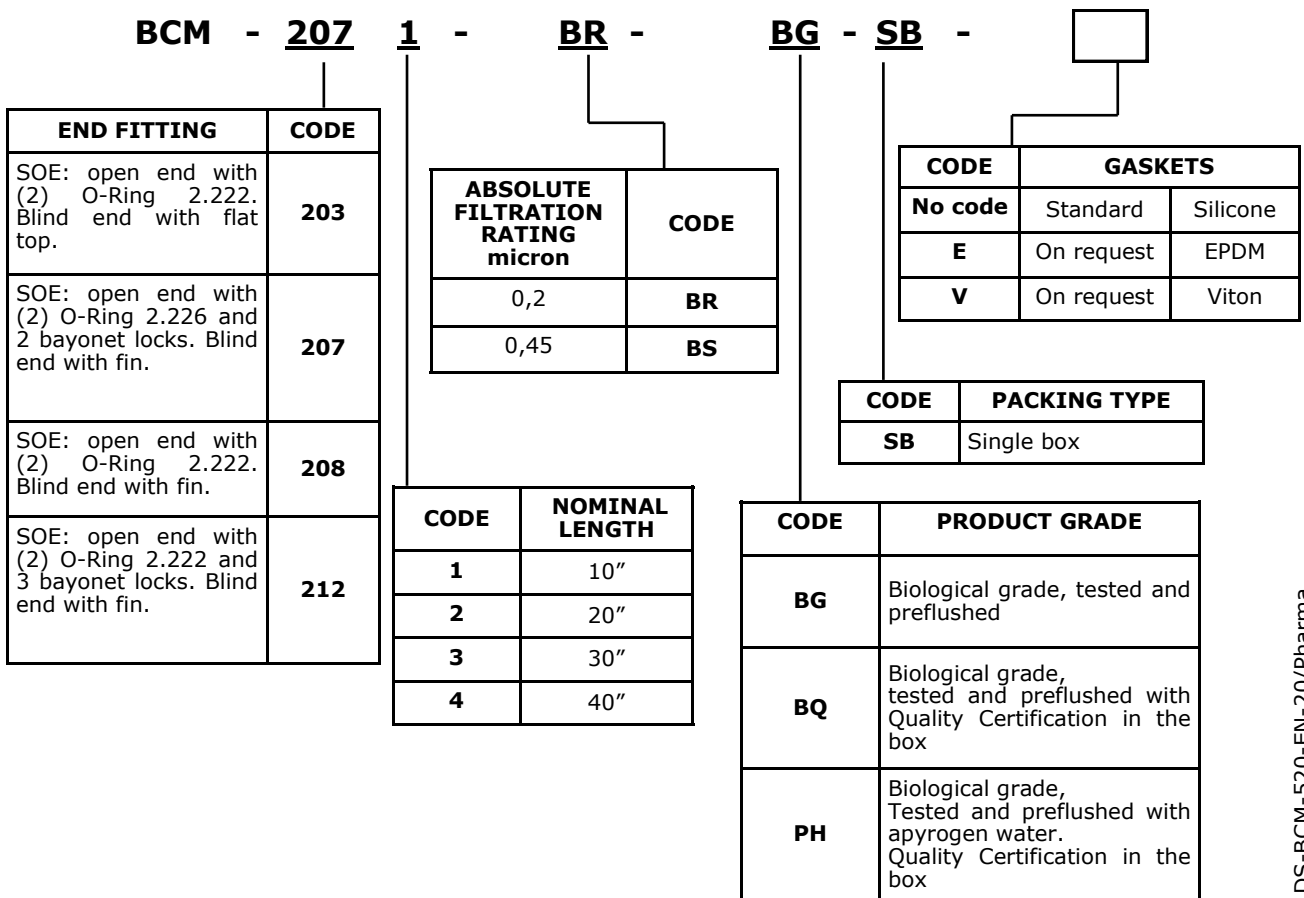
CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION >10 <sup>7</sup> CFU/cm <sup>2</sup> *	ACCEPTABLE LIMITS FOR DIFFUSION TEST WITH WATER FOR 10" CARTRIDGE (ml/min)
BR	0,2 µm	Brevundimonas diminuta	≤25 @ 2,3 bar
BS	0,45 µm	Serratia marcescens	≤20 @ 1,7 bar

\* AS PER ASTM F838

## WATER FLOW RATE FOR 10" CARTRIDGE



### BIOKLARIS Evo PHARMA NUMBER ORDERING INFORMATION



DS-BCM-520-EN-20/Pharma

#### TRACEABILITY

In order to ensure the complete traceability, each filter element is identified with Part Number, lot number, serial number and filtration rating.

#### QUALITY

Each filter element is tested during production and before final packaging.

Data contained in this bulletin are informative and subject to change without notice. User is responsible for determining whether the product fits for particular purpose and is suitable for User's applications



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