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
- Materials suitable for applications in the pharmaceutical field



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

Membrane	PES (hydrophilic)
Upstream supports	polypropylene
Downstream supports	polypropylene
Internal Core	polypropylene
External Cage	polypropylene
End caps	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.

BIO-SAFETY

Filter media and components pass USP CLASS VI Biological Reactivity and Chemical-Physical tests for USP plastics.
Specific for "PH" grade: the filter meets USP "Water for injection" requirements for particle release and the effluent is Non-Pyrogenic per USP Bacterial Endotoxins (< 0,25 EU/ml).

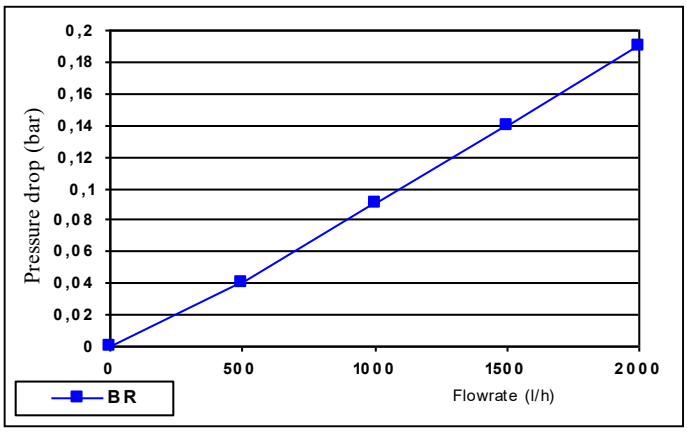
RECOMMENDED OPERATING CONDITIONS

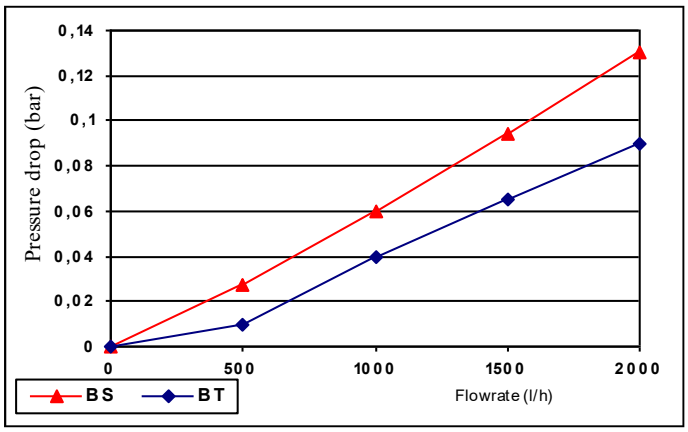
- max. continuous temperature	75 °C
- max. cumulative number of steam sterilization cycles	≥100 hours at 121 °C, ≥80 hours at 125 °C*, with max ΔP 0,3 bar (cycles of 60 minutes)
- sanitization with hot water	90 °C max
- sanitization with chemicals	can be sanitized by standard chemical agents
- regeneability	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
* maximum in-line sterilization temperature	

INTEGRITY TEST DATA

CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION $>10^7$ CFU/cm^2 *	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
BT	0,65 µm	N.A.	≤20 @ 1,1 bar
* AS PER ASTM F838			

WATER FLOW RATE FOR 10" CARTRIDGE





BIOKLARIS Evo PHARMA NUMBER ORDERING INFORMATION

BCM - 207 1 - BR - PH - SB - ☐

END FITTING	CODE
SOE: open end with (2) O-Ring 2.222. Blind end with flat top.	**203**
SOE: open end with (2) O-Ring 2.226 and 2 bayonet locks. Blind end with fin.	**207**
SOE: open end with (2) O-Ring 2.222. Blind end with fin.	**208**
SOE: open end with (2) O-Ring 2.222 and 3 bayonet locks. Blind end with fin.	**212**

ABSOLUTE FILTRATION RATING micron	CODE
0,2	**BR**
0,45	**BS**
0,65	**BT**

CODE	NOMINAL LENGTH
1	10"
2	20"
3	30"
4	40"

CODE	PRODUCT GRADE
PH	Biological grade, Tested and preflushed with apyrogen water. Quality Certification in the box

CODE	GASKETS	
No code	Standard	Silicone
E	On request	EPDM
V	On request	Viton

CODE	PACKING TYPE
SB	Single box

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.

Bea Technologies Spa
Via Newton,4 -20016 Pero (MILANO) Italy
Tel.+(39) 02 339271 / Fax+(39) 02 3390713
mail:info@bea-italy.com
web:www.bea-italy.com

The data are informative and subject to change without notice. User is responsible for determining whether the product is fit for particular purpose and suitable for User's method of application.