Van Borselen Polymeric Filter Cartridges

BorsoPes-BM
Easy-wet PES Filter Capsules

SUPPORT
- Process Validation
- Trouble Shooting
- Filterbility
- Onsite Testing
- Sizing

VALUE
- Competitive Pricing
- Robust
- Low Operational Costs
- Short Lead Times

- High flow rates at low pressure drops vs other membrane materials
- Superb chemical and thermal compatibility
- Easi-Wet technology for rapid integrity testing
- Membrane is fully validated to retain bacteria
- Meets latest EC food contact guidelines
- Available in a range of sizes and pore ratings
- Available with a range of adaptors, seals and in capsule format

BorsoPes-Biological-BM, Easi-Wet, PES membrane filters offer a key benefit that overcomes a major drawback of similar filter cartridges from competitors; they can be rapidly wetted and integrity tested with minimal usage of water. Facilities from breweries to pharmaceutical plants can benefit from consistently rapid integrity tests with integrated wetting, testing and flushing available with Van Borselen Intelligent Integrity Test (IIT) technology. IIT is a complete solution from housing and rig design to filter cartridge setup and testing of filters.

PRODUCTS
- PTFE, Metallic Housing
- Integrity Testers
- Polymeric and Metal Media

QUALITY
- GMP Manufacture
- ISO Class Cleanroom
- Validated Products
- EC 01/2011

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BorsoPes-BM filter cartridges are manufactured with a polyethersulfone (PES) membrane that allows a high flow with minimal pressure drop while ensuring full retention of contaminant bacteria and yeast. BorsoPes-BM PES membrane has low-binding characteristics that offer a significant reduction in flavour and colour loss in comparison to alternative materials.

BorsoPes-BM filter cartridges can be wetted with as little as 5 litres of water when incorporated into Van Borselen Filtration's Intelligent Integrity Test (IIT) system; wetting and testing can take place in a single operation driven by the test instrumentation. The cartridges are uniquely constructed using a propreitary process to ensure that they are easily wetted for consistent integrity testing.

Features and Benefits

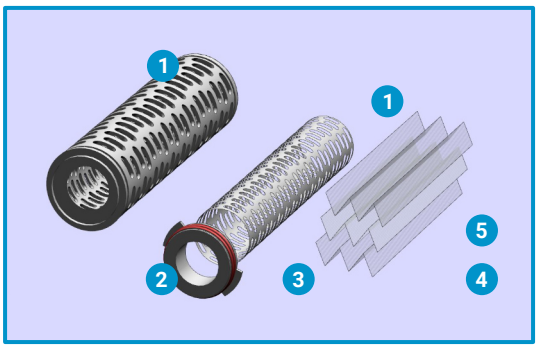
- Robust construction to withstand high pressure drops and chemical and thermal stress
- Simplified and rapid integrity testing
- Minimal adsorption of product
- High flow with a low pressure drop
- True sterile filtration at each micron rating
- Variety of connections to retrofit major competitors
- Also available in single-use capsule format

Materials of construction and regulatory standards

Purpose	Materials	Regulatory Standards
Hardware (core, cage, endcaps)	Polypropylene (including HT (high tempearture))	USP VI, ISO 10093, FDA CFR Title 21, EC 10/2011
Membrane	Polyethersulfone	USP VI, FDA CFR Title 21, EC 10/2011
Support Layer	Polypropylene	USP VI, FDA CFR Title 21, EC 10/2011
Seal Materials	Viton, Silicone, PFA, EPDM	USP VI, FDA CFR Title 21 (EPDM incompatible with Hexane extraction test)

Traceability and Integrity

- Test parameters correlate with retention of bacteria at each grade.
- Each individual module of every cartridge is tested to ensure that there is no risk of 'masking' of defective modules within a cartridge.
- Each module is marked with a batch and unique number that allows full traceability.



Finite Element Analysis optimised polypropylene cage (1)

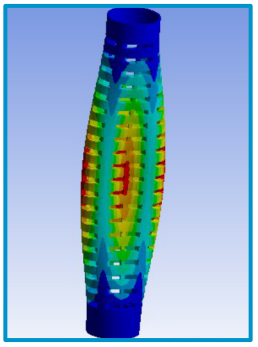
Stainless steel reinforced adaptor for multiple steam cycles (2)

FEA optimised polypropylene core (1)

Various seal materials available (3)

Polypropylene drainage and support layers (4)

Easi-wet PES membrane (4)



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Applications

Beer, Wine and Vinegar Filtration

The PES membrane used for BorsoPes-BM cartridges offers low adsorption characteristics that prevent the detrimental effects of sterile filtration on the organoleptic properties of wine. The efficient and robust membrane provides long filtration times and can be stored for months between filtration runs without degradation.

Food and Beverage Filtration

BorsoPes-BM cartridges are designed to withstand typical process chemicals used in food and beverages. They offer minimal ingredient adsorption for the make-up of buffers and growth media in biopharmaceutical applications.

Active Pharmaceutical Ingredients

BorsoPes-BM cartridges offer an economical solution for the filtration of aqueous API solutions. Easi-wet technology provides a rapid means to confirm sterility before and after batch filtration.

Water Filtration

BorsoPes-BM cartridges rated at 0.2 µm are designed to fully retain exceptionally small bacteria such as Pseudomonads that are frequently encountered as contaminants in purified USP water and, table and mineral waters.

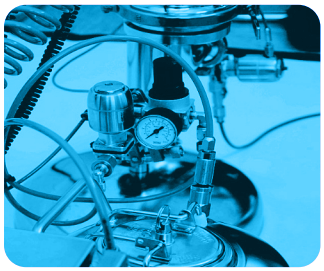
Electronics

BorsoPes-BM cartridges are flushed with low conductivity water and thus, suitable for the filtration of water and weak acid/alkali chemicals.

Regulatory Compliance

Materials approvals

- All materials of construction are compliant with FDA CFR Title 21, EC10/2011 and USP class VI
- Animal Ingredients where present meet requirements to ensure that they are free of BSE/TSE transmissible agents
- The materials of construction are free of melamine, bisphenol A and cyanuric acid
- The complete cartridges have been tested to ensure that Specific and Overall Migration Limits for both acidic and alcohol product in accordance with EC 10/2011, are not exceeded
- ISO class 8 cleanroom production
- Cartridges are flushed with purified water prior to packaging



Traceability and Integrity

To ensure that the filter cartridges are integral; each module of a cartridge is individually tested and uniquely labelled for full traceability. Onsite and laboratory-based qualification procedures (IQ, OQ and PQ) for integrity testing can be carried by Van Borselen Filtration to meet regulatory requirements. Process based qualification for bacterial retention, compatibility and extractables is available.

Steam sterilisation, autoclave and hot water sanitisation

Forward flow at 135ºC for 50 X 30 min cycles
Forward flow at 125ºC for 100 X 1 hour cycles
Autoclave at 135ºC for 50 X 30 min cycles
Hot water at 90ºC for 100 X 30 min cycles

Maximum and recommended operating pressures

Recommended max. differential pressure 2.1 bar
Maximum differential pressure 6.5 bar at 50ºC
Max. reverse differential pressure 2 bar at 50ºC

Nominal length (actual) for a 70mm diameter cartridge

5 in (124mm), 10 in (244mm), 20in (491mm), 30 in (738mm), 40 in (985mm), 50 in (1232 mm)

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Microbiological Security with Pharmaceutical GradeTesting	
Pore	**Microbial retention at ≥ log 7**
0.1 µm	Brevundimonas diminuta
0.2 µm	Brevundimonas diminuta
0.45 µm	Serratia marcescens/Oenococcus Oeni
0.65 µm	Saccharomyces cerevisiae
1.0 µm	Saccharomyces cerevisiae

Pore Size	Diffusive flow per 10 in module (at pressure)
0.1 µm	18 ml/min (2900 mbar)
0.2 µm	18 ml/min (1800 mbar)
0.45 µm	18 ml/min (1300 mbar)
0.65 µm	18 ml/min (800 mbar)
1.0 µm	18 ml/min (450mbar)

Media
BPBM

Length (in)	
1	10
2	20
3	30
4	40
05	5

Adapter style	
0	DOE
3	222/FLAT
8	222 + FIN
7	226 + FIN
2	226/FLAT
9	BS213/FLAT

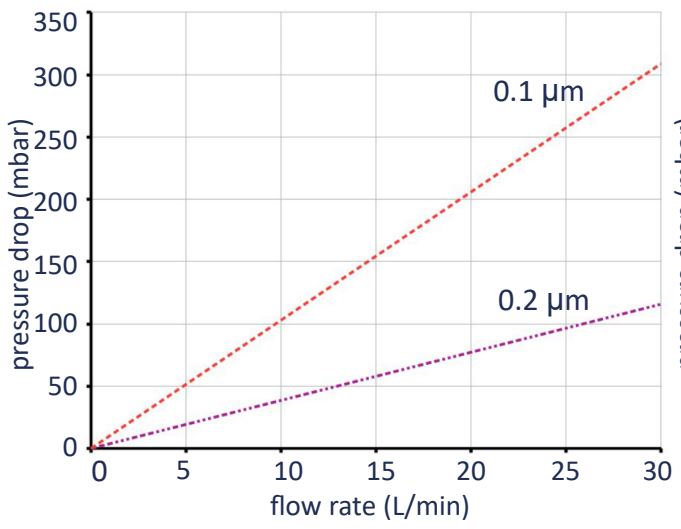
Seal	
EP	EPDM
SP	Silicone
VP	Viton
F	FEP

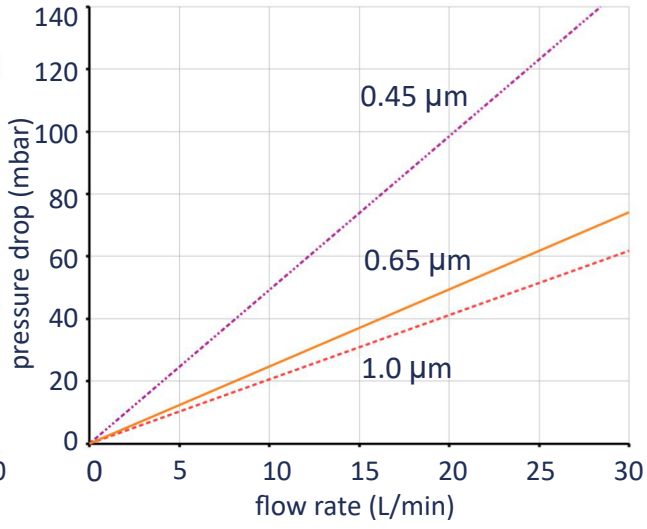
Micron Rating	
001	0.1
002	0.2
045	0.45
065	0.65
01	1

Example code
BPBM17SP002

PES membrane cartridge filter: 0.2µm pore size BS226 O-rings with a loca□on fin (code 7), 10 inches in length (6300 cm2 filter area) with silicone O-rings.

Flow vs. Clean Pressure Drop for a 10 inch Cartridge in Water





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