



Filtros PROPOR® BR

Filtros Farmacéuticos para Líquido de Polietersulfona

Filtros PROPOR® BR diseñados específicamente para reducir la carga biológica de soluciones farmacéuticas de forma rápida, efectiva y económica

Cuentan con una capa de prefiltrado hecha de tejido meltblown integral. Esta capa atrapa la suciedad mientras que la membrana de polietersulfona garantiza una excelente protección microbiótica. La reducción de carga biológica de la membrana es mayor de 5. En conjunto, esto hace a los filtros PROPOR® BR perfectos para la reducción de carga biológica en LVPs previa a la terminal de esterilización.

Los filtros PROPOR® BR también resultan perfectos para la prefiltración y reducción de biocarga previa al uso de filtros de membrana esterilizante. PROPOR® BR son filtros robustos que garantizan un resultado consistente a lo largo de varios lotes.

Regulaciones

Los materiales farmacéuticos se han manufacturado de acuerdo con cGMP, se han enjuagado con agua purificada y se han validado antes de su envío.

Los materiales farmacéuticos se ajustan a los requerimientos relevantes de:

- 21CFR Parte 177
- USP Plastics Class VI
- 121°C y equivalentes ISO10993

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Principales Beneficios

- Retención de *Brevundimonas diminuta* con un LRV > 5 para una reducción de la carga biológica eficiente
- Capas de prefiltrado adicionales para un rendimiento excelente
- Bajas propiedades de unión para minimizar la pérdida de producto por absorción
- Las cápsulas de filtro MURUS y DEMICAP pueden ser esterilizadas por autoclave y por radiación gamma

Aplicaciones

- Filtrado para la industria farmacéutica
- Prefiltrado y reducción de carga biológica

Aplicaciones Técnicas Maquinsa, S.L. dispone de una zona de manipulación bajo norma ISO 9001/2015 y en la que se manipulan los materiales bajo las norma BPF (GMPs).

Bajo demanda podemos fabricar y manipular nuestros productos en sala blanca bajo norma. Nuestras plantas pueden ser auditadas a su requerimiento.

Relacionados



Sensores Parker
SciLog®



Sistemas de Laboratorio
Automáticos



Carcasas para Filtros
Parker

PROPOR BR Filters

- liquid filters
- polyethersulphone

PROPOR BR filters have been specifically designed for the fast and cost-effective bioburden reduction of pharmaceutical solutions.

PROPOR BR filters feature an integral meltblown prefilter layer to maximize dirt holding capacity whilst the polyethersulphone membrane guarantees a bioburden log reduction of greater than 5 giving excellent microbial protection. This makes PROPOR BR filters ideal for bioburden reduction of LVPs prior to terminal sterilization.

PROPOR BR filters are also ideally suited to prefiltration and bioburden reduction prior to sterilizing grade membrane filters. The robust construction of PROPOR BR filters guarantees consistent performance on multiple batches.

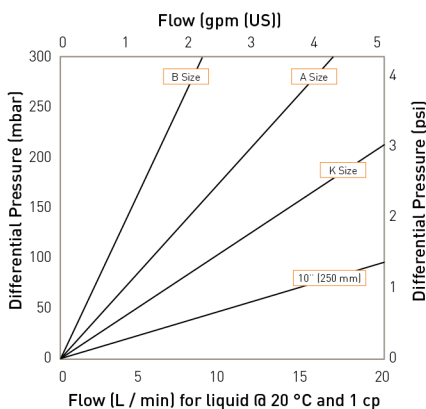
Features and Benefits

- *Brevundimonas diminuta* retention of LRV >5 for efficient bioburden reduction
- Additional prefilter layer gives excellent throughput to blockage
- Low binding for minimal product loss
- MURUS and DEMICAPs can be gamma-irradiated and autoclaved

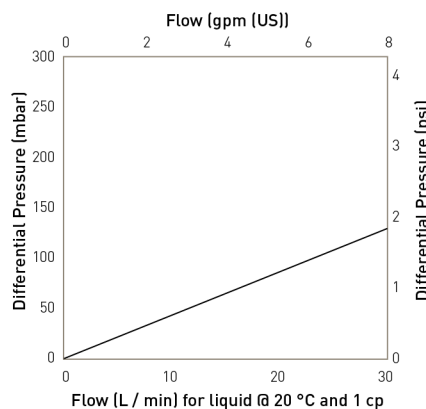


Note: PROPOR and DEMICAP are registered trademarks of Parker Hannifin Corporation.

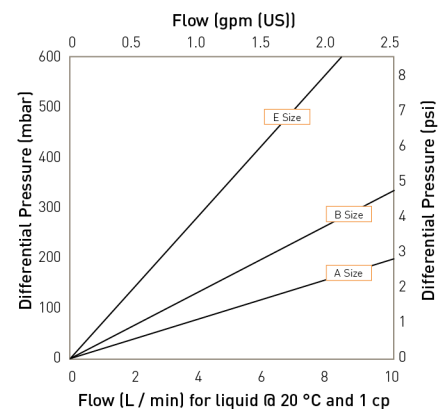
Performance Characteristics



Cartridge flow rates



MURUS flow rates (10" Size (250 mm))



DEMICAP flow rates

Specifications

Materials of Construction

- Filtration Membrane: Polyethersulphone
- Prefilter Layer: Polyester
- Upstream Support: Polyester
- Downstream Support: Polyester

Filter Cartridges

- Inner Support Core: Polypropylene
- Outer Protection Cage: Polypropylene
- End Caps: Nylon
- End Caps Insert: 316L Stainless Steel

MURUS Disposable Filter Capsules

- Core: Polypropylene
- Sleeve: Polypropylene
- End Caps Insert: 316L Stainless Steel
- Standard o-rings/gaskets: Silicone
- Capsule Body: Polypropylene
- Capsules Vent Seals: Silicone

DEMICA Filter Capsules

- Core: Polypropylene
- Sleeve: Polypropylene
- End Caps: Nylon
- Capsule Body: Nylon
- Capsules Vent Seals: Silicone
- Filling Bell: Polycarbonate

Syringe Filters

- Body: Polypropylene

Recommended Operating Conditions

Filter Cartridges

Up to 70 °C (158 °F) continuous operating temperature and higher short-term temperatures during CIP to the following limits:

Temperature °C	Temperature °F	Max. Forward dP (bar)	Max. Forward dP (psi)
20	68	5.0	72.5
40	104	4.0	58.0
60	140	3.0	43.5
80	176	2.0	29.0
90	194	1.7	24.6

MURUS Disposable Filter Capsules

Up to 25 °C (77 °F) @ 5.5 barg (79.7 psig)
Up to 60 °C (140 °F) @ 2.8 barg (40.6 psig)

Parker Hannifin certify that this product complies with the current European Council Pressure Equipment Directive (PED) - Sound Engineering Practice (SEP). This product is intended for use with Group 1 & 2 Dangerous and Harmless Liquids and Group 2 Harmless Gases at the operating conditions stated in this document. The Pressure Equipment Directive mandates that category SEP product cannot bear the CE mark.

DEMICA Filter Capsules

Up to 40 °C (104 °F) at line pressures up to 5.0 barg (72 psig).

Effective Filtration Area (EFA)

10" (250 mm):	0.55 m ²	(5.92 ft ²)
K Size:	0.26 m ²	(2.79 ft ²)
A Size:	0.20 m ²	(2.15 ft ²)
B Size:	0.10 m ²	(1.07 ft ²)
E Size:	0.05 m ²	(0.53 ft ²)
Syringe ø50 mm:	14.50 cm ²	(2.25 in ²)

Sterilization

	Autoclave		Steam-in-Place	
	Cycles	Temp	Cycles	Temp
			(30 min.)	
Cartridges	10	130 °C (266 °F)	30	130 °C (266 °F)
MURUS	5	130 °C (266 °F)	-	-
DEMICA	10	130 °C (266 °F)	-	-
Syringe	1	130 °C (266 °F)	-	-

PROPOR BR filter cartridges can be sanitized with hot water at up to 90 °C (194 °F) and are compatible with a wide range of chemicals.

For detailed operational procedures and advice on cleaning and sterilization, please contact the Technical Support Group through your usual Parker domnick hunter contact.

Biological Safety

Materials conform to the relevant requirements of 21CFR Part 177 and current USP Plastics Class VI - 121 °C and ISO10993 equivalents.

Quality Standards

Pharmaceutical grade products are manufactured in accordance with cGMP, 100% flushed with pharmaceutical grade purified water and integrity tested prior to despatch. A sample of each lot is tested to demonstrate conformity to validated claims.

Gamma-Irradiation

PROPOR BR MURUS & DEMICA disposable filters can be gamma-irradiated up to a maximum dosage of 40 kGy.

Performance Characteristics

TOC / Conductivity

The filtrate quality from a 10" (250 mm) PROPOR BR conforms to the requirements of current USP <643> (TOC) and USP <645> (conductivity) within the first 200 ml flush of purified water.

Endotoxins

Aqueous extracts from the 10" (250 mm) PROPOR BR contain < 0.25 EU / ml when tested in accordance with the Limulus Amoebocyte Lysate test.

Non-Volatile Extractables (NVE)

Total NVEs extracted in the first 5 litre flush of purified water for a 10" (250 mm) cartridge are <10 mg.

Total NVEs extracted in the first 5 litre flush of purified water for an A size 7.9" (200 mm) DEMICAP capsule are <5 mg.

Pharmaceutical Validation

A full validation guide is available upon request from Laboratory Services Group (LSG).

Oxidizable Substances

PROPOR BR filter cartridges meet current USP and EP quality standards for sterile purified water for oxidizable substances following a <1 litre water flush.

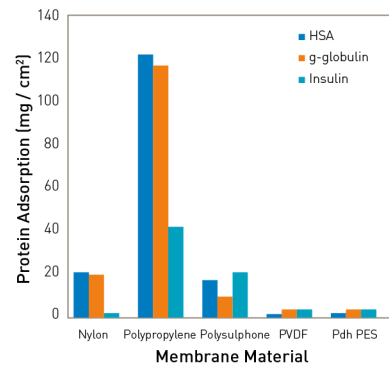
Integrity Test Data

All filters are integrity testable to the following limits when wet with water and using air as the test gas.

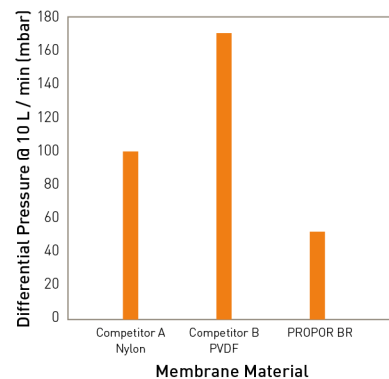
Micron Rating		0.2
Filter Cartridges / MURUS / DEMICAP		
Min. Bubble Point (barg)		2.5
(psig)		36.0
Filter Cartridges / MURUS / DEMICAP / Syringe Filters		
Diffusional Flow (barg)		1.7
Test Pressure (psig)		24.7
Filter Cartridges / MURUS / DEMICAP / Syringe Filters		
Max. Diffusional Flow (10") (ml / min)	(K)	16.0
	(A)	7.4
	(B)	6.0
	(E)	2.9
		1.2

Retention Characteristics

PROPOR BR filter cartridges are validated to an LRV > 5 by bacterial challenge testing with *Brevundimonas diminuta* to current ASTM F838 methodology (10⁷ organisms / cm² EFA minimum) with typical in-house challenge levels being 10¹¹ organisms per 10" (250 mm) module.



Protein binding on membrane materials



Flow rate comparison for bioburden reduction filters