



Filtros PROPOR® HC

Filtros Farmacéuticos para Líquido de Polietersulfona

Filtros esterilizantes PROPOR® HC diseñados específicamente para filtrar soluciones difíciles de forma efectiva y económica

La configuración de membrana optimizada PES cuenta con una capa de prefiltro altamente asimétrica. Gracias a esto, los filtros PROPOR® HC aumentan de forma significativa el rendimiento y previenen problemas asociados con el bloqueo prematuro del filtro por el uso de soluciones complejas.

Los filtros PROPOR® HC unen altas tasas de flujo con gran capacidad para maximizar el rendimiento y la velocidad de filtración. La membrana PES minimiza la pérdida de producto por absorción de proteínas o conservantes gracias a sus bajas propiedades de unión. Los filtros también tienen bajos niveles extraíbles y amplia compatibilidad química.

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

- Configuración optimizada de membrana que permite un rendimiento de hasta 10 veces mayor frente a productos de membrana de una sola capa
- Capa de prefiltro integral que puede condensar cadenas de filtrado para una mayor economía de procesamiento
- Incorpora una membrana de 0,2 µ totalmente validada. Puede ser evaluada en función de su integridad para garantizar su esterilidad
- La membrana PES minimiza la pérdida de producto por absorción
- Amplia compatibilidad química

Aplicaciones

- Filtrado para la industria farmacéutica
- Procesos que requieran amplia compatibilidad química
- Procesos de filtrado de soluciones complejas

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 normas 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 HC Filters

- liquid filters
- polyethersulphone

PROPOR HC sterilizing grade filters have been specifically designed for the effective and economical processing of difficult to filter solutions.

The optimized PROPOR HC PES membrane configuration features a highly asymmetric membrane prefilter layer, which significantly extends throughput and prevents the problems associated with premature filter blockage with complex solutions.

PROPOR HC filters are high capacity and fast flowing. The PES membrane is inherently low binding, which minimizes product loss due to protein or preservative adsorption. The filters have low extractable levels and broad chemical compatibility.

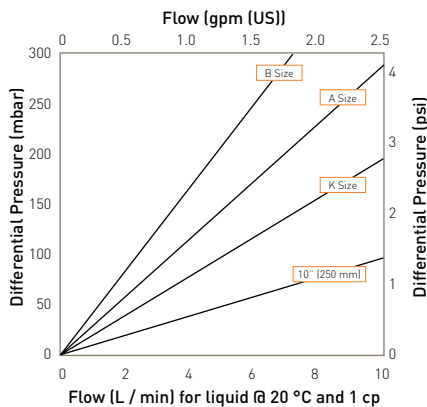
Features and Benefits

- Optimized membrane configuration allows up to ten times the throughput compared to single layer membrane products
- Integral prefilter layer can condense filter trains for greater processing economy
- Incorporates a fully validated and integrity testable 0.2 micron membrane for assurance of sterility
- Low binding for minimal product loss

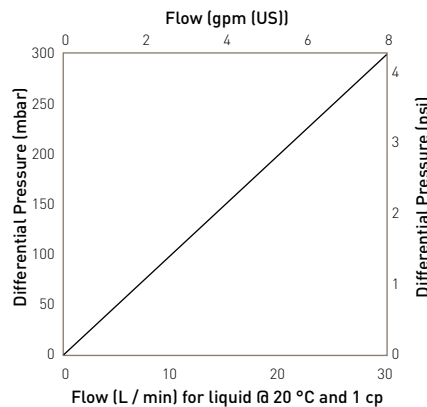


Note: PROPOR and DEMICAP are registered trademarks of Parker Hannifin Corporation.

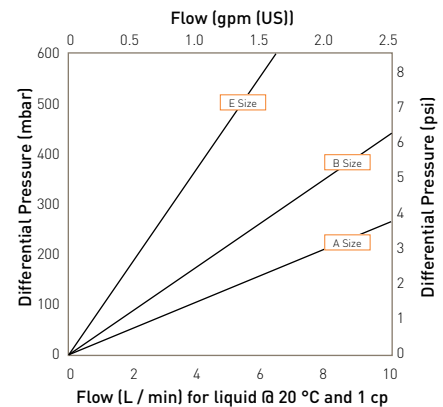
Performance Characteristics



Cartridge flow rates



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



DEMICAP flow rates

Specifications

Materials of Construction

- Filtration Membrane: Polyethersulphone
- Prefilter Membrane: Polyethersulphone
- 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

DEMICAP Filter Capsules

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

Syringe Filters

- Body: Polypropylene

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

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

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

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 European Council Pressure Equipment Directive (PED) 97/23/EC Article 3, Paragraph 3 - 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 : In compliance with PED Article 3, Paragraph 3, SEP, this product does not bear the CE mark.

DEMICAP Filter Capsules

Up to 40 °C (104 °F) at line pressures up to

5.0 barg (72 psig).

Performance Characteristics

TOC / Conductivity

The filtrate quality from a 10" (250 mm) PROPOR HC 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 HC 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 HC filter cartridges meet current USP and EP quality standards for sterile purified water for oxidizable substances following a <1 litre water flush.

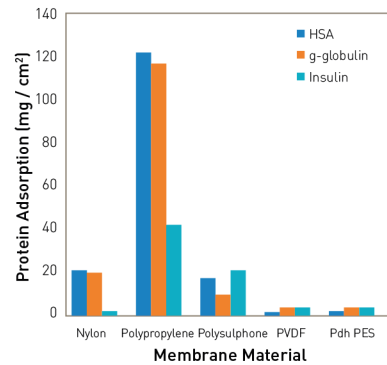
Integrity Test Data

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

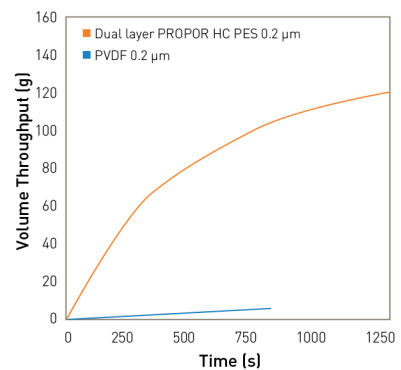
Micron Rating		0.2
Filter Cartridges / MURUS / DEMICAP / Syringe Filters		
Min. Bubble Point (barg)		3.4
(psig)		49.0
Filter Cartridges / MURUS / DEMICAP / Syringe Filters		
Diffusional Flow (barg)		2.8
Test Pressure (psig)		40.6
Filter Cartridges / MURUS / DEMICAP / Syringe Filters		
Max. Diffusional Flow (10")		18.0
(ml / min)	(K)	8.4
	(A)	6.7
	(B)	3.2
	(E)	1.4

Retention Characteristics

PROPOR HC filter cartridges are validated by bacterial challenge testing with *Brevundimonas diminuta* to current ASTM F838-05 methodology (10⁷ organisms / cm² EFA minimum) with typical in-house challenge levels being 10¹¹ organisms per 10" (250 mm) filter cartridge.



Protein binding on membrane materials



Total volume throughput (g) vs time (s) for an insulin intermediate solution