



Filtros PROPOR® MR

Filtros Farmacéuticos para Líquido de Polietersulfona

Filtros esterilizantes PROPOR® MR diseñados para la eliminación de micoplasma de forma rápida, efectiva y económica para el medio de cultivo de células en la industria biofarmacéutica

PROPOR® MR incorpora una membrana de PES altamente retentiva de 0,1 micrones. Esta membrana está validada según el estándar de la industria de las especies de micoplasma más comunes en culturas celulares contaminadas.

Gracias a la membrana asimétrica de prefiltrado integral PROPOR® MR cuenta con la configuración de membrana óptima para conseguir la máxima capacidad y tasa de flujo. La alta velocidad de procesamiento minimiza el riesgo de contaminación sin dejar de ofrecer la máxima protección frente a los micoplasmas.

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

- Incorpora una membrana de 0,2μ totalmente validada. Puede ser evaluada en función de su integridad para garantizar su esterilidad
- La membrana asimétrica de prefiltrado integral incrementa la producción para reducción de cadenas de filtrado
- Un LRV típico > 10 para *Acholeplasma laidlawii* para un control efectivo del micoplasma
- Tasas de flujo excepcionales para garantizar el tratamiento rápido del medio de cultivo de células

Aplicaciones

- Filtrado para la industria farmacéutica
- Eliminación de micoplasma en medios de cultivo celulares

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 MR Filters

- liquid filters
- polyethersulphone

PROPOR MR filters have been specifically designed for fast, effective and economical removal of mycoplasma from cell culture media in the biopharmaceutical industry.

Incorporating a highly retentive 0.1 micron rated PES membrane, PROPOR MR is validated against the industry standard *Brevundimonas diminuta* as well as *Acholeplasma laidlawii*, a common mycoplasma species found in contaminated cell cultures.

An asymmetric integral membrane prefilter layer provides PROPOR MR with the optimal membrane configuration for maximum capacity and flow rate. Quick processing times minimize the risk of contamination while still offering maximum protection from mycoplasma.

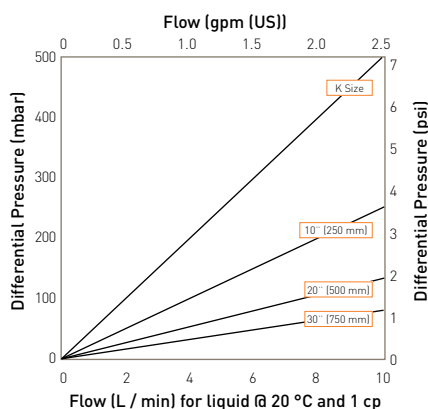
Features and Benefits

- Fully validated and integrity testable for assurance of sterility
- Integral prefilter layer increases throughputs for reduction of filter trains
- A typical LRV of >10 for *Acholeplasma laidlawii* for effective mycoplasma control
- Exceptional flow rates for quick processing of cell culture media

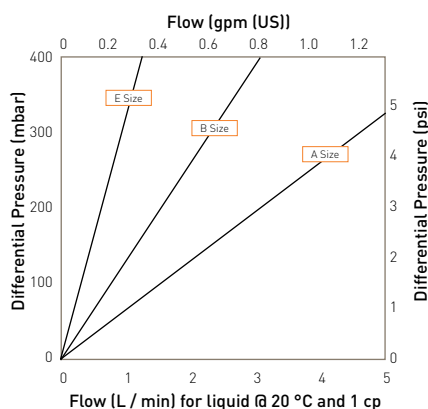


Note: PROPOR and DEMICAP are registered trademarks of Parker Hannifin Corporation.

Performance Characteristics



Cartridge & MURUS flow rates



DEMICAP flow rates

Specifications

Materials of Construction

- Core: Polypropylene
- Sleeve: Polypropylene
- End Caps: Nylon
- Filtration Membrane: Polyethersulphone
- Prefilter Membrane: Polyethersulphone

Filter Cartridges

- Upstream Support: Polypropylene / Polyester
- Downstream Support: Polyester
- Standard o-rings/gaskets: Silicone

MURUS Disposable Filter Capsules

- Upstream Support: Polypropylene / Polyester
- Downstream Support: Polyester
- Standard o-rings/gaskets: Silicone
- Capsule Body: Polypropylene
- Capsules Vent Seals: Silicone

DEMICA Disposable Filter Capsules

- Upstream Support: Polyester
- Downstream Support: Polyester
- Membrane Separation Layer: Polyester
- Capsule Body: Nylon
- Capsules Vent Seals: Silicone
- Filling Bell: Polycarbonate

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		Max. Forward dP	
°C	°F	(bar)	(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.

DEMICA Disposable 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):	0.50 m ²	(5.38 ft ²)
K Size:	0.24 m ²	(2.58 ft ²)
A Size:	0.19 m ²	(2.09 ft ²)
B Size:	0.10 m ²	(1.03 ft ²)
E Size:	0.05 m ²	(0.49 ft ²)

	Autoclave		Steam-in-Place	
	Cycles	Temp	Cycles (30 min.)	Temp
Cartridges	10	130 °C (266 °F)	5	130 °C (266 °F)
MURUS	10	130 °C (266 °F)	-	-
DEMICA	3	130 °C (266 °F)	-	-

Sterilization

PROPOR MR 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 sterilisation, please contact the Technical Support Group through your usual Parker domnick hunter contact.

Food and 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 purified water and integrity tested prior to despatch. A sample of each lot is tested to demonstrate conformity to validated claims.

Gamma-Irradiation

PROPOR MR MURUS 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 MR conforms to the requirements of current USP <645> (conductivity) within the first 1L flush of purified water and USP <643> (TOC) following a 10L flush.

Endotoxins

Aqueous extracts from the 10" (250 mm) PROPOR MR 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 1 litre flush of purified water for a 10" (250 mm) cartridge / MURUS capsule are <15 mg.

Pharmaceutical Validation

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

Oxidisable Substances

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

Integrity Test Data

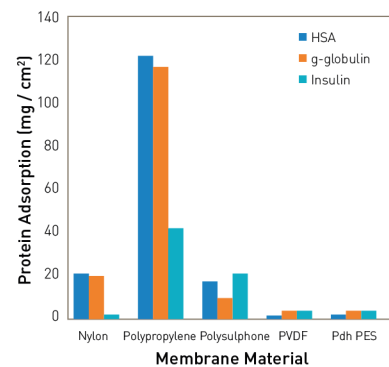
All filters are integrity testable to the following limits using air as the test gas. During diffusional flow tests filters are wet with water. Bubble points are determined in 60 / 40 v/v IPA / Water.

Micron Rating		0.1
Filter Cartridges / MURUS / DEMICAP		
Min. Bubble Point	(barg)	2.36
	(psig)	34.2
Filter Cartridges / MURUS / DEMICAP		
Diffusional Flow	(barg)	4.80
Test Pressure	(psig)	69.6
Filter Cartridges / MURUS / DEMICAP		
Max. Diffusional Flow (10")	(ml / min)	24.2
	(K)	11.5
	(A)	9.3
	(B)	4.6
	(E)	2.2

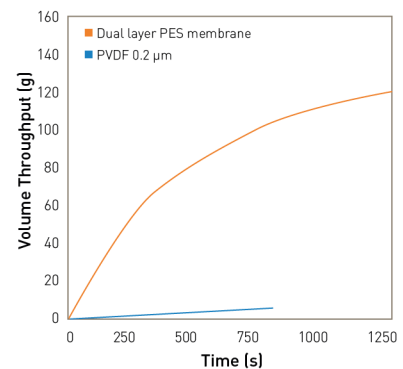
Retention Characteristics

PROPOR MR 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.

To demonstrate the mycoplasma retention capabilities of the PROPOR MR, bacterial challenge testing was conducted on a number of cartridges using *Acholeplasma laidlawii* as the challenge organism with typical LRVs greater than 10.



Protein binding on membrane materials



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