ULTRA Pure MR

FILTRATION

ULTA™ Pure MR filter cartridges and capsules consist of a sterilizing-grade 0.1 micron polyethersulphone (PES) membrane with a prefiltration layer for extended throughput (Fig 1). The filters are designed specifically for mycoplasma removal applications.

Features and benefits of ULTA Pure MR filters include:

- Removal of mycoplasma with a log reduction value (LRV) greater than 10
- Optimized membrane configuration allows up to 10 times the throughput of a traditional mycoplasma-removal filter
- Integral prefilter layer can shorten filter trains for greater processing economy
- Fully validated and integrity-testable for sterility
- Low adsorption of proteins for minimal loss of expensive product

ULTA Pure MR filters have been specifically designed to extend the throughput of a traditional mycoplasma-removal filter through the incorporation of an integral PES prefilter layer.

The optimized ULTA Pure MR membrane configuration features a highly asymmetric membrane prefilter layer, which significantly extends throughput and prevents premature filter blockage when working with complex solutions. The integral prefilter layer can also result in shortening of filter trains, for greater economy on a wide variety of intermediate and final sterilizing applications.

Fig 1 . ULTA Pure MR filters are available as cartridges and capsules.

ULTA Pure MR cartridge filters exhibit high capacity and fast flows. The inherent low protein binding properties of the MR membrane minimize product loss due to adsorption. The filters have low extractable levels and broad chemical compatibility. The membrane is hydrophilic and the filters can be easily and repeatedly integrity tested.

Performance characteristics

Water flow characteristics for filter cartridges and capsules are shown in Figure 2.

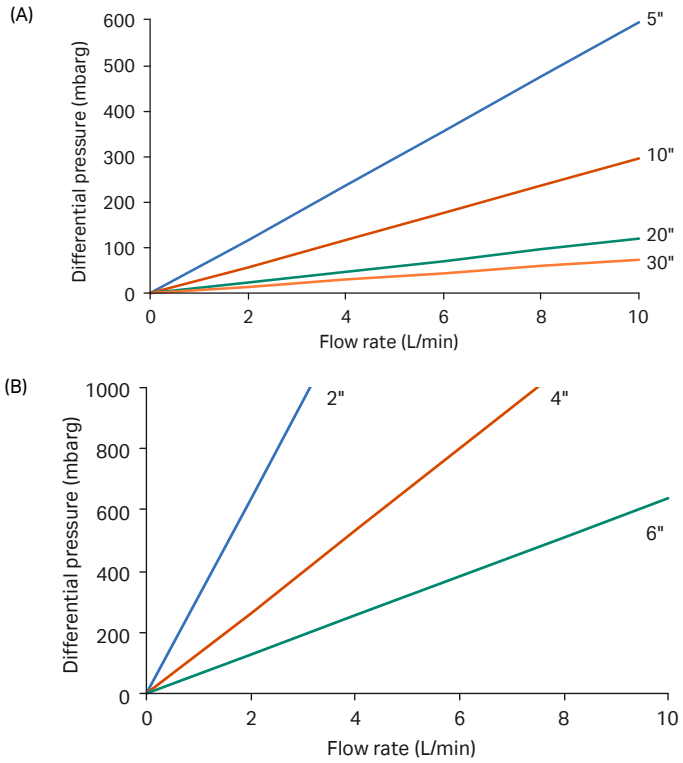

Fig 2. Water flow characteristics for (A) 5", 10", 20", 30" and (B) 2", 4", and 6" cartridges and capsules.

Total organic carbon (TOC) and conductivity

The effluent quality from ULTA Pure MR capsules conform to the requirements of USP 28<643> (TOC) and USP 28<645> (conductivity) according to Table 1.

Table 1. TOC and conductivity

	6" capsule	5" capsule
TOC	200 mL	7 L
Conductivity	200 mL	1 L

Endotoxins

Aqueous extracts from the ULTA Pure MR filter contain < 0.25 EU/mL when tested in accordance with the limulus amoebocyte lysate (LAL) test.

Nonvolatile extractables (NVE)

Total NVEs extracted in the first 1 L flush of water for injection (WFI) for a 6" irradiated capsule is ≤ 8 mg. Total NVEs extracted in the first 1 L flush of WFI for a 5" irradiated capsule is ≤ 11 mg.

Pharmaceutical validation

A full validation guide is available upon request.

Oxidizable substances

ULTA Pure MR filter cartridges meet current USP quality standards for oxidizable substances.

Integrity test data

All filters are flushed with pharmaceutical grade purified water prior to packaging and are integrity testable to micron rating 0.1.

Recommended rinse volume

The recommended volume for rinse prior to use is 3 L for a 10" cartridge.

Retention characteristics

ULTA Pure MR filter cartridges provide sterile effluent when bacterial challenge tested to methods specified in ASTM F838-05 (10^7 organisms/cm^2 minimum). ULTA Pure MR filters remove mycoplasma with a typical log reduction value (LRV) > 10 using *Acholeplasma laidlawii*, ATCC 23206.

Specifications

Recommended operating conditions for ULTA Pure MR filters are listed in Table 2. Up to 70°C (158°F) continuous operating temperature and even higher short-term temperatures can be used with these filters during cleaning in place (CIP). Specifications of ULTA Pure MR filters are listed in Table 3.

Table 2. Recommended operating conditions

	Temperature (°C)	Temperature (°F)	Max. forward dP (bar)	Max. forward dP (psi)
Filter cartridges	20	68	5.0	72.5
	40	104	4.0	58.0
	60	140	3.0	43.5
	80	176	2.0	29.0
Filter capsules (5", 10", 20", and 30")	25	77	5.5	80.9
	60	140	2.8	41.2
Filter capsules (2", 4", and 6")	40	104	5.0	72

Table 3. Technical specifications for ULTA Pure MR filters

Materials of construction	
Filtration membrane	Polyethersulphone
Prefilter membrane	Polyethersulphone
Membrane separation layer (2", 4", and 6" capsules)	Polyester
Upstream support (cartridges and 5", 10", 20", and 30" capsules)	Polypropylene
Upstream support (2", 4", and 6" capsules)	Polyester
Downstream support	Polyester
Inner core	Polypropylene
Sleeve	Polypropylene
End caps (cartridge)	Nylon
Capsule body: 2", 4", and 6"	Nylon
Capsule body: 5", 10", 20" and 30"	Polypropylene
Cartridge o-rings (standard)	Silicone
Effective filtration area (EFA)	0.5 m^2 (5.37 ft^2) per 10" element
Autoclaving	
Capsules: 5", 10", 20", 30"	10 cycles at 130°C (266°F)
Capsules: 2", 4", and 6"	3 cycles at 130°C (266°F)
Steam in place (SIP)	
Cartridges	5 cycles at 130°C (266°F)
Sanitization	ULTA Pure 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.
Biological safety	Materials conform to the relevant requirements of 21CFR Part 177 and current USP Plastics Class VI - 121°C and ISO10993 equivalents.

Ordering information

Product	Model	Code number
ULTA Pure MR 0.1 µm, code 7, 10" cartridge, silicone O-rings	CMP-MR91170S	12-4103-20
ULTA Pure MR 0.1 µm, code 7, 20" cartridge, EPDM O-rings	CMP-MR91270E	12-4103-21
ULTA Pure MR 0.1 µm, code 7, 20" cartridge, silicone O-rings	CMP-MR91270S	12-4103-22
ULTA Pure MR 0.1 µm, code 7, 30" cartridge, EPDM O-rings	CMP-MR91370E	12-4103-23
ULTA Pure MR 0.1 µm, code 7, 30" cartridge, silicone O-rings	CMP-MR91370S	12-4103-24
ULTA Pure MR 0.1 µm, 2", step HB, 3 pk	KMP-MR9102GG	12-4102-94
ULTA Pure MR 0.1 µm, 2", 0.5 in HB, 3 pk	KMP-MR9102HH	29-0235-68
ULTA Pure MR 0.1 µm, 2", 1 in TC, 3 pk	KMP-MR9102TT	12-4102-96
ULTA Pure MR 0.1 µm, 4", step HB, 3 pk	KMP-MR9104GG	12-4102-97
ULTA Pure MR 0.1 µm, 4", 0.5 in HB, 3 pk	KMP-MR9104HH	12-4102-98
ULTA Pure MR 0.1 µm, 4", 1 in TC, 3 pk	KMP-MR9104TT	12-4102-99
ULTA Pure MR 0.1 µm, 6", step HB, 3 pk	KMP-MR9106GG	12-4103-00
ULTA Pure MR 0.1 µm, 6 in, 0.5" HB, 3 pk	KMP-MR9106HH	12-4103-01
ULTA Pure MR 0.1 µm, 6 in, 1" TC, 3 pk	KMP-MR9106TT	12-4103-02
ULTA Pure MR 0.1 µm, 5 in, 0.75" TC, 1 pk	KMP-MR91H1FF	12-4103-07
ULTA Pure MR 0.1 µm, 5 in, 1.5" TC, 1 pk	KMP-MR91H1TT	12-4103-03
ULTA Pure MR 0.1 µm, 10 in, 0.75" TC, 1 pk	KMP-MR9110FF	12-4103-08
ULTA Pure MR 0.1 µm, 10 in, 1.5" TC, 1 pk	KMP-MR9110TT	29-0235-69
ULTA Pure MR 0.1 µm, 20 in, 0.75" TC, 1 pk	KMP-MR9120FF	12-4103-09
ULTA Pure MR 0.1 µm, 20 in, 1.5" TC, 1 pk	KMP-MR9120TT	12-4103-05
ULTA Pure MR 0.1 µm, 30 in, 0.75" TC, 1 pk	KMP-MR9130FF	12-4103-10
ULTA Pure MR 0.1 µm, 30 in, 1.5" TC, 1 pk	KMP-MR9130TT	12-4103-06
ULTA Pure MR 0.1 µm, 10 in, T-line 1.5" TC, 1 pk	KMPTMR9110RR	12-4103-28
ULTA Pure MR 0.1 µm, 20 in, T-line 1.5" TC, 1 pk	KMPTMR9120RR	12-4103-29
ULTA Pure MR 0.1 µm, 30 in, T-line 1.5" TC, 1 pk	KMPTMR9130RR	12-4103-30
ULTA Disc MR 0.1 µm, 47 mm disc, 50 pk	DMP-MR91-470	28-9772-06

* EPDM = ethylene propylene diene monomer rubber

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