

ULTA Prime CG

FILTRATION

ULTA™ Prime CG cartridge and capsule filters have been designed specifically for high throughput and cost effective bioburden control in the production of biopharmaceuticals where sterilizing grade filtration is not required.

ULTA Prime CG filter cartridges feature an integral meltblown prefilter layer to maximize dirt holding capacity while the polyethersulphone membrane guarantees a bioburden log reduction of greater than 5 giving excellent microbial protection. Ultra Prime CG is an economical alternative to the use of sterilizing grade filtration when sterilization of in-process feedstreams is not required.

ULTA Prime CG filter cartridges and capsules are also ideally suited to prefiltration and bioburden reduction and particulate removal prior to sterilizing grade membrane filters, and provide excellent protection of downstream processing equipment such as chromatography columns and ultrafiltration. The robust construction of ULTA Prime CG guarantees consistent performance on multiple batches.

Features

- *Brevundimonas diminuta* retention of 0.2 µm nominal and an LRV of at least 5 for efficient bioburden reduction and particulate removal
- Additional prefilter layer gives excellent capacity
- Low adsorption of proteins for minimal loss of valuable biopharmaceutical product



Fig 1. ULTA Prime CG filters

Materials of construction

Filtration Membrane: Polyethersulphone

Prefilter Layer: Polyester

Upstream Support: Polyester

Downstream Support: Polyester

Inner Support Core: Polypropylene

Outer Protection Cage: Polypropylene

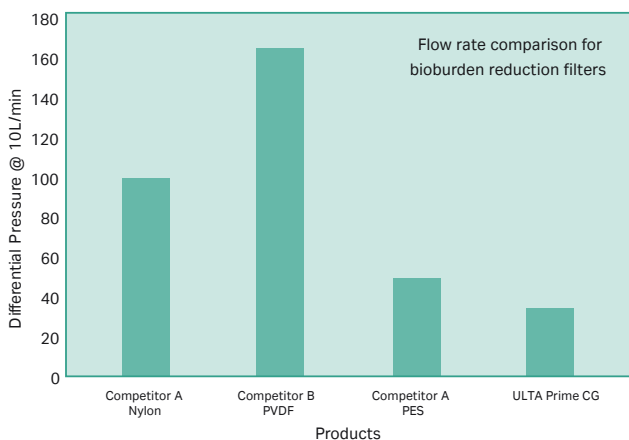
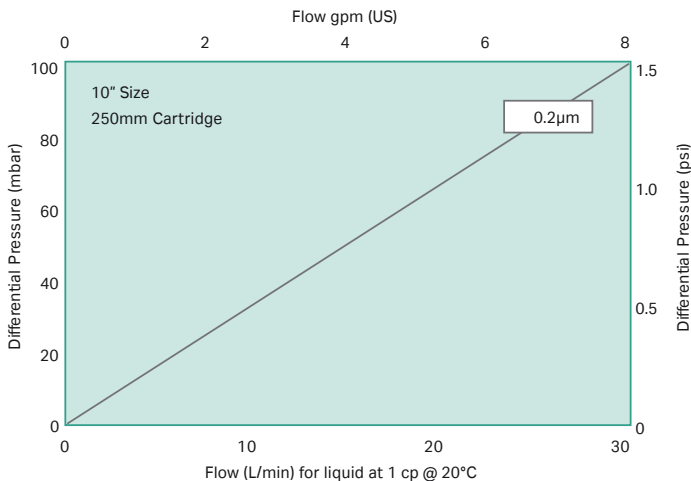
End caps: Nylon

End Cap Insert: 316 stainless steel

Standard o-rings/Gaskets: Silicone

Typical applications

- Column guard — Reduce bioburden and particulates immediately before chromatography columns
- Sterile filter protection — Prefilter solutions upstream of the sterilizing grade filter
- General bioburden control — Log reduction of bacteria when sterility is not required



Recommended operating conditions

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

Temperature		Maximum dP forward		Maximum dP reverse	
(°C)	(°F)	(bar)	(psi)	(bar)	(psi)
20	68	5.0	72	2.0	29
40	104	4.0	58	1.5	22
60	140	3.0	43.5	1.0	15
80	176	2.0	29	0.5	7
90	194	1.0	15	Not recommended	
> 100(steam)	> 212(steam)	0.3	4	Not recommended	

Filtration area

0.54 m² (5.8 ft²) per 10" (250 mm) module.

Cleaning and sterilization

ULTA Prime CG filter cartridges can be repeatedly steam sterilized *in situ* or autoclaved at up to 130°C (288°F). They 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 Cytiva contact.

Biological safety

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

Non-volatile extractables (NVE)

Total NVE's extracted in the first 5 liter flush of WFI for a 10 inch pre autoclaved cartridge is < 6 mg.

Oxidizable substances

ULTA Prime CG filter cartridges meet current USP quality standards for oxidizable substances.

TOC/Conductivity

The effluent quality from a 10 inch ULTA Prime CG conforms to the requirements of USP 28<643>(TOC) and USP 28<645> (conductivity) following a 3 liter flush.

Endotoxins

Aqueous extracts from the ULTA Prime CG contain < 0.125 Eu/mL when tested in accordance with the standard LAL test.

Retention characteristics

ULTA Prime CG filter cartridges are validated to give an LRV of at least 5 when challenged with *Brevundimonas diminuta* in accordance with methods specified in ASTM F838-05 (10⁷ organisms/cm² minimum). Typical in-house challenge levels are in the order of 10¹¹ per 10 inch module.

Integrity test data

Test Pressure: 24.7 psig (1.7 barg). Water wet @ 20°C.

Device	Diffusional flow mL/min
10 inch cartridge	16
5 inch cartridge	7.6
6 inch capsule	6.1
4 inch capsule	3.0
2 inch capsule	1.4

Cartridges

Device Type	Media Type	Special	Detail	Special	Micron Rating	Size	Code Cartridge	O-ring			
Digit 1	2	3	4	5	6	7	8	9	10	11	12
C = Cartridge D = Disc	M	P	Hyphen -	C	G	9	2	H = 5" 1 = 10" 2 = 20" 3 = 30"	0 = Code 0, 222 Double o-ring/ 7 = Code 7, 226 Locking Tab, Double o-ring/ Fin* (Flat Top 5" Only)	0	E = EPDM S = Silicone

Example: ULTA Prime CG, 226 (code 7), 10", Silicone o-ring
CMP-CG92170S

Hyphen	4	7	0	Disc
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Capsules

Device Type	Media Type	Special	Detail	Special	Micron Rating	Size	Size	End Fittings			
Digit 1	2	3	4	5	6	7	8	9	10	Inlet	Outlet
K = Capsule	M	P	Hyphen -	C	G	9	2	02 = 2" 04 = 4" 06 = 6"	T = 1.5" TC G = SHB* H = 1/2" HB	T = 1.5" TC G = SHB* H = 1/2" HB	

Example: ULTA Prime CG Capsule, 4", 1/2 Hose barb inlet, Triclamp 1 1/2" out
KMP-CG9204HT

* Stepped Hose Barb 1/4"

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