ALpHA® G





ALpHA® G Capsules

ALpHA® G is a unique absolute rated depth type filter media which has been optimized for compatibility with a gamma irradiation cycle commonly used to sterilize single-use systems. It features a tapered pore structure that provides high flow rates and throughput and delivers extraordinary dirt holding capacity. ALpHA® G media is available in absolute retention ratings from 0.6 to 20 μm.

The ALpHA® G filter is available in a wide range of capsule configurations to provide seamless scalability from laboratory work to process development through production. All ALpHA® G capsule filters utilize pleated media construction, providing surface areas as small as 0.02 m² (CM capsule configuration) up to 2.5 m² (UltraCap® H.D. 50" capsule configuration). Larger scale applications, especially those requiring multistage filtration, can be accommodated with the UltraSnap™ filter assembly. This assembly configures multiple ALpHA® G capsules into a rigid pre-assembled filtration solution.

The ALpHA® G capsule filter offers a truly plug and play clarification step for biopharmaceutical processes. The ALpHA® G depth filtration step can be integrated into a BioFlex® single-use tubing assembly and delivered sterile, ready for use, with exceedingly low and well characterized extractables and endotoxin levels. Typical use does not require a time consuming rinse step as often necessary with other clarification processes. The exceptionally low hold up volume of ALpHA® G capsule filters provides excellent product recovery without the use of elaborate post-use rinse and blow down steps.

Features and Benefits

- · Gamma irradiatable ALpHA® G capsule filters are compatible with gamma irradiation and can be ordered sterile for immediate use.
- Scalable Quickly and easily scale-up from capsules with filter surface areas of 0.02 m² to capsules with filter surface areas of 2.5 m2.
- Ready to use convenience ALpHA® G capsule filters typically do not require pre-rinse steps before use or post-use rinse and blow down steps for product recovery.
- UltraSnap™ compatible ALpHA® G UltraCap® H.D. filters can be secured in an UltraSnap™ assembly for applications requiring multistage filtration solution and/or larger surface areas than can be accommodated by a single filter. The complete UltraSnap™ assembly can be delivered as a single presterilized unit for true plug and play functionality at any scale.
- · Remarkably low, well characterized extractables



Materials of Construction

Filter Media: Polyester
Upstream Support: Polypropylene
Downstream Support: Polypropylene
Core/Outer Guard: Polypropylene
End Caps: Polypropylene
Capsule Housing: Polypropylene
Sealing Method: Thermal Bonding

All materials of construction listed above are FDA approved for food contact use per 21 CFR 177.

ALpHA® G capsules are manufactured in conformance to cGMP. ALpHA® G capsules meet the requirements as specified in the current USP Class VI plastics, physicochemical, oxidizable substances, and cytotoxicity tests. Bacterial endotoxin levels in aqueous extracts of ALpHA® G capsules are less than 0.5 EU/mL, as determined using the Limulus amebocyte lysate (LAL) test. No binders, adhesives or surfactants are used in the construction of ALpHA® G capsules. ALpHA® G capsules are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72.

Filtration Ratings

Absolute Pore Sizes (µm): 0.6, 1.2, 2.4, 5, 7,10, 20

Capsule Dimensions (nominal)

Model	Diameter	Total Dimension
CM2/GM2	1.25" (3,2 cm)	5.50" (14,0 cm)
CK2/GK2	1.25" (3,2 cm)	6.25" (15,9 cm)
CS2/GS2	2.75" (7,0 cm)	4.50" (11,4 cm)
CL2/GL2	2.75" (7,0 cm)	6.90" (17,5 cm)

UltraCap® H.D. Dimensions (nominal)

Model T-Style CR2/GR2	Diameter 3.5" (8,9 cm)	Total Dimension 11.7" (29,7cm) 21.1" (53,6 cm) 30.6" (77,7 cm) 40.0" (101,6 cm) 49.5" (125,7 cm)	(on Order Matrix) 10" (25 cm) 20" (50 cm) 30" (75 cm) 40" (100 cm) 50" (125 cm)
Inline CR2/GR2	3.5" (8,9 cm)	17.3" (43,9 cm) 26.8" (68,1 cm) 36.2" (91,9 cm) 45.7" (116,1 cm) 55.2" (140,2 cm)	10" (25 cm) 20" (50 cm) 30" (75 cm) 40" (100 cm) 50" (125 cm)

Configuration Options

ALpHA® G capsule filters can be ordered as discrete CM2/CK2, CS2/CL2, or UltraCap® H.D. capsule filters or incorporated into our BioFlex® filter/tubing assemblies and our UltraSnap™ filter assemblies. UltraSnap™ filter assemblies offer pre and final capsule filters bundled together in a presterilized filtration solution that features one inlet and one outlet connection for plug and play use.

Sterilization

ALpHA® G products are often delivered presterilized via gamma irradiation. However, they can be ordered non-sterile, and subsequently sterilized via autoclave by an end-user.

Autoclave CM2/CK2 and CS2/CL2 capsules at a minimum of 121 °C for 60 minutes or 125°C for 45 minutes. UltraCap® H.D. capsules should be autoclaved at a minimum of 121 °C for 60 minutes. Additionally, the T-style UltraCap® H.D. configuration should be placed in the autoclave with the inlet/outlet in the down position. All capsules can be repeatedly autoclaved without loss of integrity. Support heavy attached fittings (e.g. sanitary clamps) while autoclaving.

Autoclaving gamma irradiated capsules is not recommended. Capsules must not be *in situ* steam sterilized (SIP) as exposure to direct steam at 121 °C, 15 psig (1 bar), will exceed material design limits and can result in a rupture of the plastic housing.

Operating Characteristics CM2/GM2, CK2/GK2, CS2/GS2, CL2/GL2 Model

Maximum Pressure and Temperature for Liquids: 75 psig @ 32 °F to 100 °F (5,2 bar @ 0 °C to 38 °C) 35 psig @ 160 °F (2,4 bar @ 71 °C)

Maximum Pressure and Temperature for Gases: 50 psig @ 32 °F to 100 °F (3,4 bar @ 0 °C to 38 °C) 35 psig @ 160 °F (2,4 bar @ 71 °C)

Operating Characteristics UltraCap® H.D. CG2/GR2 Model

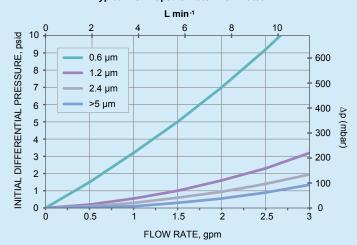
Maximum Pressure & Temperature for Liquids:

90 psig @ 32°F to 100°F (6,2 bar @ 0°C to 38°C) 55 psig @ 140°F (3,8 bar @ 60°C)

Maximum Pressure & Temperature for Gases:

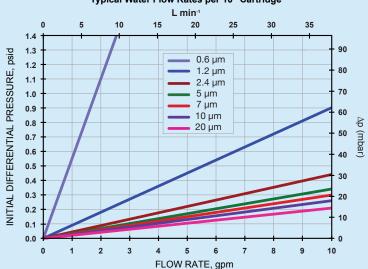
60 psig @ 32°F to 100°F (4,1 bar @ 0°C to 38°C) 35 psig @ 140°F (2,4 bar @ 60°C)

Typical CS2 Capsule Water Flow Rates



Data shown is for "CS2" style capsule with %" hosebarb connections. Consult factory for complete flow rate information.

Typical Water Flow Rates per 10" Cartridge



Ordering Information

CM2 / CK2 Capsule Options			Retention Rating (µm)
	CM2	MG	0.6
0.2 ft ²	Standard (non-sterile))	0.6
	0.2 ft² (0,02 m²)		1.2
	Gamma irradiated 0.2 ft ² (0,02 m ²)		2.4
CK2 =	Standard (non-sterile) 0.4 ft² (0,04 m²))	5
			7
GK2 =	Gamma irradiated 0.4 ft² (0,04 m²)		10
			20

Inlet / Outlet Connections

11 = 1/4" (6 mm) hose barb

22 = 3/8" (10 mm) hose barb

44 = 1/4" (6 mm) MNPT

71 = 3/4" (19 mm) TC in; 1/4" (6 mm) hose barb out

72 = 3/4" (19 mm) TC in; 3/8" (10 mm) hose barb out

77 = 3/4" (19 mm) sanitary (TC) flange

Vent / Drain Ports

0 = No vent / drain ports

1 = One, luer port with cap, inlet side

2 = Standard; two, luer ports with caps

4 = Two, sanitary valve with hose barbs

5 = One, sanitary valve with hose barb, inlet side

One, sanitary valve with hose barb, outlet side

CS2 / CL2 Capsule Options

CS2 = Standard (non-sterile)

GS2 = Gamma irradiated

GL2 = Gamma irradiated

1.0 ft2 (0,09 m2)

1.0 ft2 (0,09 m2)

CL2 = Standard (non-sterile) 2.0 ft² (0,19 m²)

2.0 ft2 (0,19 m2)

Retention Rating (µm)

0.6

1.2

2.4

5

7

10

20

0.6

1.2

2.4

5

7

10

20

MG

Inlet / Outlet Connections

00 = 1" (25 mm) sanitary (TC) flange

02 = 1" (25 mm) TC in; 3/8" (10 mm) hose barb out

09 = 1" (25 mm) TC in; 1/2" (13 mm) hose barb out

99 = 1/2" (13 mm) hose barb

22 = 3/8" (10 mm) hose barb

2B = 3/8" (10 mm) hose barb w/ filling-bell

44 = 1/4" (6 mm) MNPT

55 = 3/8" (10 mm) FNPT

66 = 3/8" (10 mm) MNPT

77 = 3/4" (19 mm) sanitary (TC) flange

88 = 3/4" (19 mm) hose barb

Vent / Drain Ports

0 = No vent / drain ports

1 = One, luer port with cap, outlet side

2 = Standard; two, luer ports with caps

4 = Two, sanitary valve with hose barbs

5 = One, sanitary valve with hose barb, outlet side

UltraCap® H.D. **Capsule Options**

CR2 = Standard (non-sterile)

GR2 = Gamma irradiated

Rating (µm) MG

Retention Capsule Length

1 = 10"

4 = 40"

5 = 50'

Body Style

T = T-style

N = Inline

2 = 20"

3 = 30"

02 = 1" sanitary flange inlet; 3/8" hose barb outlet **0C** = 1" sanitary flange inlet; 1/2" hose barb outlet

00 = 1" sanitary flange

77 = 3/4" sanitary flange

Inlet / Outlet

Connections

09 = 1" sanitary flange inlet; 9/16" hose barb outlet

08 = 1" sanitary flange inlet: 3/4" hose barb outlet

0D = 1" sanitary flange inlet; 1" hose barb outlet

22 = 3/8" hose barb

CC = 1/2" hose barb

99 = 9/16" hose barb

88 = 3/4" hose barb

DD = 1" hose barb

AA = 1/2" Flaretek®

BB = 3/4" Flaretek®

Vent / Drain Ports

T-Style

0 = No vent; no drain

1 = No vent; 1/4" sanitary drain plug

2 = Sanitary vent; 1/4" sanitary drain plug

3 = Sanitary vent; 3/4" sanitary flange gauge port; 1/4" sanitary drain plug

4 = Sanitary vent; no drain

5 = Sanitary vent; 3/4" sanitary flange gauge port; no drain

6 = No vent or drain; 3/4" sanitary flange gauge port

A = No vent; sanitary drain valve

B = Sanitary vent; sanitary drain valve

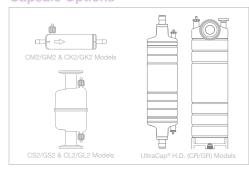
C = Sanitary vent; sanitary drain; 3/4" sanitary flange gauge port

Inline

0 = No vent; no drain

2 = Two sanitary vent/drain valves

4 = One sanitary vent/drain valve, outlet side



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