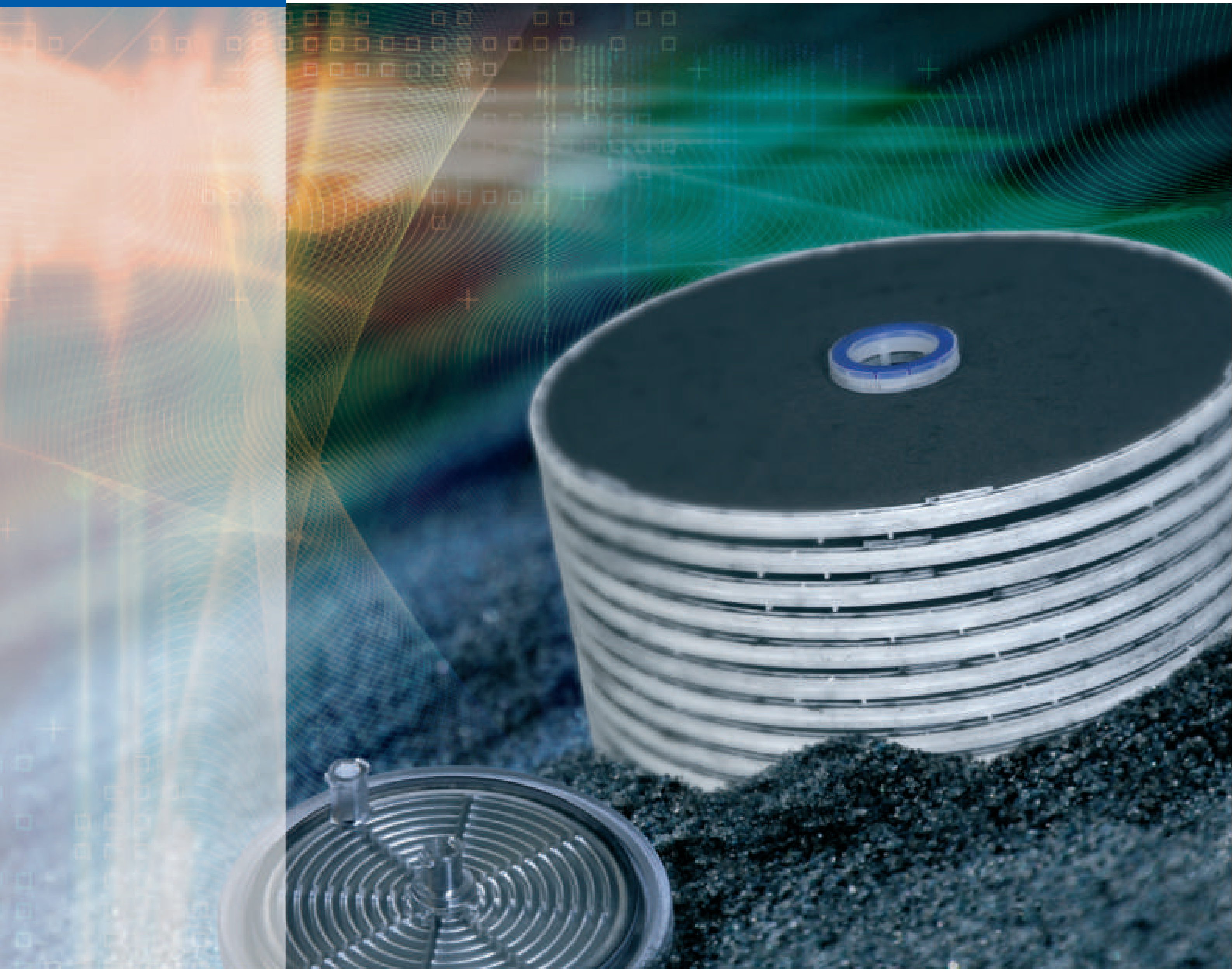
PALL Life Sciences

USD 2459



Pall SUPRAdisc™ and SUPRAcap™ Modules with Seitz® AKS Filter Media

- The Better Choice

Filtration. Separation. Solution.SM

Benefits of Pall SUPRAdisc and SUPRAcap filters with Seitz AKS filter media over bulk activated carbon

Streamlining your process with SUPRAdisc and SUPRAcap filters with AKS sheets

Powdered Activated Carbon (PAC) is widely used in the pharmaceutical industry for decolorization and removal of other trace impurities. The use of bulk PAC has significant drawbacks relating to the handling of bulk carbon powder, cleaning of process equipment, and time (costs) associated with carbon removal from the process. **Seitz** AKS filter media alleviates these concerns by immobilizing activated carbon within a matrix of cellulosic fibers, which is coupled with a downstream filter paper that eliminates any possible particle shedding. Additionally, the adsorption efficiency of **Seitz** AKS filter media is greater than an equivalent amount of bulk PAC, further reducing overall process time and increasing product yield.

Pharmaceutical processes involving the addition of Bulk Activated Carbon, generally involve 4 operations:

1. **Handling of bulk carbon and dosing into a mixing vessel**

   This can result in the distribution of carbon dust into the working environment, with potentially detrimental effects on both occupational hygiene and good manufacturing practice.

2. **Mixing of bulk carbon with product solution**

   This involves agitation for sufficient time to allow the majority of the impurity molecules to come into contact with the PAC, diffuse into the internal structure of the carbon particles, and be adsorbed onto the internal surface of the carbon. This operation typically lasts at least 30 minutes.

3. **Removal of PAC from the process after adsorption**

   Bulk carbon is usually removed by a cake filtration process, whereby the suspension is recirculated over a filter sheet or cloth supported by a porous plate. Particles build up on the surface of the filter forming a "cake", which also contributes to the filtration process. Additional "polishing" filtration steps with cartridge filters are typically required in order to remove carbon fines and provide a clear fluid for the subsequent step.

4. **Cleaning of carbon from process equipment**

   Carbon powder can become widely distributed through process equipment and can be very difficult to completely remove. This is particularly problematic for pilot plants and multipurpose plants where cleaning of process plant between batches is a critical issue to avoid cross-contamination.

Standard Process

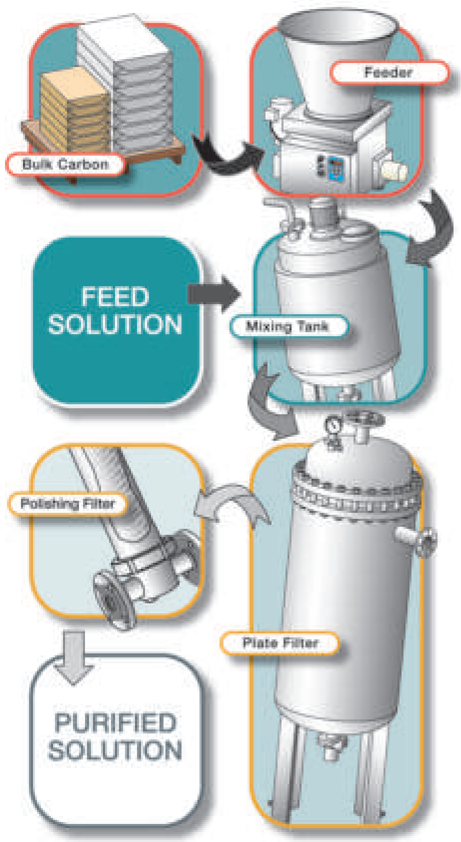


Figure 1:
A typical decolorization process involving addition of bulk activated carbon (cleaning steps not shown)

Streamlined SUPRAdisc AKS Process

Pall SUPRAdisc and SUPRAcap modules containing Seitz AKS filter media provide a streamlined process only requiring a single step.

The feed stream is simply passed once through the module at an appropriate flow rate to achieve the desired adsorption.

This saves time, resources, and expense. It is nearly 100% free of carbon dust so operators and the workspace are much better protected.

No additional mixing, filtration, or cleaning steps are needed.

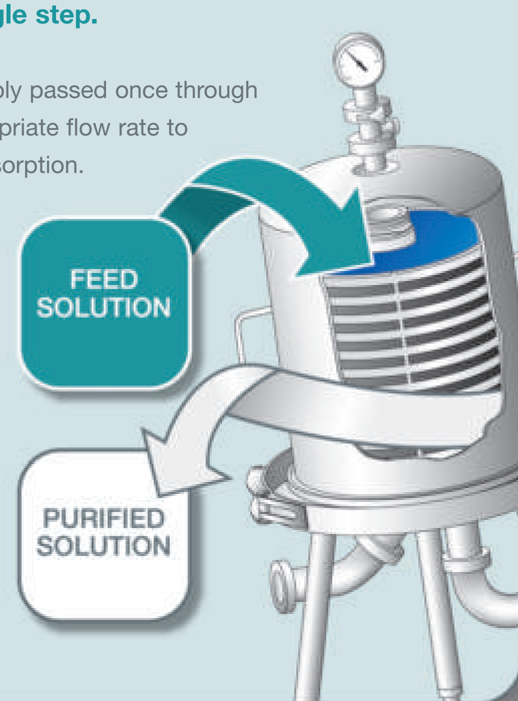


Figure 2:
A typical decolorization process involving SUPRAdisc AKS modules

Benefits of Pall SUPRAdisc and SUPRAcap filters with Seitz AKS filter media over bulk activated carbon

Improved Adsorption

In addition to streamlining the process, Pall **SUPRAdisc** and **SUPRAcap** modules with **Seitz** AKS filter media are actually more efficient at removing colors and other impurities from a solution compared to a batch process with the equivalent PAC grade (Figure 1).

There are two reasons for the improved efficiency of sheet-based adsorption compared to bulk mixing adsorption processes.

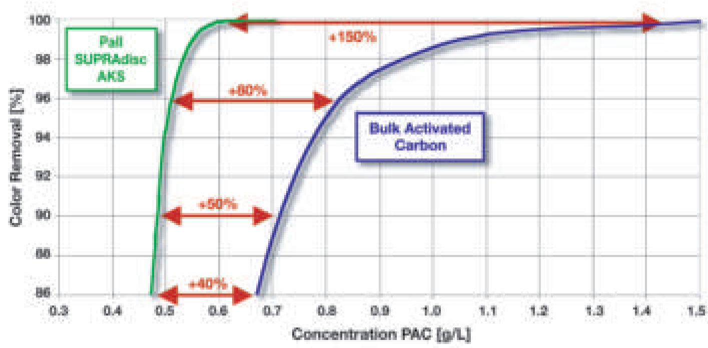
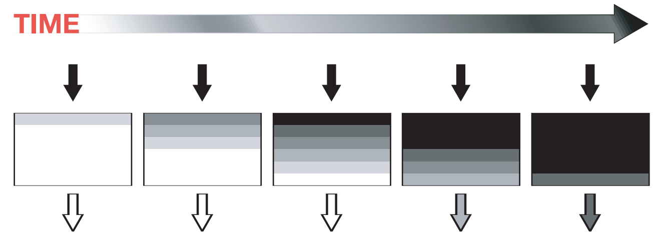


Figure 3: Comparison of decolorization between bulk carbon and carbon impregnated sheets with the same carbon grade using a customer Active Pharmaceutical Ingredient (API)

1) At an optimized flow rate, the probability of contact between the impurities and carbon particles is greater in carbon-impregnated sheets. This is due to process fluids more efficiently contacting carbon particles immobilized into a sheet matrix.

2) Because of the depth (thickness) of the sheet, it is possible to consider the structure as being made up of a series of layers containing PAC. The initial layers make first contact with the fluid and as time and increasing fluid

Figure 4: Adsorption behaviour of color within a single carbon sheet with time



volume is passed through this layer they are the first to become saturated with impurity. Subsequent layers, however, still have adsorbing sites and a capacity to adsorb impurity, which increases through the depth of the media (figure 4). In essence, having a depth of PAC and passing the fluid at an optimal flow rate through that depth enables the maximum potential of the carbon to adsorb impurity to be utilized.

Application Guidelines

Since colors, impurities and processes can vary, Pall offers nine thoroughly researched and optimized PAC grades incorporated into **Seitz** AKS filter media. These grades are based upon different raw materials and different activation methods resulting in pore structures and adsorption characteristics appropriate for adsorbing different molecular impurities (Table 1). According to International Union of Pure and Applied Chemistry (IUPAC) definitions, three groups of pores are distinguished. Macropores (above 50 nm diameter), mesopores (2–50 nm diameter) and micropores (<2 nm diameter).

Macro- and mesopores can generally be regarded as the highways into the carbon particle, and are crucial for adsorption kinetics. Large pores are used for the transport, and absorption occurs in the medium and micropores.

Small molecules, such as methylene blue, which has a molecular weight of 319.86 daltons, are mainly captured in micropores.

For larger impurity molecules, other pore structures in the carbon must be available to ensure optimal adsorption. Carbon, which can capture larger molecules, always tends to adsorb smaller impurities as well, whereas dedicated carbons for small molecules do not remove larger contaminants.

Table 1 provides an overview of how different AKS grades may suit an application based on their general characteristics. However, due to the various factors that may affect the adsorption process, Pall always recommends bench scale testing several **Seitz** AKS filter media with UpScale℠ test kits as the most reliable way of selecting the most suitable grade.

Table 1: Typical Applications and Efficiency Characteristics of Pall AKS Module Grades

AKS Grade	Typical Application	Efficiency Characteristic	Typical Molecular Weights of Target Contaminants
AKS 1	API decolorization	Ultra high efficiency	400 – 1500 daltons
AKS 2	API decolorization	Ultra high efficiency	400 – 1000 daltons
AKS 3	API decolorization	High efficiency	400 – 1000 daltons
AKS 4	General purpose	Lowest efficiency in AKS range	400 – 1500 daltons
AKS 5	Plasma fractionation	High efficiency	200 – 400 daltons
AKS 6	Plasma fractionation	High efficiency	400 – 1500 daltons
AKS 7	API decolorization	Ultra high efficiency	400 – 1500 daltons
AKS 8	API decolorization	High efficiency	400 – 1000 daltons
AKS 9	API decolorization	High efficiency	400 – 1000 daltons

Choosing the right grade and optimizing your process

Pall offers a complete range of **UpScale** products applicable from the development laboratory through the pilot plant to full production, with all 9 different AKS media grades. Media test discs are available in 47 mm, 60 mm and 90 mm diameter (other sizes upon request). Also available are highly convenient, fully disposable **SUPRAcap** 60 capsules (26 cm^2) for grade section and process development.

For pilot plant or smaller scale production, 12 in. **SUPRAdisc** AKS or **SUPRAcap** 200 lenticular modules may be used, whilst for full scale production 16 in. depth filter modules are available.

SUPRAcap 200 filters are fully encapsulated **SUPRAdisc** modules, designed for applications with hazardous materials.

The encapsulation of the module significantly reduces operator exposure and simplifies handling during change-out. Furthermore, the encapsulated modules provide a dramatic reduction in the proportion of normally wetted surfaces in the housing, resulting in faster hardware clean-up and easier cleaning validation compared to standard lenticular formats. For detailed information regarding **SUPRAcap** 200 capsules please refer to Pall publication USD 2295.

For selection and optimization studies, we recommend performing adsorption evaluation studies at a recommended range of flow rates either at your facility or in our SLS (Scientific and Laboratory Services) laboratories using appropriate **UpScale** product with AKS media. Pall specialists can provide valuable expertise, providing hands-on assistance if required and placing our extensive technical resources at your disposal.

Table 2: Media and Module Configuration Codes* for Different AKS Media Grades and Module Diameters

Media Grade	Media Code	Configuration Codes for 12 in. Modules	Amount of PAC Present per 12 in. Module (kg)	Media Area per 12 in. Module	Configuration Codes for 16 in. Modules	Amount of PAC Present per 16 in. Module (kg)	Media Area per 16 in. Module
AKS1	XAK1	212	1.4	1.35 m^2	415	3.65	3.5 m^2
AKS2	XAK2	212	1.4	1.35 m^2	415	3.65	3.5 m^2
AKS3	XAK3	214	1.3	1.6 m^2	416	3.00	3.7 m^2
AKS4	XAK4	215	0.7	1.7 m^2	419	1.85	4.35 m^2
AKS5	XAK5	214	1.05	1.6 m^2	416	2.40	3.7 m^2
AKS6	XAK6	214	1.35	1.6 m^2	416	3.00	3.7 m^2
AKS7	XAK7	212	1.4	1.35 m^2	415	3.65	3.5 m^2
AKS8	XAK8	214	1.3	1.6 m^2	416	3.00	3.7 m^2
AKS9	XAK9	214	1.3	1.6 m^2	416	3.00	3.7 m^2

* Modules with other areas available on request

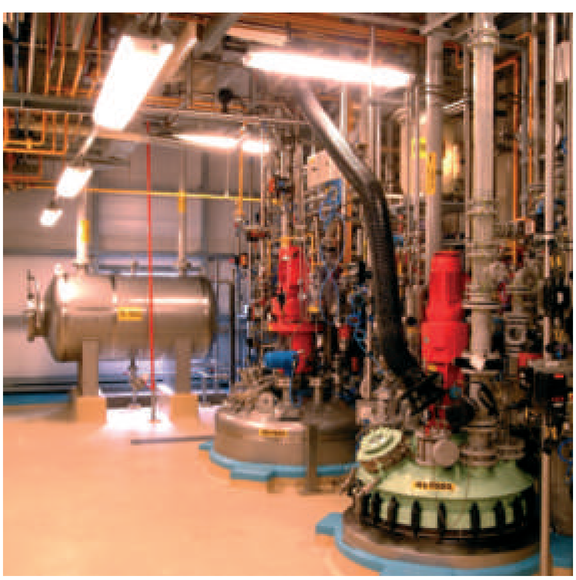
SUPRAdisc AKS Filters

Table 3: Ash and Endotoxin values for different AKS Grades

Media Grade	Typical Ash (%)	Typical Endotoxin (EU/mL)*
AKS1	<3	<0.12
AKS2	<4	<0.12
AKS3	<3	<0.12
AKS4	13	n.d
AKS5	<1	<0.06
AKS6	<3	<0.06
AKS7	<3	<0.12
AKS8	<2	<0.12
AKS9	<2	<0.12

All listed Pall SUPRAdisc AKS meet the specifications for the biological test listed in the current version of the USP Class VI 121°C and met the limits for determination of total extractables described in current 21CFR 177.2600

* values for unrinsed media



Materials of Construction

Media	Cellulose base and PAC
Plastics Components	Polypropylene (standard version) Polyamide (high temperature version)
O-rings	Platinum cured silicone elastomer or FEP encapsulated silicone or EPDM elastomer
Endcap Gaskets	Platinum cured silicone elastomer or EPDM Elastomer or PTFE

Operating Parameters*

Maximum Operating Temperature	80 °C in polypropylene design 160 °C in polyamide design
Maximum Differential Pressure	2.4 bar (35 psi) at 80 °C

Typical Operating Flow Rate**

150 – 250 L/m²/h

Sterilization

Steam in Place*	125 °C for 30 minutes at 0.3 bar differential (4.3 psi differential) maximum

Nominal Module Dimensions

Total Length	
Double O-ring Endcap Version	332 mm (13.1 in.)
Flat Gasket Endcap Version	272 mm (10.7 in.)
Total Diameter	284 mm (11.2 in.) (1) 410 mm (16.1 in.) (2)

SUPRAcap 200 AKS Filters

Materials of Construction

Media	Cellulose base and PAC
Plastic Components	Polypropylene
O-rings	Platinum cured silicone elastomer or FEP encapsulated silicone or EPDM elastomer

Operating Parameters*

Maximum Operating Temperature	90 °C
Maximum Operating Pressure	6 bar gauge (87 psi gauge) at 60°C 3 bar gauge (44 psi gauge) at 90°C
Maximum Differential Pressure	2.4 bar (35 psi) at 80 °C

Typical Operating Flow Rate**

150 – 250 $L/m^2/h$

Sterilization

Steam in Place* (3)**	125 °C for 30 minutes at 0.3 bar differential (4.3 psi differential) maximum

Nominal Dimensions

Total Length	326 mm (12.8 in)
Total Diameter	298 mm (11.7 in)

SUPRAcap 60 AKS Filters

Materials of Construction

Media	Cellulose base and PAC
Capsule	Polycarbonate
Vent	Polypropylene
Sealing Technology	Thermal bonding

Operating Parameters*

Maximum Operating Pressure and Temperature	3 bar gauge (44 psi gauge) at 40 °C
Maximim Differential Pressure	1.5 bar (22 psi)

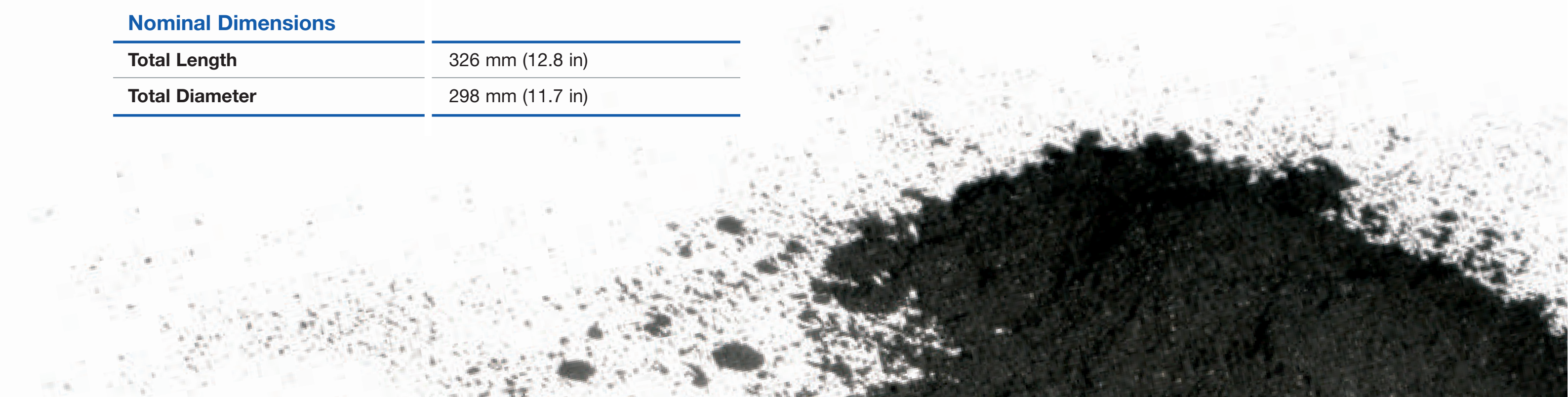
Sterilization(4)

Autoclaving at 125 °C 1 cycle x 30 minutes

Typical Filtration Area

26 cm^2 (4.04 in^2)

* with compatible fluids, which do not soften, swell or adversely affect the product or its material of construction
** Higher flow rates may be possible
*** Steam in place must only take place in the forward flow direction
(1) Filter area codes 212, 214, 215
(2) Filter area codes 415, 416, 419
(3) Only possible for modules with stainless steel insert in endcaps - code C300
(4) SUPRAcap 60 capsules must not be sterilized *in situ* by passing steam under pressure



Ordering Information

Pall Part Number: (For SUPRAdisc AKS 12 and 16 inch diameter lenticular filters only. For other products see media options in respective product datasheets)

3

Module Code	Module Version	Media Code	Endcap Code	Endcap Version	Configuration Code	Code Seal	O-ring/ Gasket Material	Plastic Code	Plastic Parts
00	Standard	See column 2 Table 2	S	Double O-Ring	See column 3 and 6 Table 2	S	Silicone Elastomer	P	Polypropylene
01	High Temperature		C	Flat Gasket		F	FEP Silicone[i]	A	Polyamide
						E	EPDM Elastomer		
						T	PTFE[ii]		

Example Part number: 300XAK1C415EP
Standard SUPRAdisc module with AKS1 media, 16 in. diameter flat gasket endcap with EPDM gasket seals, plastic parts all-polypropylene

Pall Part Number: (For SUPRAcap 200)[iii]

C3

Module Code	Module Version	Media Code	Endcap Code (S)	Endcap Version	Configuration Code	Code Seal	O-ring/ Gasket Material	Plastic Code (P)	Plastic Parts
00	Standard	See column 2 Table 2	S	Double O-Ring	See column 3 Table 2	S	Silicone Elastomer	P	Polypropylene
06[iv]	Without stainless steel ring in endcap adapter					F	FEP Silicone		
						E	EPDM Elastomer		

Example Part number: C306XAK5S214FP
SUPRAcap 200 encapsulated module without stainless steel insert in endcaps, containing AKS 5 media and supplied with FEP encapsulated silicone O-rings

Pall Part Number: (For SUPRAcap 60)

SC060

Media Code
See column 2 Table 2

Example Part number: SC060XAK3
SUPRAcap 60 encapsulated module with AKS 3 media

(i) only available for double o-ring endcap adapter (ii) only available for flat gasket endcap (iii) only available in 12 in. diameter modules with double o-ring endcap adapter (iv) Not steamable

Life Sciences

New York - USA
+1 516 484 5400 phone
+1 516 801 9548 fax
biotech@pall.com e-mail

Portsmouth - Europe
+44 (0)23 9230 3303 phone
+44 (0)23 9230 2506 fax
BioPharmUK@europe.pall.com e-mail

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PELEH/MG/CS/09.07