

ultra.bio PF-PES DL

Double Layer Polyethersulphone Membrane Cartridge Filters



ultra.bio PF-PES DL microbial rated double membrane layer filter cartridge has been developed and manufactured for the filtration of liquids in the pharmaceutical, biotechnology and other critical applications.

ultra.bio PF-PES DL utilises a naturally hydrophilic

polyethersulphone (PES) membrane with a mirrored asymmetric pore structure. The cartridge's unique built in prefiltration membrane layer provides longer life and higher throughput.

When combined with quality all-polypropylene components and high integrity manufacturing techniques, the ultra.bio PF-PES DL filter cartridge is ideally suited to the most demanding process conditions.

ultra.bio PF-PES DL cartridges are constructed in a clean room under tightly controlled conditions using advanced, highly specialised machinery. Quality and consistency of product is assured by the quality control and manufacturing procedures, which are in place throughout all stages of manufacture.

ultra.bio PF-PES DL membrane cartridges are 100% integrity tested during manufacture by the forward flow diffusion test method.

Applications

ultra.bio PF-PES DL cartridges are suitable for the sub-micronic filtration of a wide range of process liquids, in applications where the characteristics of a naturally hydrophilic membrane are required.

Typical applications include:

- Biopharmaceuticals
 For the sterilisation of biological fluids, cell culture media, sera and blood fractionations.
- Fermentation
 For providing sterile feed stock for the production of antibiotics and enzymes.
- Ophthalmic solutions

Shelf life assured through the low adsorption of preservatives, such as Benzalkonium Chloride (BAK).

• API's

For the clarification and sterilisation of a wide range of active pharmaceutical ingredients.

• LVP's

For final filtration of Total Nutritional Fluids, dextrose, amino acids and saline solutions.

• Beverages

For the clarification and sterilisation of various beverages, including the removal of yeast and spoilage organisms. Low colour removal is an additional advantage.

• Pure water supply

For use in ultrapure water treatment systems (including Water-For-Injection).





Features and Benefits

• ultra.bio PF-PES DL cartridges

ultra.bio PF-PES DL cartridges contain an optimised, validated prefiltration membrane upstream of the final micron rated membrane. This results in long life and higher throughput.

• Guaranteed microbial ratings

ultra.bio PF-PES DL cartridges are validated for bacterial removal according to HIMA guidelines and ASTM F838-05, with a log reduction value >7. They are therefore suitable for applications requiring sterilising grade filtration.

• Low protein binding

ultra.bio PF-PES DL cartridges have excellent low protein binding characteristics, typically 10 times lower than nylon, 2 times lower than polysulphone and similar to PVDF.

• Will not hydrolyse

Compared with other membranes such as nylon, the polyethersulphone membrane used in ultra.bio PF-PES DL cartridges is extremely resistant to hydrolysis. Capable of exposure in excess of 2 years, they are ideal for hot deionised water applications.

• Excellent chemical compatibility

Resistant to many process chemicals, ultra.bio PF-PES DL cartridges are suitable for use in a wide range of process applications.

• Cartridge integrity and low TOC levels

Each ultra.bio PF-PES DL module of every cartridge is individually integrity tested. Each complete filter cartridge is flushed with pure water which is inspected daily for pyrogens using the standard LAL test. When required, they can be pulse flushed with $18M\Omega$.cm pyrogen-free ultra-clean water.

Suitable for steam sterilising

ultra.bio PF-PES DL cartridges incorporating a stainless steel support ring can be subjected to steam sterilisation at $125^{\circ}C$ ($257^{\circ}F$) without loss of integrity.

• Full traceability

All ultra.bio PF-PES DL cartridges are individually and batch identified with a unique serial number. Each ultra.bio PF-PES DL cartridge is supplied with a Certificate of Quality and an operating instruction leaflet.

• Controlled manufacturing environment ultra.bio PF-PES DL cartridges are manufactured in an ISO Cleanroom environment by fully gowned staff, minimising the risk of contamination.

Cartridge Construction

ultra.bio PF-PES DL cartridges are manufactured from a multi-layer combination of irrigation mesh, prefiltration membrane, final membrane, membrane support and drainage material. ultra.bio PF-PES DL cartridges have optimal pleat geometry to maximise the available filtration area and to ensure an efficient flow through the cartridges.

An all thermal fusion bonded assembly process eliminates the use of resins and binders.

Manufactured as standard with injection moulded polypropylene inner and outer supports, ultra.bio PF-PES DL cartridges are designed with the strength necessary to withstand thermal stresses encountered during steam sterilisation and subsequent cooling. They can be steam sterilised and will retain total integrity following steaming at 125°C (257°F).

All components used in the construction of ultra.bio PF-PES DL cartridges are FDA approved to 21CFR and meet or exceed the latest EC Directives for Food Contact.





Specifications

Materials of Manufacture

Prefilter membrane:	Polyethersulphone
Final membrane:	Polyethersulphone
Membrane support:	Polypropylene
Irrigation mesh (support):	Polypropylene
Drainage layer:	Polypropylene
Inner core:	Polypropylene
Outer support:	Polypropylene
End fittings:	Polypropylene
Support ring:	Stainless steel

Cartridge Dimensions (Nominal)

Diameter:		70 mm (2.8")
Length:	1 module:	ultra.bio PF-PES DL Junior
	1 module:	254 mm (10")
	2 modules:	508 mm (20")
	3 modules:	762 mm (30")
	4 modules:	1016 mm (40")

Effective Filtration Area

Absolute Microbial	Effective Filtration Area
Rating	(each 254mm (10") module)
0.2 and 0.45µm	0.48m ² (5.2ft ²)

Cartridge Treatment

Standard:	Cleaned and flushed with pyrogen-free water.
Rinsed:	Ultra-clean, pulse flushed to give a system
	resistivity of 18MΩ.cm.

Gaskets and O-Rings

FDA approved Ethylene Propylene, FEP encapsulated, Silicone, Viton^{*} or Nitrile.

Maximum Differential Pressure

Normal flow direction at:	
20°C (68°F):	6.0 bar (87psi)
80°C (176°F):	4.0 bar (58psi)
100°C (212°F):	3.0 bar (44psi)
120°C (248°F):	2.0 bar (29psi)
Reverse flow direction at:	
20°C (68°F):	2.1 bar (30psi)
80°C (176°F):	1.0 bar (15psi)
100°C (212°F):	0.5 bar (7psi)

Operating Temperature

Maximum continuous:

85-90°C (185-194°F)



Sterilisation

In situ steam 80 x 20 minute cycles at 125°C (257°F). Hot water 100×20 minute cycles at 85-90°C (185-194°F).

Extractables

Minimum total extractables. Please refer to the ultra.bio PF-PES DL Validation Guide.

Integrity Testing

Each ultra.bio PF-PES DL module of every cartridge is individually integrity tested using the Diffusive Flow Test, which correlates to the HIMA and ASTM F838-05 bacterial challenge tests. Non-destructive integrity tests, such as Pressure Hold, Diffusive Flow and Bubble Point, can be performed by customers. Procedural details are available on request.

Clean Water Flow Rates

- Typical clean water flow rate: A 254mm (10") ultra.bio PF-PES DL single cartridge exhibits the flow-**Δ**P characteristics indicated below, for solutions with a viscosity of 1 centipoise.
 - Other solutions: For solutions with a viscosity of greater than 1 centipoise, multiply the indicated differential pressure by the viscosity in centipoise.

