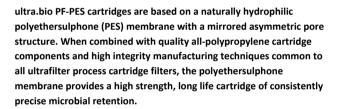


ultra.bio PF-PES

Polyethersulphone Membrane Cartridge Filters



ultra.bio PF-PES cartridges exploit the narrow pore size distribution and high void volume of the media to provide a choice of cartridges capable of meeting the requirements of most applications. Careful media selection ensures that ultra.bio PF-PES cartridges are also very suited to critical particle control down to 0.04 micron ratings. ultra.bio PF-PES cartridges offer high flux rates and low differential pressures, a feature common to polyethersulphone membranes.

ultra.bio PF-PES cartridges benefit from the low non-specific protein binding characteristics of polyethersulphone membranes. They are also highly resistant to integrity failure caused by steam sterilisation and have excellent chemical compatibility characteristics. Furthermore, since they will not hydrolyse, ultra.bio PF-PES cartridges are ideal for use in ultra pure water supply systems (18M Ω .cm).

As a consequence ultra.bio PF-PES cartridges provide a combination of features and benefits not hitherto available from cartridges based on PVDF, nylon, mixed esters of cellulose or polysulphone membranes. They are suitable for applications ranging from sterile filtration, bioburden reduction and the clarification of a wide range of process liquids and end products.



Applications

ultra.bio PF-PES 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 sub-micronic filtration of ingredients, intermediates, makeup waters and final products, including sterilisation, clarification and bioburden reduction.

· Ophthalmic solutions

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

· Electronics and semiconductors

For the sub-micronic filtration of process water and chemicals, including solvents, developers and photoresists. Applications typically include central water plant treatment and critical 'wet bench' point of use filtration.

· Fine chemicals

For the clarification and sterilisation of a wide range of process chemicals.

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), as either a sterilisation filter or for bioburden reduction.





Features and Benefits

ultra.bio PF-PES

Careful media selection means that ultra.bio PF-PES cartridges are available to suit a wide range of process critical and general purpose applications.

Guaranteed microbial ratings

ultra.bio PF-PES 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 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 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 cartridges are suitable for use in a wide range of process applications.

· Cartridge integrity and low TOC levels

Each ultra.bio PF-PES 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 $18 M\Omega.\text{cm}$ pyrogen-free ultra-clean water.

• Suitable for steam sterilising

ultra.bio PF-PES cartridges incorporating a stainless steel support ring can be subjected to steam sterilisation at 135°C (275°F) without loss of integrity.

Full traceability

All ultra.bio PF-PES cartridges are individually and batch identified with a unique serial number.

Each ultra.bio PF-PES cartridge is supplied with a Certificate of Quality and an operating instruction leaflet.

· Controlled manufacturing environment

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

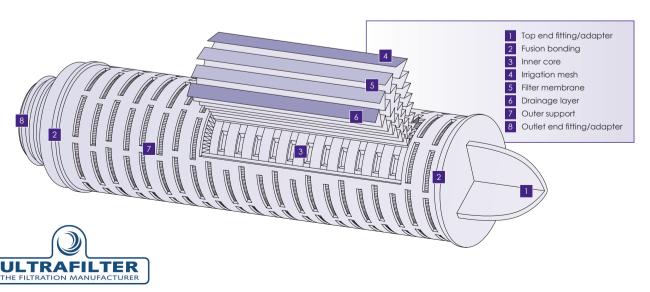
Cartridge Construction

ultra.bio PF-PES cartridges are manufactured from a multilayer combination of irrigation mesh, filter membrane, membrane support and drainage material. ultra.bio PF-PES 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 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 135°C (275°F).

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



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Specifications

Materials of Manufacture

Polyethersulphone Filter membrane: 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)

Effective Filtration Area

Absolute Microbial	Effective Filtration Area
Rating	(each 254mm (10") module)
0.04, 0.1, 0.2, 0.45, 0.65 and 1.2μm	0.69 m ² (7.4 ft 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 100 x 65 minute cycles at 135°C (275°F). Hot water 100 x 20 minute cycles at 90°C (194°F).

Extractables

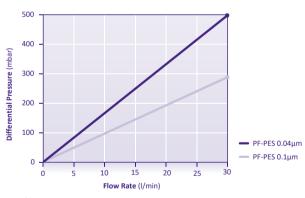
Minimum total extractables. Please refer to the ultra.bio PF-PES Validation Guide.

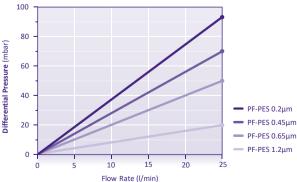
Integrity Testing

Each ultra.bio PF-PES 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 single cartridge exhibits the
 flow-ΔP 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.







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