TETPOR HP Filter Cartridges

- liquid filters
- hydrophilic PTFE

TETPOR HP filter cartridges have been specially designed to minimize protein and preservative binding in the sterilization of pharmaceutical and multi-dose ophthalmic solutions.

Adsorption of proteins or preservatives from a pharmaceutical preparation onto the filter membrane can complicate the manufacturing process and lead to costly product wastage. The unique hydrophilic PTFE membrane featured in the TETPOR HP exhibits lower levels of binding than other commonly used filtration membranes such as PES and PVDF which can prevent product loss during processing.

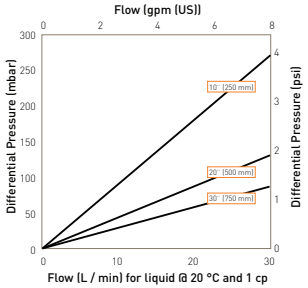
The TETPOR HP exhibits low extractable levels and the sterilizing grade membrane has comparative flow rates to PES and PVDF products. Its hydrophilicity is stable to both chemicals and heat. The product also offers an exceptionally broad range of chemical compatibility making it well suited to the processing of aggressive aqueous liquids.

Note: TETPOR is a registered trademark of Parker domnick hunter

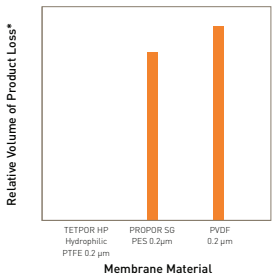
Features and Benefits

- Exceptionally low binding membrane to prevent costly product loss and process down time
- Incorporates a fully validated and integrity testable 0.2 micron membrane for assurance of sterility
- Fast flowing membrane for increased process efficiency

Performance Characteristics

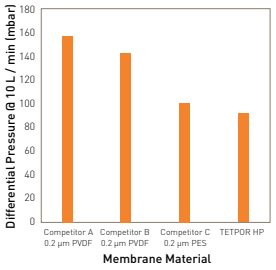


Cartridge flow rates



Comparison of product loss due to preservative binding on different filter membranes for a 0.001 % solution of benzalkonium chloride (BAK)

* *The relative volume of product loss represents the volume at which the concentration of BAK in the filtrate recovers back to 95 % of the original concentration, which is typically the point at which the filling operation can begin.*



Comparison of differential pressure of 10¨ (250 mm) sterilising grade cartridges filtering water

Specifications

Materials of Construction

Filtration Membrane:	Hydrophilic PTFE
Upstream Support:	Polypropylene
Downstream Support:	Polypropylene
Inner Support Core:	Polypropylene
Outer Protection Cage:	Polypropylene
End Caps:	Polypropylene
Standard o-rings:	Silicone

Recommended Operating Conditions

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

Temperature °C	Temperature °F	Max. Forward dP (bar)	Max. Forward dP (psi)
20	68	5.0	72.5
40	104	4.0	58.0
60	140	3.0	43.5
80	179	2.0	29.0
90	194	1.7	24.6

Effective Filtration Area (EFA)

10¨ (250 mm)	0.88 m^2 (9.47 ft^2)
20¨ (500 mm)	1.76 m^2 (18.94 ft^2)
30¨ (750 mm)	2.64 m^2 (28.42 ft^2)

Sterilization

TETPOR HP filter cartridges are validated to withstand 10 steam-in-place cycles at 135 °C (275 °F).

TETPOR HP filter cartridges 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 Parker domnick hunter contact.

Food and Biological Safety

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

Quality Standards

Pharmaceutical grade products are manufactured in accordance with cGMP, 100 % flushed with pharmaceutical purified water and integrity tested prior to despatch. A sample of each lot is tested to demonstrate conformity to validated claims.

TOC / Conductivity

The filtrate quality from a 10¨ (250 mm) TETPOR HP conforms to the requirements of current USP <643> (TOC) and USP <645> (conductivity) within the first 200 ml flush of purified water.

Endotoxins

Aqueous extracts from the 10¨ (250 mm) TETPOR HP contain < 0.25 EU / ml when tested in accordance with the Limulus Amoebocyte Lysate test.

Non-Volatile Extractables (NVE)

The quantity of NVE's obtained from a TETPOR HP cartridge during a 24 hour static soak was undetectable compared to a control sample.

Oxidizable Substances

TETPOR HP filter cartridges meet current USP and EP quality standards for sterile purified water for oxidizable substances following a <1 litre water flush.

Integrity Test Data

All filters are integrity testable to the following limits when wet with water and using air as the test gas (a minimum 20 minute purified water flush is recommended prior to integrity testing in water).

Micron Rating		0.2
Min. Bubble Point	(barg)	1.5
(60 / 40 IPA / Water (v/ v))	(psig)	21.0
Diffusional Flow	(barg)	2.2
Test Pressure	(psig)	31.9
Max. Diffusional Flow*(10¨) (ml / min)		37.0

**Note: It is also possible to integrity test the TETPOR HP in 60 / 40 IPA / Water (v / v). Maximum allowable diffusional flow for a 10¨ (250 mm) TETPOR HP in 60 / 40 IPA / Water is 16.8 ml / min.*

Retention Characteristics

TETPOR HP filter cartridges are validated by bacterial challenge testing with *Brevundimonas diminuta* to current ASTM F838-05 methodology (10^7 organisms / cm^2 EFA minimum) with typical in-house challenge levels being 10^{11} organisms per 10¨ (250 mm) module.

Pharmaceutical Validation

A full validation guide is available upon request from Laboratory Services Group (LSG).

Ordering Information

ZCMT [ ] - [ ] [ ] - [ ] - [ ]

Code | Length (Nominal)		
1	10¨	(250 mm)
2	20¨	(500 mm)
3	30¨	(750 mm)

Code | Micron		
020	0.2	µm

Code | Endcap (10¨)		
C	P-7	

Code | Variant		
HP	Hydrophilic PTFE	

Code | O-rings	
E	EPDM
P	PTFE Encapsulated Silicone
S	Silicone
V	Viton