



# TETPOR HP Filter Cartridges

- liquid filters
- hydrophilic PTFE

TETPOR HP filter cartridges have been specifically designed to minimise preservative binding for economic sterilisation of multidose ophthalmic solutions.

Preservatives are present in low concentrations in ophthalmic solutions and therefore any adsorption onto a filtration membrane can complicate the manufacturing process. Ensuring preservative levels are maintained requires a validated method of preconditioning the filters prior to processing which can be time consuming and costly in terms of product wastage.

The unique hydrophilic PTFE membrane featured in the TETPOR HP exhibits lower levels of preservative binding than other membrane types such as PES and PVDF and can practically eliminate the adsorption of preservatives from ophthalmic solutions.

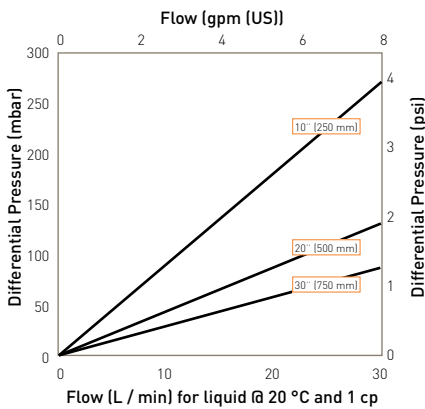
## Features and Benefits

- Eliminates preservative binding preventing product loss and process downtime
- Incorporates a fully validated and integrity testable 0.2 micron membrane for assurance of sterility
- Fast flowing membrane for increased process efficiency

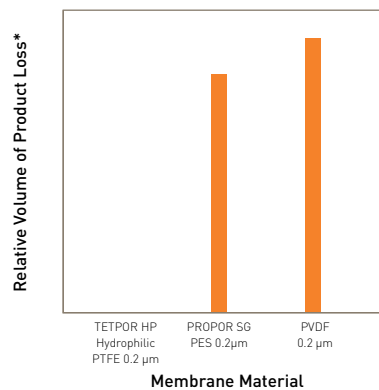


Note: TETPOR is a registered trademark of Parker domnick hunter

## Performance Characteristics

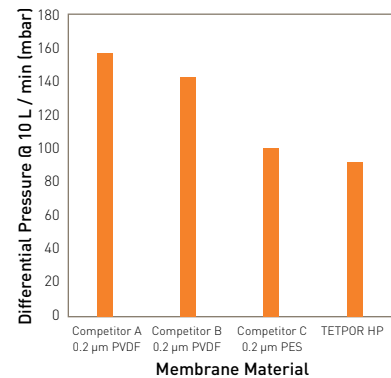


Cartridge flow rates



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 filtering 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		Max. Forward dP	
°C	°F	(bar)	(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 <sup>2</sup> ( 9.47 ft <sup>2</sup> )
20" (500 mm)	1.76 m <sup>2</sup> (18.94 ft <sup>2</sup> )
30" (750 mm)	2.64 m <sup>2</sup> (28.42 ft <sup>2</sup> )

### Sterilisation

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

TETPOR HP filter cartridges can be sanitised 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 sterilisation, 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.

### Oxidisable Substances

TETPOR HP filter cartridges meet current USP and EP quality standards for sterile purified water for oxidisable 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 (l/v) (psig)		21.0
Diffusional Flow (barg)		2.2
Test Pressure (psig)		31.9
Max. Diffusional Flow*(10 <sup>-1</sup> ) (ml / min)		37.0

*\*Note: It is also possible to integrity test the TETPOR HP in 60 / 40 IPA / Water (l/v). Maximum allowable diffusional flow for a 10" (250 mm) TETPOR HP in 60 / 40 IPA / Water is 16.8 ml / min at a test pressure of 800 mbar.*

### Retention Characteristics

TETPOR HP filter cartridges are validated by bacterial challenge testing with *Brevundimonas diminuta* to current ASTM F838-05 methodology (10<sup>7</sup> organisms / cm<sup>2</sup> EFA minimum) with typical in-house challenge levels being 10<sup>11</sup> 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)	Code   Micron	Code   Endcap (10")	Code   Variant	Code   O-rings			
1 10" (250 mm)	020 0.2 µm	C P-7	HP Hydrophilic PTFE	E EPDM			
2 20" (500 mm)				P PTFE			
3 30" (750 mm)				S Silicone			
4 40" (1000 mm)				V Viton			

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