Sartobran PH_20

Membrane Filter Cartridges for High Purity Water Applications in the Pharmaceutical Industry

Major Applications

Sartobran PH_2O filters are ideal for the final polishing filtration steps of DI water in central water treatment systems, and for other applications, where integrity testing pre- and post-filtration is required. Examples of applications are:

- Water system filtration
- Cell removal filtration from fermentation and bioreactor harvest media
- Clarification filtration prior to chromatography

Product Profile

Each cartridge is integrity tested prior to release, and is user integrity testable upon installation and after use. Sartobran-PH_2O cartridges are heat-sealed and individually flushed with ultrapure water as part of the manufacturing process. This minimizes rinse-up time prior to use.

All materials of construction are unaffected by 3 months immersion in 80°C hot water and have passed the current Class VI Plastics Test. The filtrate meets or exceeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate, and heavy metals. All filters comply with cGMP requirements for non-fiber releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Full validation information is available.

Excellent Throughput

Sartobran PH_2O filter cartridges incorporate a double layer heterogeneous membrane structure, such that the first membrane layer has a larger pore size structure than the final membrane. This provides a progressively finer particle removal and results in high flow rates and throughputs.

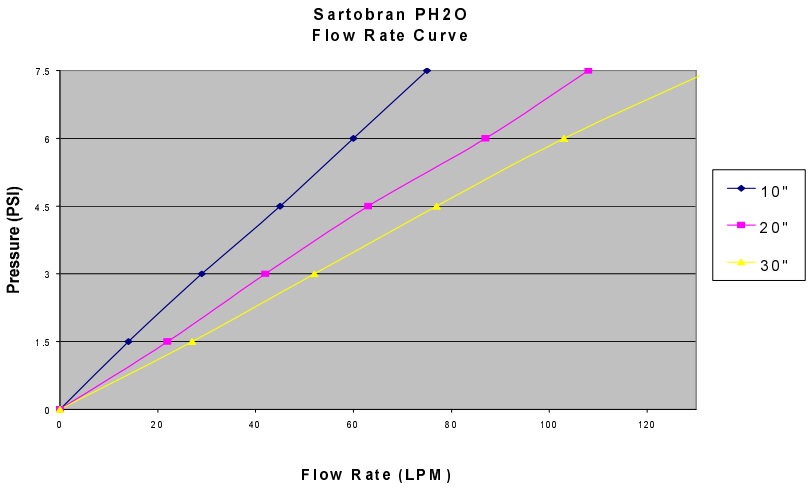
Long Service Life in Water Systems

The cellulose acetate membrane filters have excellent resistance with DI water up to 80°C and also with chemical disinfectants commonly employed in the electronics industry and pharmaceutical industry, i.e. hydrogen peroxide. As a result the filter components will not become hydrolyzed as it may occur with other materials.

Integrity Testable Membrane Filtration

In applications where filters must be integrity tested prior to filtration, Sartobran PH2O filter cartridges can be integrity tested using a validated standard Diffusion Test and Bubble Point Test.

Features	Benefits
Double Heterogeneous Membrane Layer	Higher throughputs coupled with high flow rates at low differential pressure.
Integrity Testable by Diffusion, Bubble Point and Pressure Hold Tests	Integrity of the filtration system can be verified prior to use and post-filtration
Compatible with 80°C water – continuously or alternating with cold water - for 3 months without hydrolysis.	Ideal for WFI loop systems.
Compatible with 30% hydrogen peroxide, and hypochlorite solutions	Wider choice of cleaning agents
Filtrate meets the current USP requirements for Water for Injection. All materials fulfill the requirements of CFR Title 21 for non-fiber releasing filters and the filters have passed the current USP Class VI Plastics Test.	Filters are biosafe and can be used for the filtration of pharmaceutical and biological products without the risk of affecting their activity.



Materials of Construction			
Prefilter	Cellulose Acetate	Core	Polypropylene
Membrane Filters	Cellulose Acetate	End Caps	Polypropylene
Outer Support	Polypropylene	ORings	Silicone*

*EPDM and Viton O-rings are also available. Add an E or V to the part number

Technical Data

Filtration area, standard cartridges	6.5 ft^2 per 10" element
Outer diameter and height	72 mm (2.8 ") x 10" nominal per element not including adapter
Maximum differential pressure	75 psi at 20°C 30 psi at 80°C
Maximum back pressure	30 psi at 20°C
Rinsing requirements before use	Use out of Box to meet USP-WFI specs
Rinsing requirements prior to integrity testing	Flush the filter with ambient water for 5 minutes at a differential pressure of 5 psi.
Sterilization:	Autoclaving (134°C, 30 min.) In-line steaming (up to 30 psi inlet with max. differential pressure of 5psi, 30 min.) Validated for at least 20 cycles.
Chemical compatibility:	See table in the Sartorius Validation Guide or contact Sartorius

Integrity Test Values (cartridges wetted with water): Diffusion Testing

Pore Size	Test Pressure	Max. Allowable Air Diffusion
0.2 µm	22 psi	10" - 15 ml/min 20" - 30 ml/min 30" - 45 ml/min

Integrity Test Values (cartridges wetted with water): Bubble Point

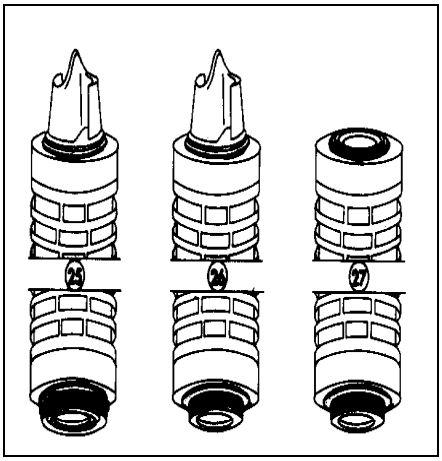
Pore Size	Bubble Point
0.2 µm	29 psi

Available Types and Order Numbers: Sartobran PH_2O Standard Cartridges

End cap/ adapter type	Pore size (nominal)	CONFIGURATION:		
Number		1-HIGH (10")	2-HIGH (20")	3-HIGH (30")
21	0.2 um	5232107G1PH2O	5232107G2PH2O	—
25	0.2 um	5232507G1PH2O	5232507G2PH2O	5232507G3PH2O
26	0.2 um	5232607G1PH2O	5232607G2PH2O	5232607G3PH2O
27	0.2 um	5232707G1PH2O	5232707G2PH2O	5232707G3PH2O

*Note- EPDM or Viton O-rings are also available. Add the letter E or V to the end of the part number.

Adapter Types



Cartridge Adapter Types

21 – Double Open End
25 - (2) 226 O-rings, lock in tabs, S-adapter top
26 - (2) 222 O-rings, S-adapter top
27 - (2) 222 O-rings, flat top

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