

WHITE PAPER

IMPROVING PROCESS EFFICIENCIES IN ULTRAPURE WATER SYSTEMS

Optimization strategies
for a competitive industry

By the year 2030, the ultrapure water industry is project to reach more than \$13.5 billion USD.

Demands for pure water are at an all-time high and there is an increasing need to abide by stringent environmental regulations. To stay competitive, it is more important than ever to optimize process efficiencies in order to save production costs and avoid the consequences of downtimes.

This white paper provides information to help educate and inform the reader on best practice methodologies.

Delivering a Quality Product

As consumer product quality and health care regulations continue to tighten, so does the demand for manufacturers to produce a cleaner, higher quality product. As a significant ingredient, power source or cleansing agent in many manufacturing processes, pure and ultrapure water are becoming a substantial part of the equation for success.

The majority of pure and ultrapure water systems must meet strict regulations of industry-specific governing bodies, such as the FDA, USP, ST108 AAMI or EU. Each of these organizations set guidelines for the production and usage of pure and ultrapure water within their respective industries. However, regardless of who sets the standard, micro-filtration is always a crucial part of the formula.

With these global challenges, the need for efficient and effective filtration systems has become an essential component to delivering quality product. Depending on the industry, the manufactured product, or the regulating body setting the rules, water quality expectations may vary dramatically from one system to another.

The one constant variable is the presence of microfiltration technologies. Whether you're looking for basic visual clarity or require something more specific such as 18 meg-ohm resistivity or full microbiological sterility and endotoxin removal, your choice of filter has a direct impact on your ability to optimize your system.





Filtration Solutions Have a Direct Impact on the Quality of your Products

Selecting the Best-Suited Media

Several factors must be considered when selecting the best-suited filtration media including the required flow rate, influent quality, and effluent requirements.

One factor to consider is influent quality. There must be adequate coverage of the filtration area (EFA), in order to fulfill the flow rate required. Depending upon the particulate distribution, and ambient conditions, coverage can be accomplished with a depth or pleated depth filter.

After solid removal, the focus shifts to the capabilities of the remaining components of the system and the desired final product water quality. If reverse osmosis, deionization, or carbon system is present, the system must be protected accordingly. This can be accomplished with the use of a high-purity pleated depth product, such as pleated polypropylene or pleated microglass, which optimizes the rating and capacity during this stage.



Additionally, the product water must be polished or filtered with a membrane, to reach the required cleanliness. In general, the polishing filter will utilize a 0.2µm hydrophilic membrane, with or without bacterial retention. Appropriate regulatory agencies or in-house company guidelines will typically provide membrane requirements for your process.

While the general process for producing pure or ultrapure water is similar from one system to the next, each process is unique and requires specific considerations.

Recognizing Differences in Process & Product

With regard to the multiple variables in each pure and ultrapure water manufacturing process, the various levels and types of filtration solutions must be considered.

Typical applications for pure and ultrapure water include:

Pure Water

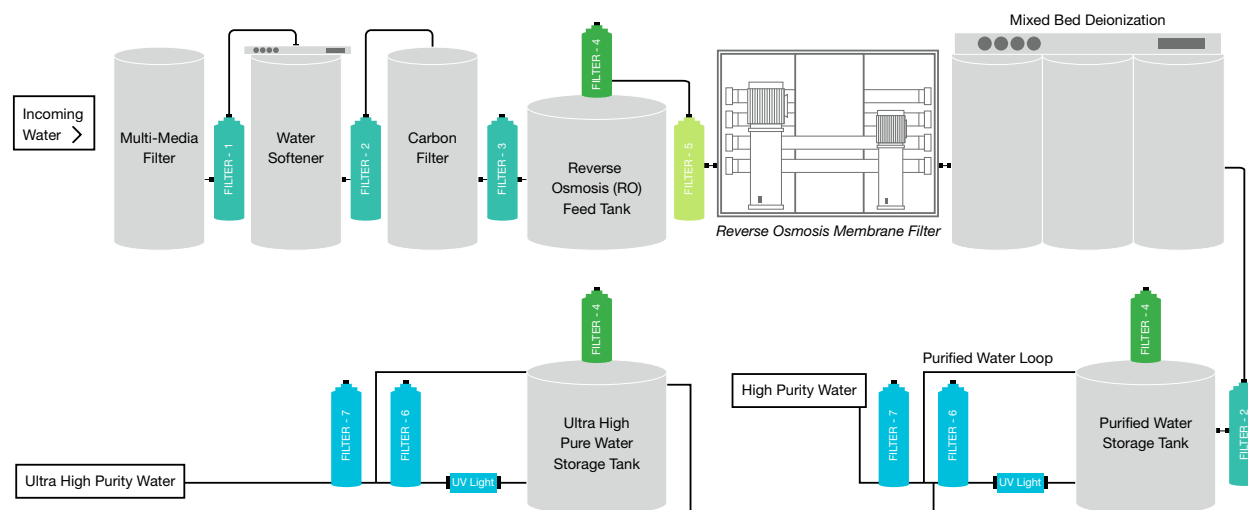
- Mixed Bed Ion Exchange
- Water Conductivity Systems
- Boiler Feed Water

Ultrapure Water

- Semiconductor Manufacturing
- Water For Injection (WFI)
- Laboratory Grade Water

Optimizing the High Purity Water Process

Before purchasing a water purification system, it is important to understand the purity process that will optimize the system.



Sediment, Particulate & Trap Filter Stages: 1, 2, 3

Pleated Polypropylene

PP, PPE, PPI, HFPP Series

Pleated Microglass

FG, FGE, HFFG Series

Polypropylene Meltblown

GWTB, GCTB, GATB Series

Activ Carbon Depth Cartridges

GCCB+ Series

Protecting the activated carbon, deionization tanks, and the RO or Ion Exchange Units (IEU) is critical. Surface or groundwater is typically treated and softened before filtration with a filter that removes particles larger than 10 microns, then filtered down to one to five microns filter to protect downstream equipment. Activ carbon cartridges can also be used. Our PP, PPE & PPI, FG and FGE cartridges are absolute rated according to the F795-88 norm.

Tank Filter Stages: 4

PTFE (Hydrophobic) Membrane

GGPTFE Series (General Grade)

BRPTFE Series (Bio-burden Reduction grade)

PPTFE Series (Sterilizing Grade)

Polysulfone (Hydrophobic) Membrane

PSH Series

Storage and fill tank vent filtration allows for bacteria and particulate-free air to pass during filling and evacuation, protecting the storage tank and its contents from contamination. This filter is typically rated at 0.2 micron and is hydrophobic and bacterial retentive, which prevents moisture airborne contaminants from entering the tank. The BRPTFE-Series has a logarithmic retention value of 7.4 on aerosolized bacteriophage, preventing process contamination.

Pre-Filtration Filter Stages: 5

Pleated Polypropylene

PP, PPE, PPI, HFPP Series

Pleated Microglass

FG, FGE, HFFG Series

Removes fine particles and suspended organic matter and serves as pre-filtration to the RO and deionization system. If water has IEU treatment, a 5-micron filter may be installed between the IEU and the water storage tank to prevent fractured beads from entering.

Bio-Burden/Polishing Filter Stages: 6 & 7

Polyethersulfone (Hydrophilic) Membrane

GEPES Series (Electronics Grade)

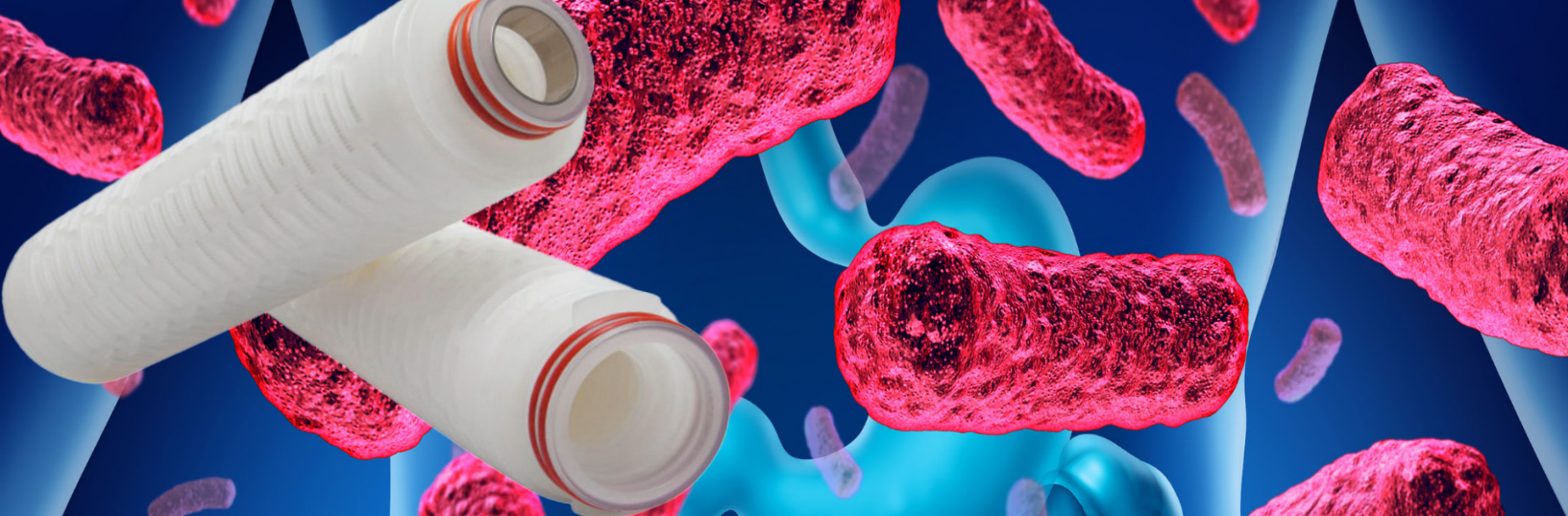
GFPES Series (Food & Beverage Grade)

BRPES Series (Bio-Burden Reduction Grade)

PPES Series (Pharmaceutical Grade)

BRHNY Series (Bio-Reduction Grade Nylon +)

Reduces and removes microorganisms and contaminants down to 0.2 micron as final filtration to high purity applications and as further polishing in downstream ultra high purity water systems.



Filtration Solutions for Endotoxin Removal

The importance of endotoxin removal

Endotoxins present in the water systems used in fine chemical applications are harmful for consumption and must be eliminated. Endotoxins are molecules present in the outer membrane of certain Gram-negative bacteria, such as Escherichia Coli and Salmonella. They are released when these bacteria are destroyed, constituting a potential health hazard. Chemically, these bacterial membrane residues are mainly composed of amphiphilic lipopolysaccharides, combining a lipid and a complex sugar. Endotoxins are water-soluble and highly resistant to heat; even prolonged contact with boiling water fails to eliminate them. Dangerous to organisms, it is crucial to remove them from water systems used in the fine chemicals and food industries.

BRHNY+ Series Endotoxin Test Study Summary

For endotoxin retention, we have developed the BRHNY+ Series membrane cartridges. Featuring a positively charged Nylon 6.6 membrane. They have been proven in independent laboratory testing to remove endotoxins by 100% to non-detectible levels with a challenge concentration of 6.25 Endotoxin Units per milliliter (EU/ml) and a sensitivity of 0.005 EU/ml.

A BRHNY+0.05A10C4S filter was challenged with a solution of pyrogen-free water dosed with 6.25 EU/ml. Twenty liters of challenge solution were pushed through the filter at a flow rate of 4 L/min for 20 total cycles. Influent and effluent samples were collected at defined time points. The test filters were effective in retaining bacterial endotoxin at a total challenge of approximately 1.57×10^6 EU as demonstrated by all effluent samples being free of endotoxin below the detection limit of 0.005 EU/ml after cycles #1, #5, #10, #15, and #20. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211, and 820.

BRHNY+ Series Microbial Retention Performance

Data presented below describes representative results of testing in accordance with the protocol for the evaluation of bacterial retention characteristics of membrane filters. Per the ASTM F858-15a test methodology, each test filter is challenged with a suspension of the referenced microbe, containing at least 1×10^7 colony forming units (CFU) per cm^2 of effective filtration area.

The sterility of the complete apparatus is tested before

the challenge. Each filter is challenged at a pressure of 30 psi. The collected effluent is quantified using $0.45\mu\text{m}$ assay membranes. Integrity testing is conducted pre-sterilization, post-sterilization, and post-challenge. Testing is performed in compliance with US FDA Good Manufacturing Practice (GMP) regulations 21 CFR Parts 210, 211, and 820.

MICROBIAL RETENTION EFFICIENCY			
Filter Grade	Challenge, Typical, CFU/cm	Total Challenge, Typical, CFU	Log Reduction Value, LRV
BRHNY+0.1	1.35×10^7	9.7×10^{10}	>9.1
BRHNY+0.05			>10.1



Filtration Elements by Removal Capability

Meltblown Products (>5.0 micron filtration)

- Water Grade Polypropylene Meltblown Cartridge
 - GWTB
- High Performance Grade Polypropylene Meltblown Cartridge
 - GCTB
- Absolute Grade Polypropylene Meltblown Cartridge
 - GATB

Pleated Products (0.2-5.0 micron filtration) •

Pleated Microglass Filter Cartridge

- FG, FGE
- Pleated Polypropylene Filter Cartridge
 - PP, PPE, PPI
- High Flow Filter Cartridge
 - HFFG, HFPP

Membrane Products (< 1.0 micron filtration) • Food and Beverage Grade Polyethersulfone

- GFPES
- GEPES Electronics Grade Polyethersulfone
 - GEPES
- Bio-Burden Reduction Grade Polyethersulfone
 - BRPES
- Pharmaceutical Grade Polyethersulfone
 - PPES
- Bio-Burden Reduction Grade PTFE
 - BRPTFE
- Pharmaceutical Grade PTFE
 - PPTFE
- Hydrophobic Polysulfone
 - PSH
- Bio-Reduction Grade Nylon
 - BRHNY+

Global Filter Tailors Filtration Solutions To Fit Your Needs.



SEPARATE YOURSELF FROM YOUR COMPETITION

Global Filter's industry-leading products allow various UHP water applications. Our high-purity pleated depth and membrane filter cartridges lead the industry in quality, performance, and cost-effectiveness. Our customers receive hands-on support in several specialized areas including unparalleled customer service, technically trained staff, efficient customization of products, and stocking agreements.



Quality Products

Pleated & Depth Cartridges
Liquid Bag Filters
Cartridge & Bag Vessels



Reliability

Reduce Costly Downtime
Robust Construction
Cost-Effective



Fast Delivery

On-Hand Inventory
Minimal Lead Times
Easy Access to Products

Global Filter Main Advantages

- Production in 10 days
- Manufacturing facilities in Europe, North America and Japan
- Competitive prices and highest value in the industry
- The design, development and manufacture of all our products meet the construction standards D.E.S.P 2014/68/EU, NSF, USP, FDA, CE 1935/2004
- Technical support from initial conversations to implementation and continued process assistance
- Our solutions are based on our expertise as well as laboratory and industrial certified testing
- We are able to offer products for small-scale production as well as higher volume operations



Global Filter Wide Range of Vessels To Fit Your Needs.

Industrial and sanitary vessels ready to ship

Global Filter offers an extensive range of cartridges and bag filter housings. Our vessels meet the requirements for the broadest range of applications and industries. Not only do we have versatile vessel products, we offer a wide range of vessel accessories to enhance your filtration products and systems.

Our extensive stock of industrial and sanitary vessels allows you to customize your application, with the shortest lead times available.

FILTER VESSELS





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