

WHITE PAPER

IMPROVING PROCESS EFFICIENCIES IN PHARMACEUTICAL PREPARATIONS

Optimization strategies
for a competitive industry

The european pharmaceutical market size was valued at 282.75 billion euro in 2020 and is expected to expand at a compound annual growth rate(CAGR)of 5.4% from 2021 to 2028.

Demands for pharmaceutical preparations are at an all-time high and there is an increasing need to abide by stringent quality 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 pharmaceutical preparations must meet strict regulations of industry-specific governing bodies, such as the FDA, EPA, USP, or EU. Each of these organizations set guidelines for the production and usage active pharmaceutical ingredients within their respective industries. However, regardless of who sets the standard, micro-filtration is always a crucial part of the process.

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, quality expectations may vary dramatically from one system to another.

The one constant variable is the presence of micro-filtration technologies. Whether you're looking for basic clarification or require something more specific such as sanitisation 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 effective filtration area (EFA), in order to capture the bulk of incoming solids. 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 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 active pharmaceutical ingredient must be purified or filtered with a membrane, to reach the required cleanliness. In general, the final filter will utilize a 0.2µm membrane, with or without some form of bacterial retention. Appropriate regulatory agencies or in-house company guidelines will typically provide membrane requirements for your process.

While the general process for producing API 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 Active Pharmaceutical Ingredients' manufacturing process, the various levels and types of filtration solutions must be considered.

Typical applications for pharmaceutical preparations include:

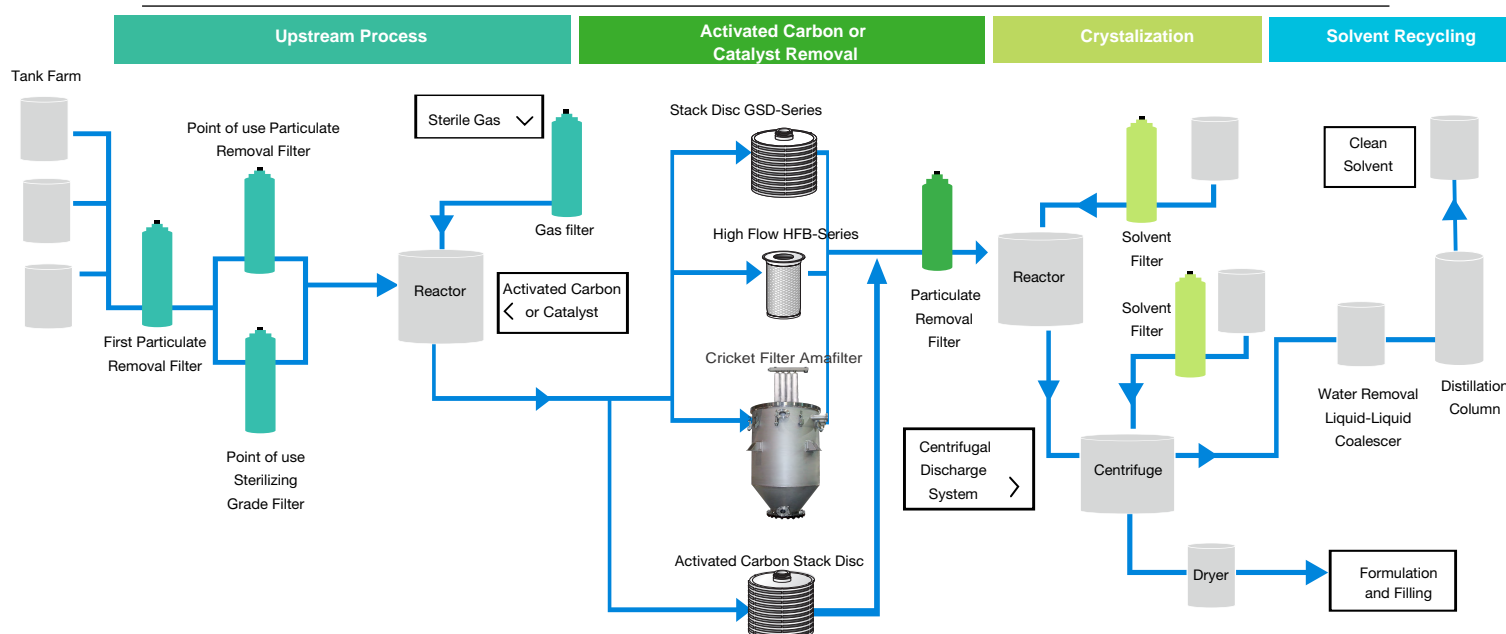
Active Pharmaceutical Ingredients (API)

- Upstream Process Filtration
- Catalyst Removal
- Active Carbon Removal
- Crystalization
- Solvent Filtration

Ultrapure Water

- Liquid Filtration
- Sterilizing Grade Filtration
- Gas / Vent Filtration

Optimizing the API Process



Upstream Process

First Particulate Removal Filter

GCTB-Series Meltblown Cartridges
GTCH Vessel Cartridge Vessel

Point of use Particulate Removal Filter

PP-Series Polypropylen Pleated Cartridges
GFHD Mono Cartridge Vessel

Point of use Sterilizing Grade Filter

WCPE-Series PES Membrane Cartridges
GSTL Sanitary Vessel

Gas Filter

PPTFE Series (Sterilizing Grade)
GSTL Sanitary Vessel

Filtration of raw materials is important to ensure the best productivity during chemical reaction or treatment. Global Filter product range offer solutions to remove contaminants from solids particles to microorganisms :

Cost effective solution for low solid contents: GCTB range
Efficiency driven solution for very fine particles (0,2µ) : WCPE range
Steril liquid filtration (microorganisms removal) GPES Range
Steril Gas filtration : PPTFE range

Activated Carbon or Catalyst Removal

Catalyst Removal

GSD-Series Stack Discs or
HFB-Series High Flow Cartridges
Amafilter Cricket Filter
GHLS-Series

Activated Carbon Removal

Activated Carbon GSD Stack Discs
Lenticular Vessel

Particulate Removal Filter

PP-Series Polypropylen Pleated Cartridge
GTCH Multi Cartridge Vessel

During production it could be necessary to add solids such as activ carbon or catalysis which will be removed after the treatment or reaction. Depending on the solid quantity a first main step could be necessary to remove the majority of the catalysts . Amafilter's Cricket filter is one of the best solution for this step. For small batches or after the main filtration we offer several solutions in accordance with your process.

Our HFB-Series High Flow cartridge is one of the recommended solutions as it offers a safer and healthier option, Our GHLS- Series cartridge offer a reliable solution for catalysis recovering throughout its life time and especially after several cycles.

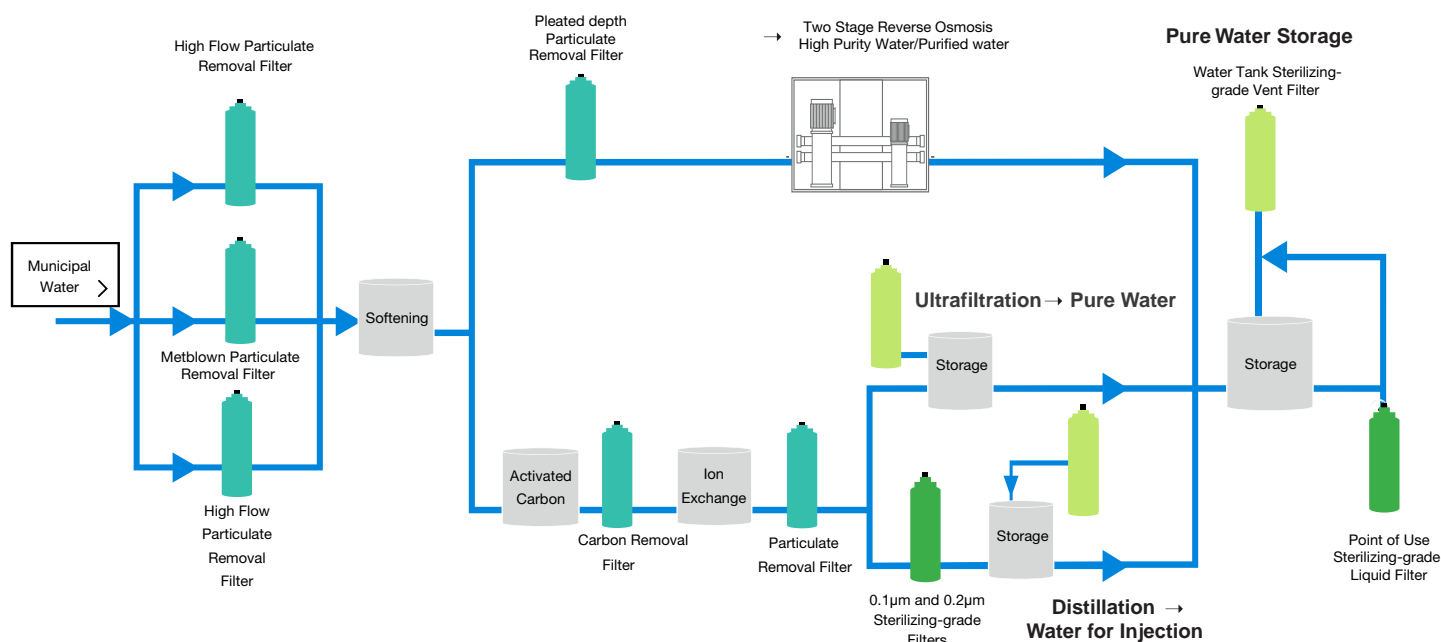
Crystalization

Solvent Filtration

PP-Series Polypropylen Pleated Cartridge
GFHD Mono-Cartridge Vessel
GPFA Membrane Cartridge

In several steps, solvents are necessary and producing high purity solvent on site can be really cost effective. Our PP-Series pleated cartrides and GPFA-Series Membrane cartrides with absolute efficiencies down to 0.05 with high chemical compatibility are the best solutions to fulfill your requirements.

Optimizing the Water Purification Process



Liquid Filters

High Flow Particulate Removal Filter

HFPF Series

Meltblown Particulate Removal Filter

GTWB Series Polypropylen Meltblown cartridges

Pleated Depth Particulate Removal Filter

GHLS 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. Depending on your flow rate and water quality, the first filtration solution should reduce your wastes and be cost effective.

Sterilizing Grade Liquid Filter

0.1µm and 0.2µm Sterilizing Grade Filters

PPES Series Pharmaceutical Grade PES Membrane
GSTL Sanitary Vessel

Point of Use Sterilizing Grade Liquid Filter

BRPES Series
BRHNY+ Series

Reduces and removes virtually 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. Our range of membrane cartridges could serve all your needs from particle removal (WCPE-Series) to endotoxin removal (BRHNY+), to meet your quality requirements.

Tank Vent Filters

Tank Sterilizing Grade Vent Filter

PPTFE Series Pharmaceutical Grade PTFE Membrane
GSTL Sanitary Vessel

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.

Global Filter Tailors Filtration Solutions To Fit Your Needs.

SEPARATE YOURSELF FROM YOUR COMPETITION

Global Filter's industry-leading products allow various fine chemicals 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. Our products are manufactured in Europe.



Quality Products

Constant Quality
50 Years of Experience in the
Fine Chemical Industry
Product manufactured in our plants
ISO 9001 Quality System Management
CE 1935 / 2004 , FDA, GMP



Reliability

Reduce Costly Downtime
Robust Construction
Cost-Effective
Agile Organisation
Filtration Total Cost Ownership
Management



Fast Delivery

On-Hand Inventory
Minimal Lead Times
Easy Access to Products
3 Manufacturing Plants Worldwide

FILTER VESSELS





Filtration Elements by Removal Capability

High Flow and Lenticular modules (< 10.0 micron filtration)

- High Flow Pleated Cartridge
 - HFB
- Stack Discs
 - GSD
 - Active Carbon Stack Discs

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 Depth Products (0.2-5.0 micron filtration)

- Pleated Microglass Filter Cartridge
 - FG
- Pleated Polypropylene Filter Cartridge
 - PP

Pleated Membrane Products (< 0.2 micron filtration)

- Bio-Burden Reduction Grade Polyethersulfone
 - BRPES
- Pharmaceutical Grade PTFE
 - PPTFE



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