

API Manufacturing - Filtration Solutions



High-Value Filtration Systems

API Manufacturing

Excipients and APIs used in the manufacture of pharmaceuticals must comply with regional health and drug regulatory authorities before receiving GMP certification. Masterfilter **filter cartridges, capsules, discs, and depth filters** are available with filter media made of **glass fiber, PP, Nylon, PTFE, PES, cellulose, activated carbon, and stainless steel**. Our product solutions help protect the manufacturing process from contaminants while extending service life and optimizing operating costs.

Liquid				Gas		Steam
Particulate		Microbial	Decolorising	Particulate	Microbial	Particulate
Melt-Blown Depth Filtration	Pleated Depth Filtration	Membrane Filtration	Depth Filtration	Pleated Depth Filtration	Membrane Filtration	Pleated/Depth Filtration
 PP MBK-A, MBK-T	 PP APK, HPK, APKM, APKV	 PTFE SLF-L, PFA	 Cellulose LCMZ, DFD, DFC, DFS	 PP APK	 PTFE SLF-T, SLF-HT, PFA	 SS SDF-S, SDF-P, SDF-M
 NYLON MBN	 NYLON NYPC, NYTC	 PES PESA, PESE, PESS, DPES	 Carbon ACP, LCMK, DFD, DFC, DFS	 GF SLF-G		
	 PTFE SLF-L, PFA					
	 GF LGFK					

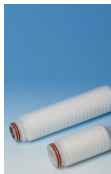
Masterfilter provides professional technical and scientific assistance to microfiltration, separation and purification solutions. Our goal is to deliver innovative high quality products on time.

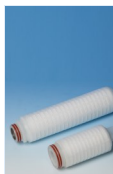
Capabilities

- Wide range of products
- High production capability
- All filter media available and in all configurations
- Custom warehouse
- Short Lead time
- Application expertise
- Cost optimization
- Fast response time
- Feasibility study and validation services guaranteed

API Manufacturing - Liquid Filtration

Liquid			
Particulate		Microbial	Decolorising
Melt-Blown Depth Filtration	Pleated Depth Filtration	Membrane Filtration	Depth Filtration
 PP MBK-A, MBK-T	 PP APK, HPK, APKM, APKV	 PTFE SLF-L, PFA	 Cellulose LCMZ, DFD, DFC, DFS
 NYLON MBN	 NYLON NYPC, NYTC	 PES PESA, PESE, PESS, DPES	 Carbon ACP, LCMK, DFD, DFC, DFS
	 PTFE SLF-L, PFA		
	 GF LGFK		

Melt-Blown		Pleated	
 MBK-A Absolute rated Polypropylene cartridge 0.3 to 50 µm	 MBK-T Non woven Polypropylene cartridge 1 to 75 µm	 MBN Melt-blown Nylon cartridge	 APK Absolute rated Polypropylene cartridge 0.2 to 10 µm
• 5 to 8 layer design • High dirt holding capacity • Compatibility with most chemicals and solvents	• High dirt holding capacity • No wetting agents, solvents, surfactants, binders or adhesives	• High dirt holding capacity • Temperature up to 120 °C • Excellent chemical compatibility	• High dirt holding capacity • Excellent flow rates • Compatibility with most chemicals and solvents

Pleated			
 HPK Nominal rated Polypropylene cartridge 0.2 to 50 µm	 APKM Absolute rated Polypropylene cartridge 0.2 to 70 µm	 APKV Pre-stabilization Polypropylene cartridge 0.45 to 3 µm	 NYPC Hydrophilic charged Nylon cartridge 0.2 to 0.45 µm
• All PP construction • Superior flow rates • Broad chemical compatibility	• 5 to 7 layer design • Excellent flow rates • Low pressure drop • High efficiency	• High porosity • Excellent flux rates • High retention capacity • Increased performance	• Double layer • Water wettable • High filtration efficiency • Low pressure drop

Pleated			
 NYTC Hydrophilic non-charged Nylon cartridge 0.2 to 1 µm	 SLF-L Hydrophobic PTFE cartridge 0.2 to 10 µm	 PFA Hydrophobic PTFE cartridge 0.2 to 10 µm	 LGFK Superfine Glass fiber cartridge 0.1 to 5 µm
• Double layer • Water wettable • High filtration efficiency • Low pressure drop	• Excellent flow rates • Strong solvents, highly corrosive fluids, strong oxidant fluids	• All-fluoropolymer material • Superior resistance • High temperature and pressure capabilities	• Absolute retention rate • No adhesives or binders • Very low level of extractables

API Manufacturing - Liquid Filtration

Membrane



SLF-L
Hydrophobic
PTFE
cartridge
0.2 to 10 µm

- Excellent flow rates
- Strong solvents, highly corrosive fluids, strong oxidant fluids



PFA
Hydrophobic
PTFE
cartridge
0.2 to 10 µm

- All-fluoropolymer material
- Superior resistance
- High temperature and pressure capabilities



PESA
Asymmetric,
hydrophilic **PES**
cartridge
0.2 to 1.2 µm

- Excellent flow rates
- Full retention
- Very low absorption
- Repeatability of integrity test



PESE
Asymmetric,
hydrophilic **PES**
cartridge
0.2 to 5 µm

- Excellent flow rates
- High dirt holding capacity
- Easy wettable
- 100% integrity tested

Pleated



PESS
Symmetric,
hydrophobic **PES**
cartridge
0.2 to 1.2 µm

- Low diffusion flow
- High surface area
- Excellent flow rates
- High efficiency



DPES
Double-layer
PES
cartridge
0.2 to 0.65 µm

- Double layer
- Optimized microbial retention
- Unique thermal resistance



LCMZ
Cellulose and
inorganic filter aid
modules
0.02 to 30 µm

- Excellent filtration efficiency
- High dirt holding capacity
- Single or double layer
- EFA up to 3.7 m²



LCMK
Cellulose with
Activated Car-
bon modules
0.3 to 4 µm

- Excellent retention ability
- Excellent performance
- Single layer
- EFA up to 3.7 m²

Depth Filtration



DFD
Cellulose or
Activated Car-
bon discs
0.02 to 30 µm

- Excellent filtration efficiency
- High dirt holding capacity
- Single or double layer
- EFA up to 23 cm²



DFCL
Cellulose
standard
capsules

- Excellent filtration efficiency
- High dirt holding capacity
- Single or double layer
- EFA up to 585 cm²



DFC
Cellulose or
Activated Car-
bon big capsules
0.02 to 30 µm

- Excellent filtration efficiency
- High dirt holding capacity
- Single or double layer
- EFA up to 0.5 m²



DFS
Cellulose or
Activated Car-
bon modules
0.02 to 30 µm

- Excellent filtration efficiency
- High dirt holding capacity
- Single or double layer
- EFA up to 1.4 m²

Depth Filtration



ACP
Carbon
impregnated
cartridge
0.1 to 5 µm

- Ideal for chlorine reduction
- Available in 2 grades
- Length from 5 to 40 inches
- FDA approved

API Manufacturing - Gas and Steam Filtration

Gas		Steam
Particulate	Microbial	Particulate
Pleated Depth Filtration	Membrane Filtration	Pleated/Depth Filtration
 PP APK	 PTFE SLF-T, SLF-HT, PFA	 SS SDF-S, SDF-P, SDF-M
 GF SLF-G		

Pleated	Membrane		
 APK Absolute rated Polypropylene cartridge 0.2 to 10 µm • High dirt holding capacity • Excellent flow rates • High chemical compatibility	 SLF-G Superfine micro Glass fiber cartridge 0.01 to 5 µm • High dirt holding capacity • Low pressure drop • Steam sterilisable • High surface area	 SLF-T Permanently, hydrophobic PTFE cartridge 0.2 µm • Excellent flow rates • High security for wet and dry gases • High chemical compatibility	 SLF-HT Hydrophobic PTFE cartridge 0.2 µm • Excellent flow rates • High security for wet and dry gases • High temperature resistance

Membrane
 PFA Hydrophobic PTFE cartridge 0.2 to 10 µm • All-fluoropolymer material • Superior resistance • High temperature and pressure capabilities

Pleated / Depth		
 SDF-S Powder Sintered Stainless Steel cartridge 0.1 to 100 µm • All stainless steel • High temperature resistance • High separation efficiency • Excellent permeability	 SDF-P Pleated Stainless Steel Wire Cloth cartridge 0.1 to 100 µm • All stainless steel • High temperature resistance • High flow rates • Cleanable and reuseable	 SDF-M Pleated Stainless Steel Felt cartridge 1 to 60 µm • All stainless steel • Welded construction • High flow rates • Cleanable and reuseable

API Manufacturing - Filter Housings

Liquid Filter Housings



The Masterfilter Liquid Filter Housings are manufactured for filtration of liquids. They are available in 2.5, 5, 10, 20 and 30-inch lengths. The housings are marked with a unique serial number for traceability. These filter housings are available with a range of pharmaceutical compliant vents and inlet/outlet connections and different configurations.

Features:

- T-style, Inline and Self-drainable design
- Multi-cartridge housings
- Manufactured in accordance with European regulations
- Fully sanitary design
- Fully industrial housing
- Special materials available (e.g. Hastelloy C22, Titanium)

Gas Filter Housings



The Masterfilter Gas Filter Housings are manufactured for filtration of gases. They are available in 2.5, 5, 10, 20 and 30-inch lengths. The housings are marked with a unique serial number for traceability. These filter housings are available with a range of pharmaceutical compliant vents and inlet/outlet connections and different configurations.

Features:

- T-style and Inline design
- Multi-cartridge housings
- Manufactured in accordance with European regulations
- Fully sanitary design
- Fully industrial housing
- Special materials available (e.g. Hastelloy C22, Titanium)

Lenticular Housings



The Masterfilter Lenticular Filter housings consisting of a bottom part with three legs and a detachable housing dome. The bottom part with the inlet and outlet socket contains the centering and mounting unit for holding the lenticular filter with a flat adapter or double O-ring adapter type.

Features:

- Inline design
- Manufactured in accordance with European regulations
- Fully sanitary design
- Special materials available (e.g. Hastelloy C22, Titanium)

API Manufacturing - Services

Technical Support

Getting pharmaceutical APIs to the market demands high investments for the manufacturers and so a wide product range and high value technical support facilitates manufacturing timescale.

With the availability of generic and proprietary filter medias for use in drug manufacturing, selecting the correct filter media is critical to ensure full compliance and optimization of the filtration process.

Technical Services

Our technical services provide testing of fluids and an evaluation of current procedures. Filter analysis includes microscopy and other resources to measure particle counts, turbidity, pH, etc.

- Filterability test (FI/SDI)
- Filtration system configuration
- Troubleshooting / Fault analysis
- Contaminant identification (FTIR, SEM, LM)
- Integrity test on and off site
- Flow decay curves
- Sterilisation method and effect on filter integrity
- Process optimization
- Filtration system assessment

Validation Support

Masterfilter can offer our customers full support on Validation of Sterile Filters for their process. Whether it is on existing filters or for the introduction of alternative filters, as part of the control change process. With global changes and uncertainties on supply chains it is important that fast and robust validation support is available to minimize risks to production in critical processes, to speed production process changes or, simply, reduce manufacturing costs. The services we can offer include:

- Viability
- Microbial challenge also with specific micro-organism
- Compatibility
- Adsorption
- Extractables and Leachables
- Integrity test value with product
- Toxicity assessment
- Filtration system assessment

Integrity Test Equipment



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