

3M Purification Inc.

Filter Systems for Small Molecule Pharmaceutical Purification

3M Purification Inc.

Core Filtration Applications

3M Purification Inc. is a leader in advanced depth filter systems and membrane-based separations, offering a wide range of products for all stages of pharmaceutical processing and sterile filtration from bench-top to pilot-scale to manufacturing-scale operations.

Active Pharmaceutical Ingredients (API's) refer to the active chemicals used in the manufacture of drugs. API's are purified by a series of unit operations that include key filtration steps to the purity required in a final drug formulation.

3M Purification's core filtration technologies address the demanding applications in pharmaceutical processing for small molecule and API applications. Regulatory requirements demand the highest quality product standards along with documented evidence of manufacturing processes. 3M Purification products in the pharmaceutical industry meet the demands of regulatory agencies throughout the world and are used by some of the largest and most respected pharmaceutical manufacturers in the industry.

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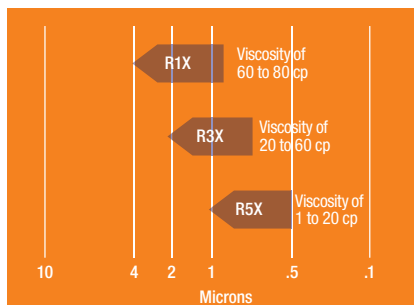
- Products and services
- Full documentation

Adsorptive Depth Filtration

Color Reduction

Activated carbon is used in the pharmaceutical industry to remove impurities from active ingredient manufacturing. These impurities are typically derived from chemical reactions that produce colored by-products. These colored by-products must be removed to maintain drug purity and produce high-quality, on-spec intermediate compounds. Activated carbon use in powdered form presents three primary areas of concern to the pharmaceutical manufacturer, namely operator exposure to carbon dust, the quality of the process and the operating costs associated with the use and handling of bulk activated carbon. 3M Purification's Zeta Plus Activated Carbon media incorporates immobilized activated carbon in our depth filtration technology to decolorize and remove contaminants from pharmaceutical process streams.

Figure 1. Grades of Zeta Plus Activated Carbon Media



Zeta Plus Activated Carbon media are available in different filtration ratings in order to deal with products of different viscosity. The figure to the left is used to determine optimum filter selection. Different types of carbon can be specified as required.

Zeta Plus Activated Carbon Media Benefits

Optimized Process

Carbon type is selected based on contaminant removal efficiency; activated carbon is fixed in filter matrix and the flow is forced through the matrix at constant flux, increasing process efficiency.

Reduced Operator Exposure to Carbon Dust

Carbon dust is virtually eliminated due to carbon incorporated into depth filtration media.

Cleanliness

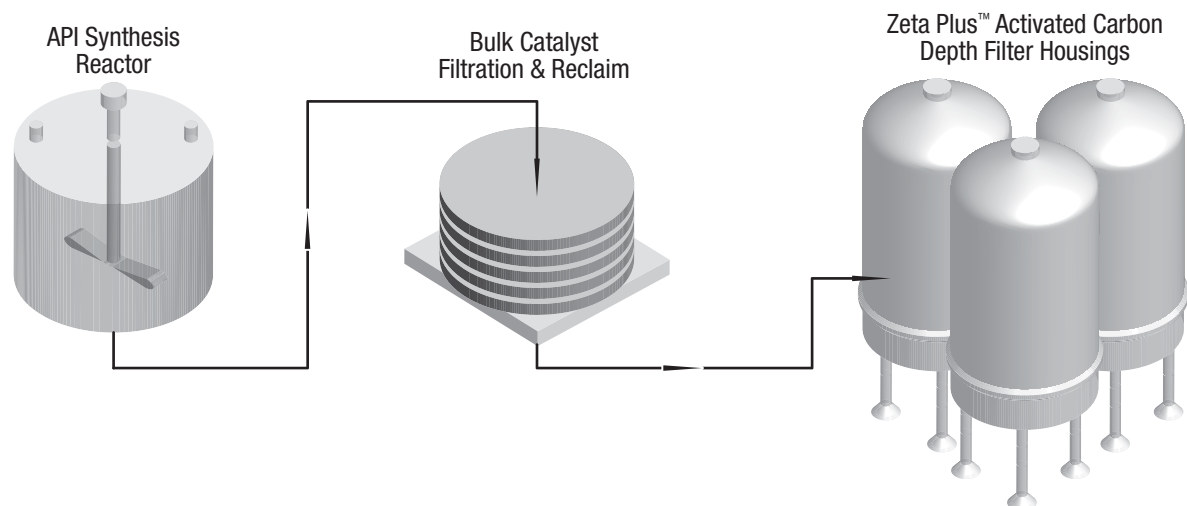
Cleaning and handling concerns with bulk activated carbon are minimized; cleaning validation between batches is streamlined.

Shorter Batch Times

Batch times are reduced as contaminant removal takes place at constant rate; bulk activated carbon filtration step eliminated.



Figure 2. Zeta Plus Activated Carbon Color & Dissolved Solids Reduction



Reduction of Dissolved Solids

Most synthetic drug products utilize a variety of intermediates during processing. These intermediates can include active drug components, solvents or fine chemicals used in processing, excipients and as precursors to final drug formulation. Dissolved contaminants in various forms in these intermediates must be reduced to ensure product quality and safety requirements. Sources of contamination can include catalysts used in synthesis, process tanks, valves and piping, raw materials and by-products produced as a result of multi-step synthesis reactions. 3M Purification's positively charged Zeta Plus™ depth filters may represent an efficient method for dissolved contaminant reduction in pharmaceutical active ingredient manufacturing. Zeta Plus depth filters consist of a cellulose matrix, inorganic filter aid and a cationic resin. The resin component binds the cellulose and the filter aid and imparts a positive charge to the filter medium. Negatively charged contaminants and complexes can be adsorbed to the Zeta Plus media by electrostatic attraction. In addition, contaminants of sufficient size can be removed by mechanical entrapment within the Zeta Plus depth filter matrix. Zeta Plus depth filters are provided in a wide range of formulations and grades in order to provide effective contaminant removal properties. Please reference Table 1 below.

Zeta Plus™ depth filters are available in a variety of configurations including filter sheets and cartridges ranging in size from laboratory to full-scale production. Zeta Plus™ filter cartridges are the most convenient form for efficient filtration.

Zeta Plus™ Depth Filter Benefits

Improved Process Efficiency

A variety of Zeta Plus media formulations allows for product selection to maximize contaminant removal and throughput, and improve process efficiency.

Scalable

A large range of available product sizes enables pilot testing and scale-up with the same filter media materials that will be used in full-scale systems.

Product Validation

A Regulatory Support File is available to ease validation and regulatory submissions by providing important documentation.

Figure 3. Nominal Retention Capacity of Zeta Plus™ SP Series Filters

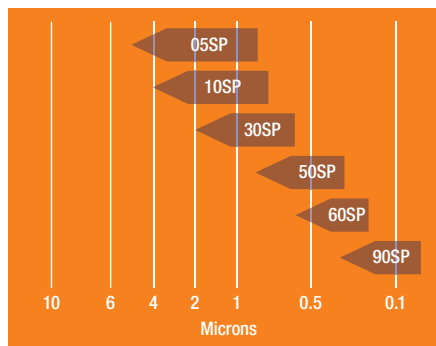


Table 1. Zeta Plus Depth Filter Media

Media Series	Description	Applications	Grades Available
LA Series	Low extractable levels	Small & large volume parenterals, blood fractions	30, 50, 60, 90
SP Series	Solids recovery & clarification	API solutions, blood products	05, 10, 30, 50, 60, 90
DELP Series	Lipid-specific adsorbent formula	Removal of lipids & surfactants	DELP08

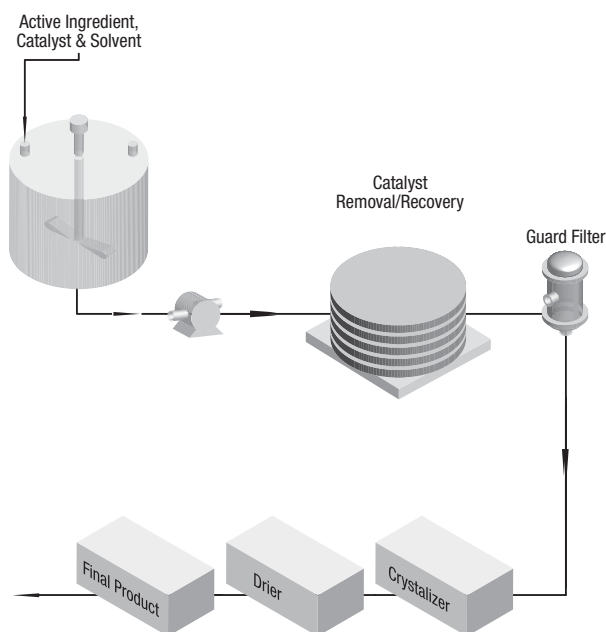
Solids Removal, Recovery & Reclaim

Solids removal and catalyst recovery is a common application in pharmaceutical production at various stages in the operation. Heavy-metal catalysts are used to promote hydrogenation reactions in active pharmaceutical ingredient manufacture. A variety of carriers or supports are used for the precious metals, including alumina, zeolites and carbon. These precious metal catalyst supports must be removed from the batch prior to downstream processing. Their high cost along with environmental regulations requires these solids to be captured and reclaimed at high yields. An effective filtration system is needed that effectively removes these particles from the process stream and helps protect the operator from contacting these hazardous materials. 3M Purification offers various filtration options for solids removal and recovery applications. Please reference Table 2 below.

Table 2. Solids Removal & Recovery Filtration Options

3M Purification Product	Media Available/Type	Micron Rating
CUNO™ CTG-Klean enclosed packs	Betapure™ NT-P, multi-layer polypropylene depth	0.5–70 µm

Figure 4. Solids Removal & Recovery Application



Solvent & Bulk Chemical Filtration

Chemicals and solvents used in pharmaceutical manufacturing include alcohol, acetone, methylene chloride and numerous other bulk chemicals for raw materials. Active pharmaceutical ingredients are synthesized through chemical reactions that use solvents together with other ingredients including catalysts. These bulk chemicals should be free of particulate matter and contaminants prior to their use in manufacturing processes in order to maintain process integrity and overall product quality. Filtration ratings range from coarse to fine and include filter cartridges for tank venting. Please reference Table 3 below.

Table 3. Solvent & Bulk Chemical Filtration Options

Application	3M Purification Filter	Material	Micron Rating
Coarse filtration - cartridges (> 5 µm)	Betapure™ NT-P	Multi-layer polypropylene	0.5–70 µm
Fine filtration (< 5 µm)	Betafine™ PPG Series	Pleated polypropylene, graded porosity	0.2–10 µm
Tank venting	LifeASSURE™ PFS Series	Hydrophobic PTFE	0.2 µm, sterilizing grade

Product Benefits

Fine Filtration

Betafine™ series cartridges feature absolute rated, polypropylene media that provides a wide range of chemical compatibility. Betafine™ PPG series filters feature graded porosity polypropylene media that offers excellent capacity and throughput. Filters provided with validation support documentation for implementation into existing processes.

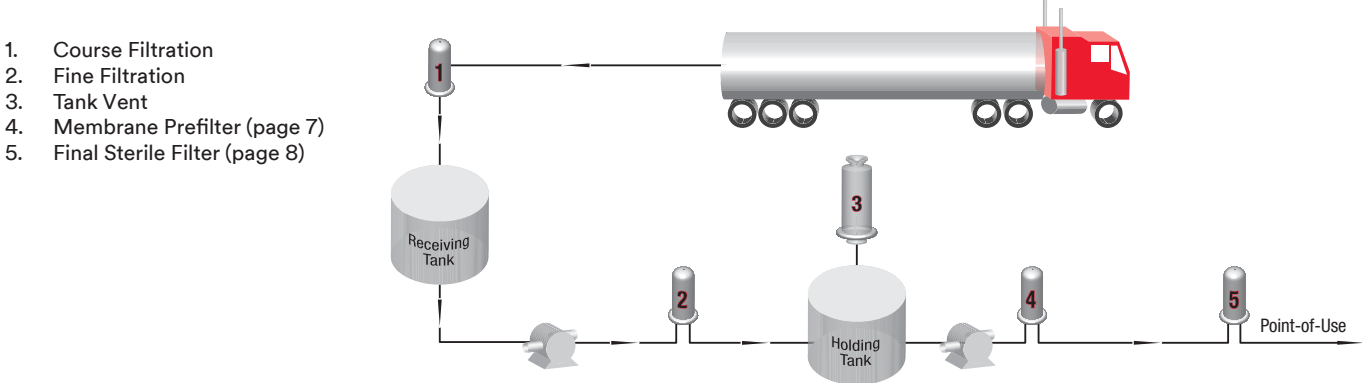
Course Filtration - Cartridges

3M Purification cartridge filters for coarse particle (>5 µm) reduction provide exceptionally high flow rates with low differential pressures, extending filtration life and reducing the number of filter change-outs.

Tank Venting

LifeASSURE™ PFS series filter cartridges and capsules combine high flow with a liquid validated, bacteria retentive, hydrophobic PTFE filter membrane. Structural components are polypropylene, optimized for long on-stream air service.

Figure 5. Solvent & Bulk Chemical Filtration Application



Endotoxin & Bioburden Reduction

Bioburden reduction is a common application used in the pharmaceutical industry to provide clarification of pharmaceutical process streams. Control of bioburden in pharmaceutical processing is critical in order to maintain product quality and to improve overall process economics. Prefilters are typically used in line with sterilizing grade filters to help protect and prolong the life of downstream sterile filters. In some non-sterilizing grade applications, prefilters are used as stand alone filters to help protect downstream equipment or as a safety filtration step in the process flow.

Effective bioburden reduction/prefilters exhibit the following performance characteristics:

- High throughput and product yield
- Long service life
- Effective protection of downstream sterilizing grade filters
- Chemically compatible with process fluids

Please reference Table 4 below for 3M Purification’s product portfolio for bioburden reduction and prefiltration.

Product Benefits

LifeASSURE™ SP Series Filters

A single-layer charge modified Nylon 6,6 membrane, these filters offers enhanced particle and endotoxin reduction via electrostatic charge on the membrane.

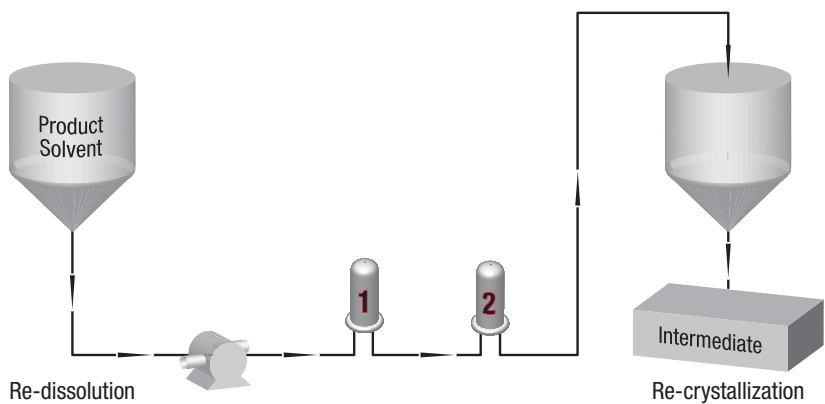
Betafine™ PPG Series Filters

A polypropylene media, absolute-rated, graded porosity high-flow filter cartridge, Betafine PPG series filters offer good chemical resistance and durability in demanding applications.

Table 4. Bioburden Reduction/Prefiltration Options

Application	3M Purification Filter	Material	Micron Rating
Endotoxin reduction	LifeASSURE™ O2OSP Series	Pleated charge-modified Nylon 6,6	0.2 µm
Prefiltration	Betafine™ PPG Series	Pleated polypropylene, graded porosity	0.2–10 µm
Bioburden reduction	LifeASSURE™ PNA Series	Pleated polyethersulfone (PES)	0.45 µm

Figure 6. Bioburden Reduction/Prefiltration Application



Sterilizing Grade Filtration (liquid & gas)

Sterilizing grade filtration requires robust filters designed for performance certification to standards established by regulatory agencies, including absolute retention of certain microorganisms and certification of filter integrity by the manufacturer. 3M Purification supplies a variety of filter options for use in sterilizing grade filtration applications.

The applications for these products include:

- Nitrogen filtration and tank venting
- Parenterals (SVP, LVP)
- Biologicals
- High Purity DI water and WFI systems
- Ophthalmics

Figure 7. Sterile Filtration Application

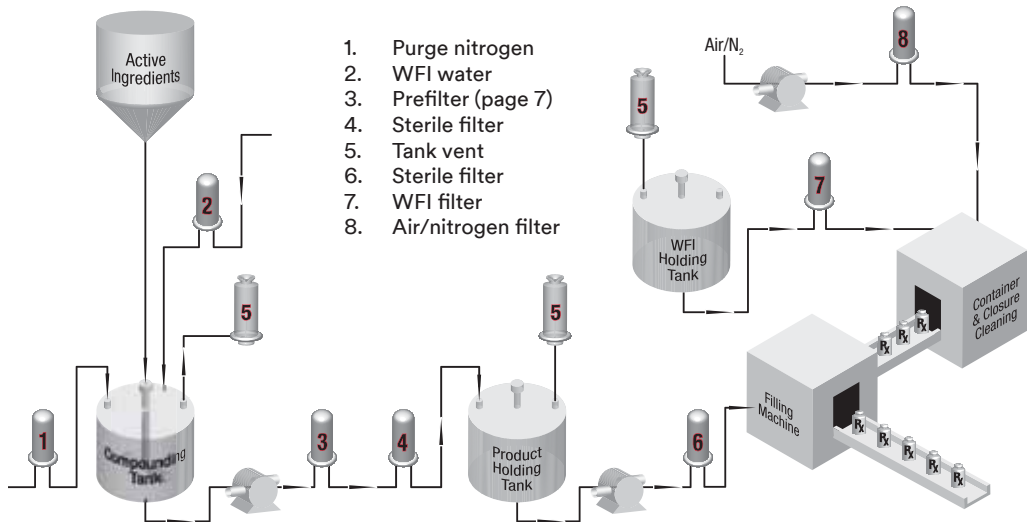


Table 5. Sterilizing Grade Filtration Options

Application	3M Purification Filter	Material	Micron Rating
Purge nitrogen/sterile tank venting (1, 5, 8)	LifeASSURE™ PFS Series	Hydrophobic PTFE membrane	0.2 µm
DI/WFI water (2, 7)	LifeASSURE™ SP Series	Charge-modified, Nylon 6,6	0.2 µm
Ophthalmic/LVP, SVP (4, 6)	LifeASSURE™ PDA Series	Dual-layer, asymmetric polyethersulfone (PES)	0.1 or 0.2 µm

Product Benefits

LifeASSURE™ PFS Series Filters

Combining high flow with a liquid validated, bacteria retentive hydrophobic PTFE membrane for long on-stream service in vent filtration and purge nitrogen applications.

LifeASSURE™ SP Series Filters

Utilizing a charge-modified Nylon 6,6 media to retain negatively charged biological and particulate contaminants including endotoxins.

LifeASSURE™ PDA Series Filters

Incorporating two layers of graded porosity polyethersulfone (PES) membrane that provide high contaminant capacity, fast flow rates and reliable sterilizing filtration performance.

Utilities & Plant Services

The water, steam and utilities used in pharmaceutical production is typically filtered to remove particles, scale and impurities prior to its use. 3M Purification offers a variety of filter options to meet the needs of these utility applications.

Water filtration is perhaps the most common application in the pharmaceutical industry. Different standards for water quality exist in the pharmaceutical industry depending on the application.

- USP Water for Injection (WFI)—for product formulation, equipment and container cleaning and WFI steam production.
- USP Purified Water—for equipment and container cleaning, fermenter make-up water (sterile filtered) and clean steam production.
- Utilities water—for heating/cooling process equipment.

Figure 8. Water Filtration Options

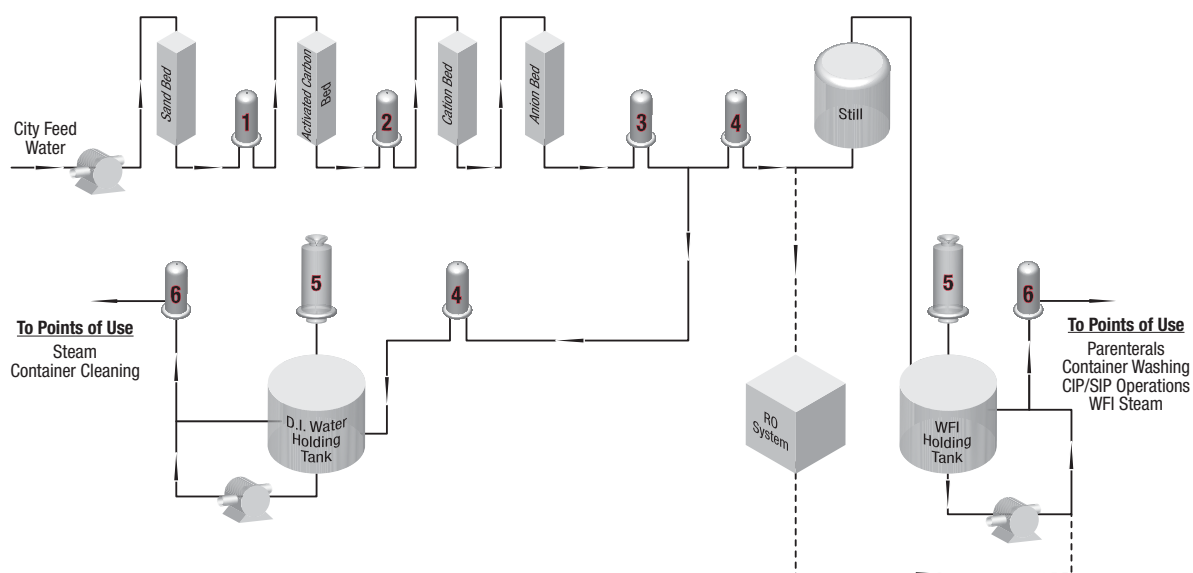


Table 6. Water Filtration Options

Application	3M Purification Filter Options	Material	Micron Rating
1. Removal of silica particles 2. Carbon fine removal 3. Resin trap filter	Betapure™ NT-P Betafine™ PPG	Multi-layer polypropylene Graded porosity pleated polypropylene	0.5–70 µm 0.2–10 µm
4. Sterile tank vent	LifeASSURE™ PFS Series	Hydrophobic PTFE membrane	0.2 µm
5. Sterile filtration, point-of-use	LifeASSURE™ SP Series LifeASSURE™ PDA Series	Charge-modified Nylon 6,6 Polyethersulfone (PES)	0.2 µm 0.2 µm

Filter Validation

3M Purification supplies products and services to help pharmaceutical manufacturers ease regulatory compliance and meet the exacting demands of the industry. 3M Purification Validation Services streamlines filter regulatory compliance, saving our customers time. Our goal is to provide well-designed, properly executed and completely documented test protocols on 3M Purification filter products in their intended applications.

Validation Services

Our scope of services in validation support consulting includes:

- Integrity testing: provides product specific integrity test parameters for the fluids being used in the application.
- Bacterial retention, chemical compatibility and extractable testing: execution of these tests to confirm a given filter's performance under actual process conditions.

Validation Products

3M Purification offers a variety of products that support customer validation to help meet regulatory requirements:

- Filter Validation Guides: provide extensive regulatory information for sterilizing grade filters.
- Regulatory Support Files: Provided for filters upstream of sterile filters.

Global Locations

3M Purification can provide on-site validation support around the world or in one of our state-of-the-art laboratories located in Europe, USA, China, India and Brazil.



Lenticular Style Depth Filter Products

3M Purification offers an extensive range of Zeta Plus™ depth filter capsules and cartridges to meet virtually any process flow requirement. Lenticular style depth filter capsules are designed to facilitate the scale-up of processes between the laboratory bench and the plant floor. Process-scale cartridges come in a variety of sizes to accommodate a wide range of application conditions to handle the most critical clarification and depth filter applications in pharmaceutical manufacturing.

BC25 Capsules

The BC25 capsule configuration is used for laboratory evaluation and small volume filtration. The BC25 capsule is supplied with 25 cm² of most 3M Purification depth filter media offerings, for simple laboratory evaluation of the media in your application. The BC25 capsule is available in two connection options, luer and sanitary. BC1000/2000 capsules are available with the Zeta Plus Activated Carbon media.



8”, 12” & 16” Diameter Zeta Plus™ Cartridges

Zeta Plus™ cartridges utilize the same media as the BC disposable capsule products, enabling linear and predictable scale-up as batch volumes increase. The range of diameters and lenticular filter cells per cartridge provides a flexible product family that can be designed to accommodate almost any process flow rate.

Table 7. Lenticular Style Depth Filtration Options

Lenticular Filtration Unit	Effective Filtration Surface Area/Unit
BC25 capsule	3.9 in² (25 cm²)
8” dia., 2-cell plug-in style	0.7 ft² (650 cm²)
8” dia., 5-cell plug-in style	1.8 ft² (0.16 m²)
8” dia., 7-cell plug-in style	2.5 ft² (0.23 m²)
8” dia., 6-cell	2.1 ft² (0.20 m²)
8” dia., 7-cell	2.5 ft² (0.23 m²)
8” dia., 8-cell	2.8 ft² (0.26 m²)
12” dia., 9-cell	9.2 ft² (0.85 m²)
12” dia., 12-cell	12.3 ft² (1.1 m²)
12” dia., 16-cell	16.4 ft² (1.5 m²)
16” dia., 1-cell	2.5 ft² (0.23 m²)
16” dia., 2-cell	5.0 ft² (0.46 m²)
16” dia., 8-cell	19.8 ft² (1.8 m²)
16” dia., 12-cell	29.8 ft² (2.8 m²)
16” dia., 16-cell	39.7 ft² (3.7 m²)

Note: The table above is for reference only; not all Zeta Plus filter grades are available in the lenticular types listed in the table. Contact 3M Purification for specific information and product availability.

Membrane Filter, Capsules, & Cartridges

3M Purification supplies filter membrane and sheet media filter products in wide variety of formats including disposable capsules and full-scale cartridges. The wide range of product formats allows for simple scale-up from the laboratory bench to full-scale production.



50 mm Disposable Filter Capsules

50 mm disposable filter capsules are ideal for laboratory scale filtration or for evaluating 3M Purification filter media prior to pilot-scale work. Containing the same filter media as full size 3M Purification capsules and filter cartridges, the 50 mm capsules are a convenient, low hold-up volume method to determine various filtration parameters such as retention, compatibility and filtrate attributes.

The 50 mm capsule is available with our polyethersulfone (PES) and PTFE 0.2 micron rated medias.

Filter Capsules*

Disposable filter capsules are designed for critical small volume filter applications and are available in a variety of filter media options.

“C” style capsules available in 2.5” and 5” lengths

“J” style capsules available in 10,” 20” and 30” lengths



Standard Filter Cartridges*

Standard filter cartridges are available in a variety of lengths, end connections and O-ring sealing options to tailor filter cartridges to the needs of your specific application.

Filter cartridges are available in 5”, 10”, 20”, 30” and 40” lengths as well as a variety of end modifications.

* Contact 3M Purification for specific product availability information in desired format.

Filter Housings & Engineered Systems

3M Purification offers an extensive range of cartridge filter housings to meet almost any process flow requirement. Designed for the production environment, 3M Purification sanitary design cartridge housings are available for laboratory bench to pilot plant to full-scale production.



Lenticular Style Zeta Plus™ Depth Filter Housings

These housings are designed to accommodate our line of Zeta Plus™ lenticular depth filters. This range of housings includes:

- Models 8ZP1P and 12ZP1P: designed for one 8" (8ZP1P) or one 12" (12ZP1P) filter cartridge.
- Model ZPB: ZPB bolt-style enclosure housings accept from one to four 8", 12" or 16" diameter standard Zeta Plus filter cartridges.

3M™ Series Filter Housings

These housings are designed to accommodate our full range of filter cartridge products:

- 3M™ ZMS series Mini-cartridge: small volume, critical filtration and sterile filtration applications.
- 3M™ ZVS series (in line) and ZMS ("T" line): Designed to accept a single 10", 20", 30" or 40" filter cartridge.
- 3M™ ZWB series: multi-cartridge housings designed for three, five, seven or 12 cartridges in 10", 20", 30" and 40" lengths.



Custom Engineered Systems

3M Purification's capabilities include a full-service Engineering Department that provides custom engineered filter housings. Custom engineered filter housings can be provided with pumps, gauges, piping, optional feed loops and other options to meet your specific needs.

Product Reference Guide

These tables list the products that are mentioned in this brochure

Zeta Plus™ Adsorptive Depth Filter products*				
Activated Carbon Series	Carbon-based adsorptive depth filter	Various carbon grades & porosities	Color & odor reduction	70-0201-8733-5
LA Series	Low extractable level depth media grade	30, 50, 60, 90 grade	SVP & LVP, blood fractions	70-0201-8860-6
SP Series	Solids recovery & clarification grade	05, 10, 30, 50, 60, 90 grade	API solutions, blood products	70-0201-8869-7
DEL Series	Lipid-specific adsorbent formula	DELP08	Selective removal of lipids & surfactants	70-0201-8854-9

* All lenticular depth filter products available in BC25 capsule, BC1000/2000 capsule (Activated Carbon only), 8", 12" and 16" lenticular cartridges.

Cartridge filters for particulate removal				
Betapure™ NT-P	PP media w/flow distribution channels	0.5–70 µm	Coarse/fine particle reduction	70-0201-8721-0
Betafine™ PPG	Pleated PP, graded porosity	0.2–10 µm	Fine particle reduction	70-0202-1001-2

Application Development & Engineering

3M works closely with customers to solve difficult filtration challenges and recommend the most efficient, economical filter systems. Application Engineering specialists perform on-site testing and utilize filtration application expertise to partner with customers.

3M Purification - Solutions

When looking for pharmaceutical filtration solutions, the industry has turned to 3M Purification for performance. 3M Purification has achieved a leadership position by striving to be the best supplier of high-quality products designed to provide cost effective solutions. 3M Purification understands that each application is unique and there is always an alternative. 3M Purification has both the experience and advanced material technology throughout its products to provide quality improvements and dramatic cost savings for the customer.

Product	Description	Ratings/Grades Available	Applications	Literature Reference
Cartridge filters for bioburden reduction & prefiltration				
LifeASSURE™ SP Series	Pleated charged Nylon 6,6	0.2 µm	Endotoxin reduction	70-0201-8891-1
Betafine™ PPG Series	Pleated PP, graded porosity	0.2–10 µm	Prefiltration	70-0202-1001-2
LifeASSURE™ PNA Series	Polyethersulfone (PES)	0.45 µm	Bioburden reduction	70-0202-6776-4

Sterilizing grade cartridge filters				
LifeASSURE™ PFS Series	Hydrophobic PTFE membrane	0.2 µm	Purge nitrogen, sterile vent filtration, gases	70-0201-8715-2
LifeASSURE™ SP Series	Charge-modified, Nylon 6,6 membrane	0.2 µm	WFI, DI water	70-0201-8738-4
LifeASSURE™ PDA Series	Dual-layer, asymmetric polyethersulfone (PES) membrane	0.2 µm	Biologicals, protein purification	70-0201-8687-3

3M™ Filter housings for lenticular cartridges				
8ZP1P & 12ZP1P	304 & 316L SS housing	8ZP1P for plug-in style, 8" cartridge 12ZP1P for 12" cartridge	Lab use, small volumes	70-0201-8857-2
ZPB	316L SS housing for lenticular depth filters	Swing bolt closure	Production depth filtration	70-0201-8762-4

3M™ Cartridge filter housings				
ZVS & ZMS	316L SS housings for single, 10", 20", 30" or 40" cartridge	ZVS: In-line inlet/outlet ZMS: "T"-line inlet/outlet	Intermediate, critical & sterilizing grade filtration	70-0201-8883-8
ZWB	316L multi-cartridge filter housings are available in 3, 5, 7 and 12-around	Swing bolt closure	Production-scale critical & sterilizing grade filtration	70-0201-8884-6

The 3M Purification products listed in this table represent a chosen sample of products available for sale; please contact your local 3M Purification sales representative for information on additional products not listed in this table.

Quality Management & ISO Standards

3M Purification works to provide high quality fluid purification and filtration products and consistent technical support. 3M Purification filtration systems are designed and manufactured to the most stringent industry standards to assure the reliability of 3M Purification systems that our customers have come to expect.

3M Purification has established a global quality management program which encompasses all facets of its operations. An essential part of the 3M Purification program is the creation of multi-function teams whose combined expertise is devoted to continuous improvement of processes, procedures and quality systems. In addition, the 3M Purification system ensures the active support and participation of senior management. 3M Purification is fully committed to the tenets of the quality management program and provides a support system for the quality process. The media, cartridges, and capsules are manufactured globally in facilities with quality management systems registered to ISO Standards to ensure consistency in meeting product specifications. The manufacturing process, quality controls, and regulatory oriented compliance reports are documented in a Drug Master File on record with the FDA.

Product Use

Intended uses: Manufacturing of pharmaceutical (drug) products, including active pharmaceutical ingredients and vaccines.

Prohibited uses: As a component in a medical device that is regulated by any agency, and/or globally exemplary agencies, including but not limited to: a) FDA, b) European Medical Device Directive (MDD), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA); Applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring FDA Food Contact compliance without use restrictions.

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