3M Purification

Zeta Plus™ LP Series

Filter Media

Zeta Plus™ LP series media are depth filter media composed of inorganic filter aid and cellulose, are extremely low in extractables, and are designed specifically for the pharmaceutical industry. The Zeta Plus™ LP series filter media are constructed with highly purified cellulose to minimize ß-glucan extractables and false positive LAL test results. The positive charge exhibited by the filter media results in increased particle reduction efficiency. The high contaminant capacity of the filter medium prolongs final filter life when LP media are used as a prefilter. Exacting quality controls assure maximum product performance for each production lot.

Zeta Plus™ LP series filter media are manufactured to procedures described in 3M Purification's Drug Master file on record with the FDA. Zeta Plus™ LP series filter media are manufactured in accordance with a strict quality assurance program. Each media lot is tested for flow, density, charge capacity, organic and inorganic extractables, and pyrogenicity (LAL Clot Tests). In addition, Zeta Plus™ filter cartridge packaging is labeled with a lot identification number to provide complete traceability from the media batch to the finished product.

Applications

Blood Products	Antibiotics	Diagnostics
Intravenous Solutions	Growth Media	Pharmaceutical & Bioprocess Fluids

Characteristics

Superior Particle Reduction

Zeta Plus™ LP series filter media offers advantages in contaminant reduction because of its strong electrokinetic properties. In addition to the mechanical exclusion of particles by its depth loading feature, LP media adsorbs contaminants too small for reduction by mechanical straining. Since most particles in suspension have been shown to be negatively charged, virtually all contaminants can be reduced with the proper grade selection.

Features & Benefits

Low LAL Reactivity.
- LP filter medium is non-pyrogenic, and is unlikely to cause false positive results.

Depth filtration media designed to retain contaminants by mechanical entrapment and electrokinetic adsorption.
- High contaminant holding capacity for economical filtration and reliable particle reduction.

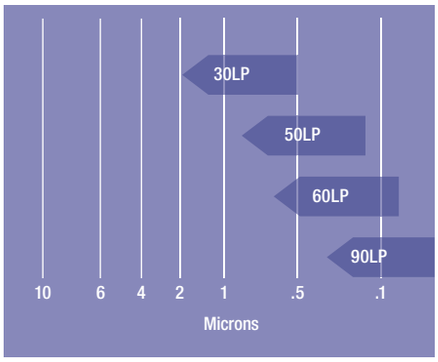
Full range of scaleable capsule and cartridge filter configurations.
- Allows pilot testing and scale-up with the same materials that will be used in full-scale systems.

FDA Drug Master File and USP Class VI Biological Safety.
- Eases validation and regulatory submissions by providing vital documentation and traceability.

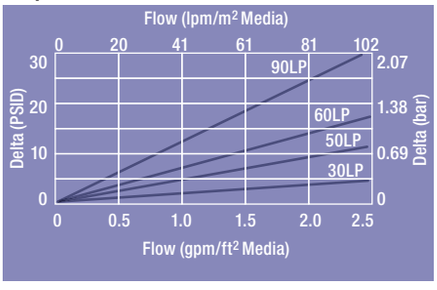
Self-contained, single-use disposable capsule and cartridge modules.
- Reduced labour time for changeouts and elimination of cleaning validation.

Tested and optimized for pharmaceutical and biological service.
- Safe for critical pharmaceutical, bioprocessing and biological applications.
- Components meet USP Class VI Biological Safety Tests and requirements of CFR 21.

Chart 1: Grade Selection



Graph 1: Water Flow Rate



1 gpm/ft² = 40.7 lpm

Media Grade Selection

The Zeta Plus™ LP series filter media are available in four grades. Mechanical straining alone is indicated by grade in Chart 1. Chart 1 is intended for use as a guide to nominal micron rating. Particles smaller than the rated pore size will be reduced by Zeta Plus™ LP series filter media due to electrokinetic adsorption. Actual operating conditions and the product to be filtered should be considered in grade selection. Technical support in optimal grade selection is provided by 3M Technical Representative. The optimal filtration system for your particular application can be determined by on-site test equipment or sample evaluation in our Applications Laboratory.

Flow Rates

Graph 1 depicts the flow rate for clean water. Although the flow rates decrease when fluids higher than 16 cps are filtered, an efficient flow rate can be achieved with proper media type selection.

Pyrogenicity

The Zeta Plus™ LP series filter media are tested for pyrogenicity using the LAL Clot method. All grades contain <0.25 EU/ml, indicating that the Zeta Plus™ LP series filter medium is non-pyrogenic and is less likely to cause false positive results.

Extractables

Zeta Plus™ LP series filter media are designed to be extremely low in extractables. A Regulatory Support File, available on request, provides the typical inorganic extractions from the Zeta Plus™ LP series filter medium. For more information contact your local representative.

Cartridge Construction

Zeta Plus™ LP series filter media are available in both flat stock (sheets and discs) and cartridges. Cartridges are constructed from individual cells. Each cell is constructed with a molded polypropylene edge seal and internal separator. The cells are assembled into a cartridge under a predetermined compression and made into a single unit by three 316 stainless steel bands with polypropylene cell separators.

Filter Sheets and Discs

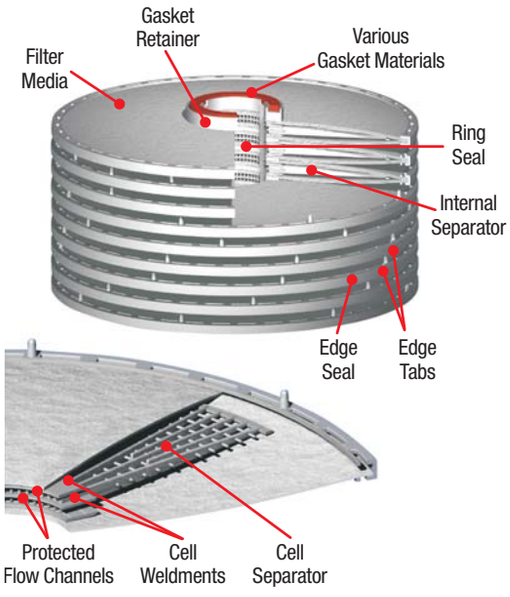
Zeta Plus™ LP series filter media are available in die-cut discs and sheets for use in plate and frame filter presses. Because of the higher flow capabilities and greater contaminant retention of Zeta Plus™ LP series filter media as compared to other types of filter sheets, it is often possible for filter press users to reduce their filter sheet usage by 20 to 50% in processing equivalent volumes of products. Because LP media may be used with a wide range of solutions and under varying filtration conditions, the extractable levels and other test data presented here should be used as a guide only. Extractable levels and other filter properties should be determined and compared with existing standards of acceptance for the particular application in which the filters will be used.

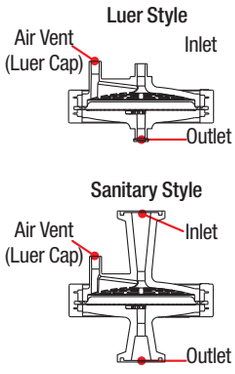
Capsule Configurations

For faster and easier trial runs, Zeta Plus™ LP series filter media are available in BC Capsules, self-contained, disposable filter devices. The Zeta Plus Encapsulated System includes capsule filters with effective filtration areas at 170 cm², 340 cm², 1020 cm², 0.23 m², and 2.5 m². They are ideal for both the scale-up studies as well as large scale production. Please ask your 3M Technical Representative for more information on Zeta Plus™ Encapsulated System and Zeta Plus™ Scale-Up Capsule single-use products.

Figure 1: Zeta Plus™ LP Series Configurations

Zeta Plus Cartridges | BC25 | BC1000/2000





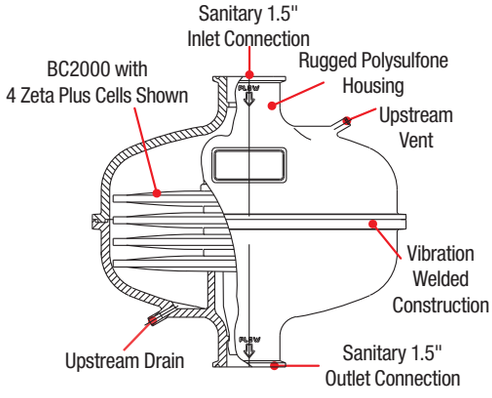


Table 1: Zeta Plus™ LP Series Materials of Construction

Configuration	Component	Material
BC25 Capsule	Capsule Shell	Polypropylene
	Overmold	Glass Filled Polypropylene
BC1000 & 2000 Capsules	Capsule Shell	Polysulfone
	Cartridge Support, Cell Separators, Edge Seal & Vent Cap	Polypropylene
Zeta Plus™ Cartridges	Cartridge Support, Cell Separators & Edge Seal	Polypropylene
	Compression Bands	316 Stainless Steel

Table 2: Zeta Plus™ LP Series Filter Cartridge Surface Area

Cartridge Configuration	Effective Filtration Area
BC25 Capsule	25 cm^2
BC1000 Capsule	650 cm^2
BC2000 Capsule	1300 cm^2
45109 (8 diameter cartridge, 8-cell)	260 cm^2
45167 (8 diameter cartridge, 7-cell, o-ring plug-in)	0.23 m^2
Z8FA2NPX2 (8 diameter cartridge, 2-cell plug-in)	650 cm^2
Z8FA4NPX2 (8 diameter cartridge, 4-cell plug-in)	1300 cm^2
45230 (12 diameter cartridge, 15-cell)	1.4 m^2
45237 (12 diameter cartridge, 12-cell)	1.1 m^2
45244 (12 diameter cartridge, 9-cell)	0.85 m^2
45245 (12 diameter cartridge, 16-cell)	1.5 m^2
Z16P (16 diameter cartridge, 14-cell)	3.2 m^2
Z16H (16 diameter cartridge, 16-cell)	3.7 m^2
Z16H (16 diameter cartridge, 17-cell)	3.9 m^2
Z16R (16 diameter cartridge, 14-cell)	3.2 m^2
Z16T (16 diameter cartridge, 16-cell) 30LP and 50 LP	3.7 m^2
Z16R (16 diameter cartridge, 17-cell) 60LP and 90LP	3. 9 m^2

Table 3: Recommended Operating Parameters

Maximum Operating Pressure	**BC25 Capsules**	2.8 bar maximum inlet pressure, 2.4 bar maximum capsule pressure drop.
	BC1000/2000 Capsules	5.52 bar @ 25°C, 2.75 bar @ 60°C maximum inlet pressure; 2.4 bar maximum capsule pressure drop.
	Standard Zeta Plus Cartridges	2.4 bar maximum cartridge pressure drop.
Maximum Operating Temperature	**BC25 Capsules**	40°C
	BC1000/2000 Capsules	60°C
	Zeta Plus Cartridges	82°C
Recommended Pre-use Rinse	**All**	54 L/m^2
Sterilization Parameters	**BC25 Capsules**	Autoclave 30 min. at 121°C (1 cycle).
	BC1000/2000 Capsules	Autoclave 30 min. at 121°C (up to 3 cycles).
	Standard Zeta Plus Cartridges	Autoclave or In situ steam sterilize 30 minutes @ 126°C (3 cycles)

Zeta Plus™ LP Series Filter Media Ordering Guide

BC Capsules

Catalog Number	Configuration	Media Grade
BC0025	L - Luer S - Sanitary	30 LP 50 LP 60 LP 90 LP
BC1000 (8” 2 cell) BC2000 (8” 4 cell)	A - Single Pack B - 3 Pack	

8” Diameter Cartridges

Catalog Number	No. of Cells	Configuration	Material	Gasket Material	Packaging Code	Media Grade
Z8FA (8” Plug In Style)	2 (2 cell) 4 (4 cell)	N - None	P - Polypropylene	A - Silicone B - Fluorocarbon C - EPR D - Nitrile K - PTFE-Encapsulated Fluorocarbon	2 -Standard	30 LP 50 LP 60 LP 90 LP

Basic Cartridge Design	Gasket Material	Media Grade
45109 (8” - 8 Cell)	11 - Nitrile 13 - Fluorocarbon 14 - EPR	30 LP 50 LP 60 LP 90 LP
45167 (8” - 7 Cell) Plug In	01- Nitrile 02 - EPR 03 - Fluorocarbon 04 - Silicone	

12” Diameter Cartridges

Basic Cartridge Design	Geometric Variation	Gasket Material	Media Grade
45237[1] (12” - 12 Cell) 45244[1] (12” - 9 Cell) 45245[1] (12” - 16 Cell)	01- Unfilled Polypropylene Edge Seal 02 - Talc Filled Polyproylene Edge Seal	A - Silicone B - Fluorocarbon C - EPR D - Nitrile E - PTFE	30 LP 50 LP 60 LP 90 LP

16” Diameter Cartridges

Basic Cartridge Design	Configuration	Gasket Material	Media Grade	Lifting Handle[2]
Z16	P - 14 cell H - High area[3] R - 14 cell (Hastelloy® bands) T - High area (Hastelloy bands)	A - Silicone B - Fluorocarbon C - EPR D - Nitrile E - PTFE	30 LP 50 LP 60 LP 90 LP	H - with Handle

[1] Omit “H” from part number if lifting handle is not required. Bodyfeed cartridge available, please order 45802 (16”, 9 cell)

[2] High Area Cell Count - 16 cells for grade 30 & 50; 17 cells for grade 60 & 90.

Important Notice

The information described in this literature is accurate to the best of our knowledge. A variety of factors, however, can affect the performance of the Product(s) in a particular application, some of which are uniquely within your knowledge and control. INFORMATION IS SUPPLIED UPON THE CONDITION THAT THE PERSONS RECEIVING THE SAME WILL MAKE THEIR OWN DETERMINATION AS TO ITS SUITABILITY FOR THEIR USE. IN NO EVENT WILL 3M PURIFICATION BE RESPONSIBLE FOR DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM THE USE OF OR RELIANCE UPON INFORMATION. It is your responsibility to determine if additional testing or information is required and if this product is fit for a particular purpose and suitable in your specific application.

Limitation of Liability

3M Purification Pty Limited will not be liable, to the extent permitted by law, for any loss or damage from the use of the Product(s), whether direct, indirect, special, or consequential, regardless of the legal theory asserted, included warranty, contract, negligence or strict liability.

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