

# Zeta Plus™ LP Series Filter Media

Zeta Plus™ LP series filter products are designed specifically for the pharmaceutical industry. The depth filter media is composed of inorganic filter aid and cellulose. The Zeta Plus LP series filter media utilizes purified cellulose to minimize  $\beta$ -glucan extractables and false positive LAL test results when measuring extractable endotoxins. The positive charge exhibited by the filter media results in increased particle reduction efficiency.

Zeta Plus LP series products are manufactured in accordance with a strict quality assurance program. Each media lot is tested for flow, density, organic, inorganic and bacterial endotoxin extractables. 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.

## Characteristics

### Superior Particle Reduction

Zeta Plus LP series filter media offers advantages in contaminant reduction because of its 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.



## Applications

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

## 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 <88>Class VI Biological Reactivity Tests.

- Eases validation and regulatory submissions by providing vital documentation and traceability.

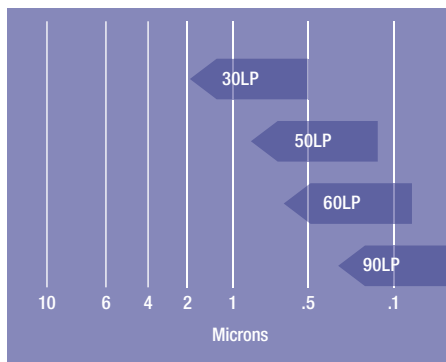
### Self-contained, single-use disposable capsule and cartridge modules.

- Reduced labor time for changeouts and elimination of cleaning validation.

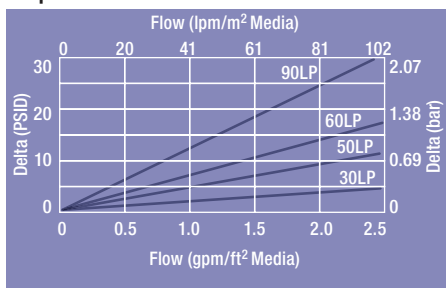
### Tested and optimized for pharmaceutical and biological applications.

- Components are compliant with USP <88> Class VI Biological Reactivity Tests

**Chart 1: Grade Selection**



**Graph 1: Water Flow Rate**



## 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 your local distributor or 3M. The optimal filtration system for your particular application can be determined by on-site test equipment or sample evaluation in our 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.

## Extractables

The Zeta Plus LP series filter media are tested for extractable bacterial endotoxins 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.

Zeta Plus LP series filter media are designed to be low in extractables. A Regulatory Support File, available on request, provides the typical organic and 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 pharmaceutical solutions and under varying filtration conditions, the extractable levels and other test data provided by 3M 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 cm<sup>2</sup> (0.18 ft<sup>2</sup>), 340 cm<sup>2</sup> (0.37 ft<sup>2</sup>), 1020 cm<sup>2</sup> (1.10 ft<sup>2</sup>), 0.23 m<sup>2</sup> (2.4 ft<sup>2</sup>), and 2.5 m<sup>2</sup> (27.0 ft<sup>2</sup>). They are ideal for both the scale-up studies as well as large scale production. Please refer to Literature 70-0202-3967-2 for more information on Zeta Plus Encapsulated System and Zeta Plus Scale-Up Capsule single-use products.

Figure 1: Zeta Plus™ LP Series Configurations

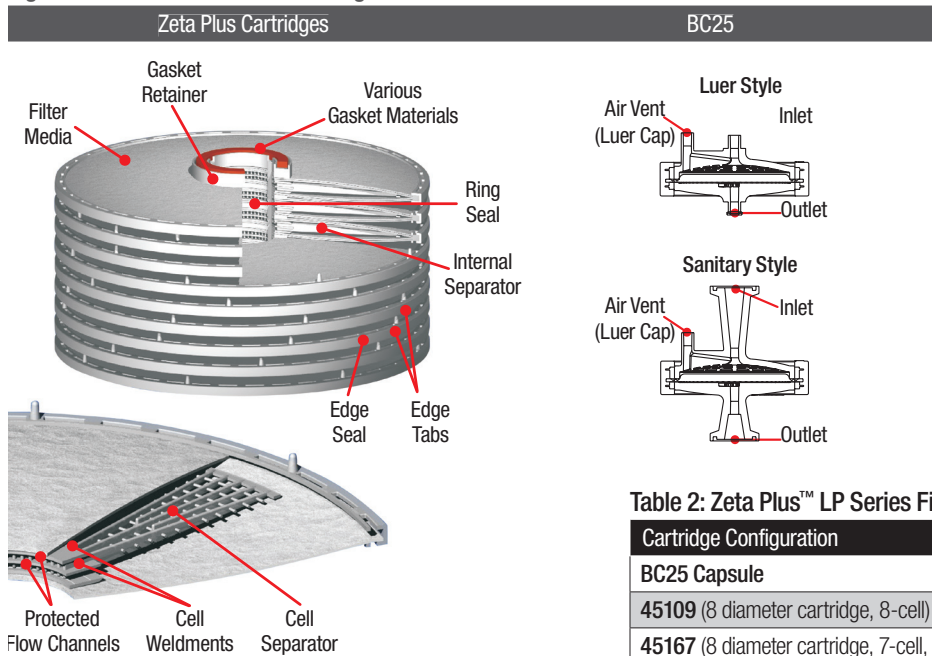


Table 1: Zeta Plus™ LP Series Materials of Construction

Configuration	Component	Material
BC25 Capsule	Capsule Shell	Polypropylene
	Overmold	Glass Filled 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 <sup>2</sup> (3.9 in <sup>2</sup> )
45109 (8 diameter cartridge, 8-cell)	260 cm <sup>2</sup> (2.8 ft <sup>2</sup> )
45167 (8 diameter cartridge, 7-cell, o-ring plug-in)	0.23 m <sup>2</sup> (2.4 ft <sup>2</sup> )
Z8FA2NPX2 (8 diameter cartridge, 2-cell plug-in)	650 cm <sup>2</sup> (0.7 ft <sup>2</sup> )
Z8FA4NPX2 (8 diameter cartridge, 4-cell plug-in)	1300 cm <sup>2</sup> (1.4 ft <sup>2</sup> )
45230 (12 diameter cartridge, 15-cell)	1.4 m <sup>2</sup> (15.4 ft <sup>2</sup> )
45237 (12 diameter cartridge, 12-cell)	1.1 m <sup>2</sup> (12.3 ft <sup>2</sup> )
45244 (12 diameter cartridge, 9-cell)	0.85 m <sup>2</sup> (9.2 ft <sup>2</sup> )
45245 (12 diameter cartridge, 16-cell)	1.5 m <sup>2</sup> (16.4 ft <sup>2</sup> )
Z16P (16 diameter cartridge, 14-cell)	3.2 m <sup>2</sup> (34.7 ft <sup>2</sup> )
Z16H (16 diameter cartridge, 16-cell)	3.7 m <sup>2</sup> (39.7 ft <sup>2</sup> )
Z16H (16 diameter cartridge, 17-cell)	3.9 m <sup>2</sup> (42.2 ft <sup>2</sup> )
Z16R (16 diameter cartridge, 14-cell)	3.2 m <sup>2</sup> (34.7 ft <sup>2</sup> )
Z16T (16 diameter cartridge, 16-cell) 30LP and 50 LP	3.7 m <sup>2</sup> (39.7 ft <sup>2</sup> )
Z16R (16 diameter cartridge, 17-cell) 60LP and 90LP	3.9 m <sup>2</sup> (42.2 ft <sup>2</sup> )

Table 3: Recommended Operating Parameters

Maximum Operating Pressure	BC25 Capsules	2.8 bar (40 psig) maximum inlet pressure, 2.4 bar (35 psid) maximum capsule pressure drop.
	Standard Zeta Plus Cartridges	2.4 bar (35 psid) maximum cartridge pressure drop.
Maximum Operating Temperature	BC25 Capsules	40°C (104°F)
	Zeta Plus Cartridges	82°C (180°F)
Minimum Required Pre-conditioning Flush	All	54 L/m <sup>2</sup> (1.33 gal/ft <sup>2</sup> ) with water, or other suitable fluid, at a volumetric flow rate up to 1200 L/m <sup>2</sup> /hr
Sterilization Parameters	BC25 Capsules	Autoclave 30 min. at 121°C (250°F) (1 cycle).
	Standard Zeta Plus Cartridges	Autoclave or <i>In situ</i> steam sterilize 30 minutes @ 126°C (259°F) (3 cycles)

# Zeta Plus™ LP Series Filter Media Ordering Guide

## BC Capsules

Catalog Number	Configuration	Media Grade	Formulation
BC0025	L - Luer S - Sanitary	30-50-60-90	LP

## 8" Diameter Cartridges

Catalog Number	No. of Cells	Configuration	Material	Gasket Material	Packaging Code	Media Grade	Formulation
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	30-50-60-90	LP

Basic Cartridge Design	Gasket Material	Media Grade	Formulation
45109 (8" - 8 Cell)	13 - Fluorocarbon	30-50-60-90	LP
45167 (8" - 7 Cell) Plug In	03 - Fluorocarbon 04 - Silicone		

## 12" Diameter Cartridges

Basic Cartridge Design	Geometric Variation	Gasket Material	Media Grade	Formulation
45237 <sup>1</sup> (12" - 12 Cell) 45244 <sup>1</sup> (12" - 9 Cell) 45245 <sup>1</sup> (12" - 16 Cell)	01 - Unfilled Polypropylene Edge Seal 02 - Talc Filled Polypropylene Edge Seal	A - Silicone B - Fluorocarbon E - PTFE	30-50-60-90	LP

## 16" Diameter Cartridges

Basic Cartridge Design	Configuration	Gasket Material	Media Grade	Formulation	Lifting Handle <sup>2</sup>
Z16	P - 14 cell H - High area <sup>3</sup> R - 14 cell (Hastelloy® bands) T - High area (Hastelloy bands)	A - Silicone B - Fluorocarbon E - PTFE	30-50-60-90	LP	H - with Handle

<sup>1</sup> Omit "H" from part number if lifting handle is not required. Bodyfeed cartridge available, please order 45802 (16", 9 cell)

<sup>2</sup> High Area Cell Count - 16 cells for grade 30 & 50; 17 cells for grade 60 & 70.

Product Use
<b>Identified uses:</b> Manufacturing of pharmaceutical (drug) products, including active pharmaceutical ingredients and vaccines.
<b>Prohibited uses:</b> 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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