

3M Purification

Zeta Plus™ EXT Series

Featuring Dual Zone SP Filter Media



- Increased throughput with high turbidimetric efficiency
- Enhanced protection of downstream membrane filters
- A complete particle retention range from coarse to fine
- Open grade EXT filters are designed for primary clarification
- Consolidation of multiple filter stages resulting in lower processing costs

The Zeta Plus EXT Series filter featuring dual zone SP Filter media extends depth filtration capacity and protection of downstream membranes thereby extending filter life and lowering overall filtration costs. Zeta Plus EXT Series is a family of advanced dual zone depth filters designed to provide optimal clarification of bioprocess, biological and pharmaceutical fluids. Zeta Plus EXT Series filters consist of two distinct layers, or “zones”, of filter media with the upstream zone more open than the downstream zone. This structure enhances the contaminant holding capacity of the filter media, since larger particles are trapped in the upper zone and smaller particles are trapped in the lower zone, reducing premature plugging and extending service life.

Applications

**Clarification of mammalian cell culture process fluids
(cell separation)**

**Protection of downstream processes including membrane
(0.2, 0.1 micron) filters and chromatography columns**

Clarification of bacteria and yeast cell lysates

Endotoxin and nucleic acid removal

Clarification of colloidal and haze forming contaminants

Applications

EXT filters with SP media are optimized for clarification of mammalian cell harvest fluids, clarification of high protein concentration feed streams and for optimal protection of downstream sterilizing grade membrane filters. Zeta Plus SP media is composed of an inorganic filter aid, cellulose and a proprietary resin system that imparts a positive charge to the filter matrix.

Superior Performance

Advances in mammalian cell line engineering, DNA transfer vector and cell culture media have increased protein yields in mammalian cell cultures by a factor of 10 over the last decade. This increase in part is due to the increased cell titers at harvest. Thus the biopharmaceutical industry has encountered a new challenge to improve primary cell clarification while minimizing protein loss. Zeta Plus EXT Series filters with SP media are designed to fulfill this unmet need. Zeta Plus SP media is an advanced cellulose-based depth filtration media, designed to retain contaminants by both mechanical entrapment and electrokinetic adsorption. Zeta Plus filter media is composed of high surface area filter aids embedded in a cellulose fibre matrix. During the manufacturing process molecules carrying a positive charge are chemically bonded to the filter matrix permanently forming an interconnected filtration structure with positively charged electrokinetic capture sites. The resulting porous depth filter is a tortuous network of charge enhanced flow channels capable of removing bacteria, particulate, cellular debris and submicronic contaminants.

Figure 1: Zeta Plus EXT Series Performance

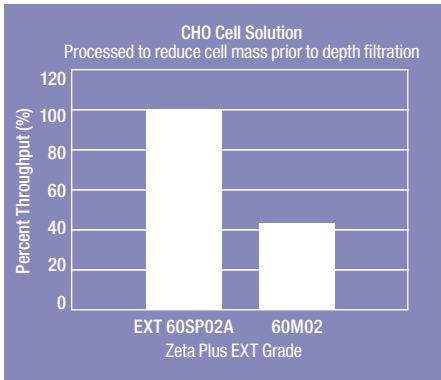


Figure 1 illustrates the superior Zeta Plus EXT Series filter performance using mammalian cell culture fluids. EXT filters provide both superior throughput and turbidimetric efficiency, outperforming standard Zeta Plus filters by a margin of 2:1 in throughput. To the end user, this superior performance translates into lower processing costs, smaller filter assemblies and enhanced protection of downstream membrane filters.

Regulatory Support

Zeta Plus EXT Series filters with SP media are manufactured in accordance with an ISO 9001:2000 Quality Management system. All materials of construction are 21 CFR listed and filter components successfully passed the USP Class VI Biological Reactivity test. Each filter includes a certificate of quality and, to ease validation and regulatory submission, a regulatory support file is available.

Cartridge Construction

Individual cells of EXT SP media are assembled together with polypropylene separators under predetermined compression and unitized by three, 316 stainless steel bands.* Each cell is constructed using thermoplastic rubber moulded edge seals and polypropylene separators for high performance. Filter cartridges are available in 8 and 16-inch diameters, with surface area ranging from 0.16 m² to 2.77 m² per cartridge.

Feasibility and Sizing Trials

Zeta Plus EXT Series is available in autoclavable and fully disposable BC25 capsules. With 25 cm² and 0.10 m² of filtration area, the ready-to-use BC filter capsule is ideal for feasibility and sizing trials.

Pilot Scale and Small Volume

For pilot scale and small volume trials, the Zeta Plus EXT Series is available in 8" diameter cartridges. Other units available are 1- and 2-cell 16" diameter cartridges. Small scale pilot runs are recommended to confirm grade selection prior to scale up.

Grade Selection

The Zeta Plus EXT Series with SP filter media is available in 11 grades. Figure 2, on the facing page, is provided as a guide to proper grade selection based on nominal retention ratings and can be used in conjunction with the recommendations in Table 1 to determine the appropriate filter grade for your application. Operating conditions and the fluid being filtered impact retention performance. 3M Purification recommends small scale pilot runs to confirm grade selection prior to scale up. 3M Purification's Scientific Applications Support Services (SASS) staff can assist in grade selection as well as assist in on-site evaluations. Filter system optimization can also be conducted at 3M Purification's laboratory facilities.



Zeta Plus BC25 & BCE03 filter capsules are ideal for feasibility, sizing, small volume, and pilot scale trials.

Figure 2: Nominal Retention Ratings

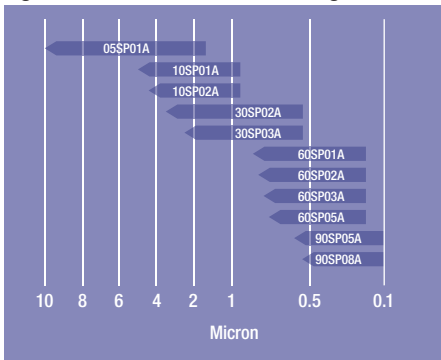


Table 1: Application Recommendations

Application	Recommended Grades
Coarse (primary) clarification	05SP01A, 10SP01A, 10SP02A, 30SP02A, 30SP03A, 60SP01A
Fine Clarification	60SP05A, 90SP05A
Cell broth centrate and high protein concentration feed clarification	60SP02A, 60SP03A, 60SP05A, 90SP05A, 90SP08A
TFF, membrane protection	60SP03A, 60SP05A, 90SP08A
Endotoxin, nucleic acid removal	90SP05A, 90SP08A

Table 1 is intended as a guide. Grade selection and performance should be confirmed with small-scale pilot trials.

*Except Z08E05, 8" plug-in style cartridge, which is unitized by a polypropylene post.

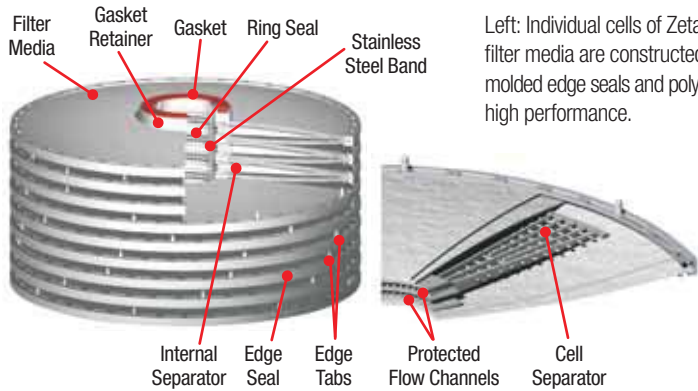


Table 2: Effective Cartridge Surface Area

Cartridge Configuration	Surface Area
BC25 Capsule	25cm ²
BCE03 Capsule	0.10 cm ²
Z08 E05 (8 diameter cartridge plug-in, 5-cell)	0.16 m ²
Z08 E06 (8 diameter cartridge DOE, 6-cell)	0.20 m ²
Z08 E07 (8 diameter cartridge DOE, 7-cell)	0.23 m ²
Z12 E11 (12 diameter cartridge, 11-cell)	1.00 m ²
Z16 E01 (16 diameter cartridge, 1-cell)	0.23 m ²
Z16 E02 (16 diameter cartridge, 2-cell)	0.46 m ²
Z16 E08 (16 diameter cartridge, 8-cell)	1.8 m ²
Z16 E12 (16 diameter cartridge, 12-cell)*	2.8 m ²

*Z16E12 (16" diameter cartridge, 12-cell) wet weight (65 lb/ 29 kg) may require lifting assistance.

Table 3: Recommended Operating Parameters

Maximum Operating Pressure	BC25 Capsules: 40 psig maximum inlet pressure, 35 psid maximum capsule pressure drop. BCE03 Capsules: 80 psig @ 25°C (40 psig @ 60°C) maximum inlet pressure, 35 psig maximum capsule pressure drop. Standard Zeta Plus Cartridges: 35 psid maximum cartridge pressure drop.
Maximum Operating Temperature	BC25 Capsules: 40°C BCE03 Capsules: 60°C Standard Zeta Plus Cartridges: 82°C
Recommended Pre-use Rinse	53.8 l/m ² at 20 lpm/m ²
Autoclave/Steam in Place Parameters	BC25: Autoclave 30 min. at 121°C (1 cycle). BCE03 Capsules: Autoclave 30 min. at 121°C (up to 3 cycles). Standard Zeta Plus Cartridges: <i>In-situ</i> steam 30 min. at 126°C (3 cycles).
Recommended Flow Rates*	BC25 Capsule: 3-30 ml/min. BCE03 Capsules: 0.1-1.0 lpm Standard Zeta Plus Cartridges: 1-10 lpm/m

*Lower flow range recommended for maximum throughput.

Sanitary Housings

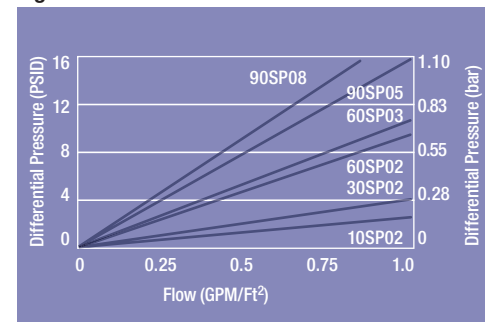
3M Purification provides a wide array of standard and specially designed sanitary filter housings to accommodate Zeta Plus EXT Series filter cartridges. All housings are designed with the pharmaceutical and bioprocessing industries in mind and feature 316L polished surfaces and easy to clean components, along with accessories such as CIP spray balls. Custom designed skid systems incorporating Zeta Plus and membrane cartridge filter housings, together with process piping, flow control and complete validation documentation (IQ, OQ), are also available.

Zeta Plus EXT Series cartridges can be retrofitted into 3M Purification's existing standard Zeta Plus housing offering. To accommodate both 1- and 2- cell 16" diameter EXT cartridges, 3M Purification has specially designed two sanitary short dome housings that minimize working and hold up volumes.

Filter Flow Rates

Figure 3 displays initial flow rates obtained with 20°C clean water. Optimum flow rates vary by application however in general, the flow rate per unit area (flux) should not exceed 10 lpm/m² of filter media for best performance. Lower flux rates often result in longer service life, greater throughputs and superior system economics.

Figure 3: Flow vs. Differential Pressure



NOTE:

1 bar = 100 kPa

1 gpm/ft² = 40.7 lpm/m²

Zeta Plus™ EXT Series Featuring Dual Zone SP Filter Media Ordering Guide

8" Diameter Cartridges

Catalog Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z08	E - EXT	05 - 5 cell	P - Polypropylene Plug In	A - Silicon	05SP01A (5 & 6 cell) 10SP01A (5 & 6 cell) 10SP02A (5 & 6 cell) 30SP02A (5 & 6 cell) 30SP03A (5 & 6 cell) 60SP01A (5 & 6 cell) 60SP02A (5 & 6 cell) 60SP03A (5 & 6 cell) 60SP05A (5 & 7 cell) 90SP05A (5 & 7 cell) 90SP08A (5 & 7 cell)
		06 - 6 cell	A - Stainless Steel Bands		
		07 - 7 cell	A - Stainless Steel Bands		

Part Number Example: Z08E05PA60SP05A. All 8" cartridges are packaged two units per box.

12" Diameter Cartridges

Catalog Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z12	E - EXT	11 - 11 cell	A - Stainless Steel Bands B - Hastelloy® Bands	S - Silicon	60SP05A 120SP05A 90SP05A 120SP08A 90SP08A 120SP10A

Part Number Example: Z12E11AA60ZA05A. All 12" cartridges are packaged two units per box.

16" Diameter Cartridges

Catalog Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z16	E - EXT	01 - 1 cell 02 - 2 cell 08 - 8 cell	A - Stainless Steel Bands	A - Silicon	05SP01A 60SP02A 10SP01A 60SP03A 10SP02A 60SP05A 30SP02A 90SP05A 30SP03A 90SP08A 60SP01A

Part Number Example: Z16E08AA60SP05A. 1-cell and 2-cell cartridges are each packaged two units per box. 8-cell cartridges are packaged one unit per box.

BC Series for Feasibility & Sizing Trials

Catalog Number	Grade
BC0025L (Luer) BC0025S (Sanitary)	05SP01A 60SP02A 10SP01A 60SP03A 10SP02A 60SP05A 30SP02A 90SP05A 30SP03A 90SP08A 60SP01A

Part Number Example: BC0025S60SP05A.

BC Series for Pilot Scale & Small Volume

Catalog Number	Number of Cells	Packaging	Grade
BCE	03 - 3 cell	A - Single Filter	05SP01A 60SP02A 10SP01A 60SP03A 10SP02A 60SP05A 30SP02A 90SP05A 30SP03A 90SP08A 60SP01A

Part Number Example: BCE03A60SP05A.

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.

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3M Purification Pty Limited

140 Sunnholt Road
Blacktown NSW 2148
AUSTRALIA

Tel. 1300 367 362
Fax. 1800 671 599

www.3mpurification.com.au

New Zealand

PO BOX 33-246
North Shore 0740
Auckland, NEW ZEALAND

Tel. 0800 362 886
Fax. 0800 362 880

www.3m.com/nz

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