# LENNTECH

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# Zeta Plus<sup>TM</sup> CA, LA and SA Series

Zeta Plus<sup>TM</sup> CA, SA and LA Series filter media are specifically designed for processes that require a high degree of filtration and low aluminium extractables. The media is made of inorganic filter aids cationic resin and cellulose.

#### **Grade choice**

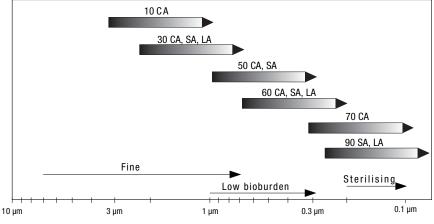
The Zeta Plus CA, SA and LA Series filter media are available in a broad range of grades and configurations. Mechanical straining capability for each grade is indicated below. This is intended for use as a guide to nominal micron rating. Particles smaller than the rated pore size may be removed via electro-kinetic adsorption. Actual operating conditions and the product to be processed will influence absolute performance. The optimal filtration system for your particular application can be determined by on-site testing and a range of small capsules are available for scaling experiments.

# Pharmaceutical grade

Zeta Plus CA, SA and LA Series filter media is manufactured to procedures described in 3M Purification's Drug Master Files on record with the FDA. They are non-toxic in accordance with the USP Class VI, "Biological Safety Test for Plastics" and meet the strict requirements specified in the Drug Master File, including product control and traceability.



Picture 1: Zeta Plus™ family



Graphic 1: Zeta Plus™ CA, SA & LA Grade Selection

# **Applications**

Examples of applications include:

#### Bio-pharmaceutical

- Small and large volume parenterals
- Dialysates
- Blood fractions
- · Cell harvest broth

# Features and benefits

Depth filtration media designed to retain contaminants by mechanical entrapment and electro-kinetic adsorption

• High contaminant holding capacity for economical filtration and reliable particle removal

# 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

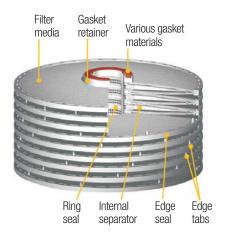
# Self-contained, single-use disposable capsule and cartridge modules

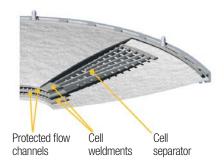
• Reduced labour time for change-outs and elimination of cleaning validation

#### 3M Purification high purity pre-extracted filter aid

· Low extractable, fast rinse-up







Graphic 2: Zeta Plus™ cartridge construction



Zeta Plus<sup>™</sup> production-scale cartridge systems including 8", 12" and 16" diameter systems can meet the scale-up needs of a growing process

#### Filter media selection

Zeta Plus cartridges have been designed to provide clean, easy to use filtration systems that offer significant advantages over conventional filter press operations. The Zeta Plus CA, SA and LA Series have been designed to be heat (both *in situ* steam and autoclave for one hour at 121 °C) and chemically sterilised.

## Cartridge and capsule construction

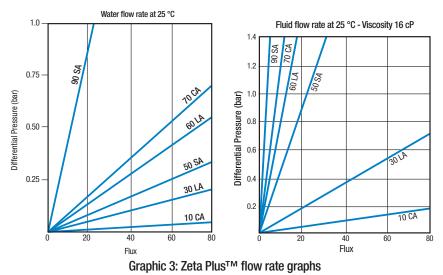
Cartridges and capsules are constructed from individual cells of Zeta Plus filter media assembled together with polypropylene separators under predetermined compression. Standard cartridges are unitised by three 316 stainless steel bands. Plug-in cartridges and Zeta Plus BC 1000/2000 utilise a polypropylene post. Each cell is constructed using polypropylene moulded edge seals and separators for high performance. Various gasket materials are available depending upon application. Filter cartridges are available in 8", 12" and 16" diameters.

# Filter sheets and discs

Zeta Plus 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 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 percent in processing equivalent volumes of products.

#### **Efficient flow rates**

The graphs below depict the flow rates per unit area (flux) for clean water and a 16 cP fluid. Although the flow capacity is decreased by high viscosity solutions, an efficient flow rate can be achieved with proper media type selection.



## **Quality control**

The Zeta Plus CA, SA and LA cartridges are manufactured in accordance with a strict quality assurance programme following ISO regulations. Each media lot is sample audited for flow, density, charge capacity, organic and inorganic extractables and pyrogenicity. In addition, Zeta Plus CA, SA or LA cartridge packaging is labelled with a lot identification number to provide complete traceability.

# **Regulatory support**

Zeta Plus CA, SA and LA Series filters are produced from materials which are 21CFR listed and filter components have successfully passed USP Class VI Biological Reactivity Tests.

## **Compatibility**

Temperature, contact time, chemical concentration, flow rate, aeration and differential system pressure are all variables that can affect chemical compatibility of filter materials. Therefore it is always advisable to perform tests replicating process conditions to determine ultimate compatibility. Table 1 is provided as a guide only. Please contact your local 3M Purification SASS team for further support on validation and compatibility.

Table 1: Chemical compatibility							
Chemicals	-	CA (60°C	Gaskets				
onomicals.	max.)	Max.)	Max.)	nitrile	fluorocarbon	ethylene propylene	silicone
Ethyl acetate	G	G	G	Р	Р	Р	F
Acetone 100%	G	G	G	Р	G	G	G
Acetic acid 5%-20%	G	G	G	G	G	G	G
Benzene	G	G	G	Р	F	Р	F
Chloroform dry	G	G	G	Р	G	Р	F
Methylene chloride	G	G	G	Р	F	Р	Р
1.4 - dioxane	G	G	G	Р	Р	Р	Р
Dimethyl formamide	G	G	G	F	Р	Р	No Data
Ethanol 50%	G	G	G	G	F	G	G
Ethanol 10%	G	G	G	G	F	G	G
Ethyl acetate	G	G	G	F	G	Р	F
n-heptane	G	G	G	G	G	Р	F
Hexane	G	G	G	G	G	Р	F
Methyl ethyl ketone (MEK)	G	G	G	Р	Р	G	G
Methanol	G	G	G	G	Р	G	G
Methyl isobutyl ketone (MIBK)	G	G	G	Р	Р	G	G
Petroleum ether	G	G	G	F	G	Р	F
Sodium hydroxide 2%	F/P	F/P	F/P	F	G	G	G
Toluene	G	G	G	Р	G	Р	F
1.1.1 trichlorethane	G	G	G	Р	G	Р	F
Water (ambient)	G	G	G	G	G	G	G
Water (82 °C)	G	Р	G	G	G	G	G
Xylene	G	G	G	Р	G	Р	F

Explanation of ratings:

# **Extractables**

A static soak test of Zeta Plus filter materials was performed to determine the amount of organic and inorganic compounds extracted by various solvents using atomic adsorption spectrophotometry. The values in the following table are the average amounts to be expected in ppb/m² of media after a 54 l/m² rinse with water.

# **Operating parameters**

Table 3: Recommended operating parameters						
	Maximum operating pressure	Maximum operating temperature	Recommended flush	Sterilisation parameters	Maximum flow rate (flux) (in lpm/m²)	
Standard & special pre-coat Zeta Plus™ cartridges	2.4 bar	82 °C <sup>1</sup> For CA: 60 °C <sup>1</sup>	54 l/m² at 20 lpm/m²	Autoclave or <i>in situ</i> steam sterilisation for 1 hour at 121 °C	1.2 to 12	
	Inlet pressure: 2.75 bar Media pressure: 2.4 bar	40 °C ¹	54 l/m² at 20 lpm/m²	Autoclave for 30 minutes at 121 °C (1 cycle)	1.2 to 12	
Zeta Plus™ BC1000 and BC2000 Series capsules	Inlet pressure: 5.5 bar at 25 °C 2.75 bar at 60 °C Media pressure: 2.4 bar	60 °C ¹	54 l/m² at 20 lpm/m²	Autoclave for 30 minutes at 121 °C (up to 3 cycles)	1.2 to 12	
<sup>1</sup> Note: See above comment on Compatibility.						

90 mm disc media						
	Extractables quantity in ppb					
Extractables	90 LA	90 SA	70 CA			
Aluminium	<107	<107	<107			
Iron	104	156	66			
Zinc	102	78	68			
Copper	<54	<54	<54			
Nickel	<161	<161	<161			
Lead	<107	<107	<107			
Cadmium	<10	<10	<10			
Chromium	<32	<32	<32			

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G = Satisfactory - to maximum temperature given for material, unless restriction is noted.

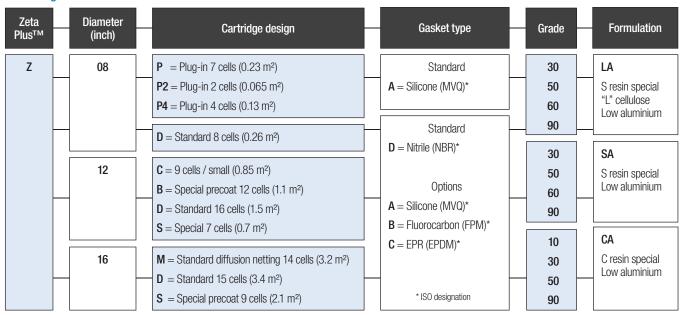
F = Fair - to maximum temperature given for material, unless restriction is noted.

P = Not recommended.

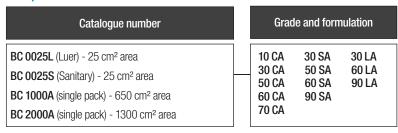


# Zeta Plus<sup>™</sup> CA, LA and SA Series filters - Ordering guide

#### 1. Cartridges



#### 2. Capsules



## 3. Sheets

By request, Zeta Plus<sup>TM</sup> media can also be supplied in sheet format. Please contact your local 3M Purification representative for further details on how to order.

#### **Important Notice**

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