

3M Separation and Purification Sciences Division

3M™ Zeta Plus™ Filters with LA Series Media

Regulatory Support File Supplement

3M™ Zeta Plus™ Filters with LA Series Media Regulatory Support File Supplement

This document is a supplement to the 3M™ Zeta Plus™ Filters with LA Series Media Regulatory Support File.

This supplemental document covers the special filter configurations that are customized and available for current customers. The special filter configurations are summarized below. The filter materials of constructions and filter performance are covered by 3M™ Zeta Plus™ Filters with LA Series Media Regulatory Support File (RSF). However, the USP <87> statement that is in the RSF does not apply to products containing the Nitrile (NBR) or EPDM (EPDM) gaskets.

Product configurations listed below may not be commercially available or may not be available to all customers. Please contact your 3M account representative for questions on available product configurations in your country.

There may be additional product configurations not listed here that are still covered by this Regulatory Support File Supplement or the associated Regulatory Support File. Please contact your 3M Account Representative with questions regarding product configurations not listed below that may be covered by this document.

3M™ Zeta Plus™ 8-Inch Filter Cartridges

Table 1. 3M™ Zeta Plus™ 8-Inch Filter Cartridge Product Descriptions: Single Layer Media							
Manufacturing Facility	Product Description Examples: 451091150LA , Z8FA4NPC260LA, Z08DD50LA						
United States	Diameter Designation			Gasket Material		Grade	
	45109 - 8 cell			11 – Nitrile (NBR) 14 – EPDM (EPDM)		30LA 50LA 60LA 90LA VR06	
	45167 - 7 cell Plug-in			01 – Nitrile (NBR) 02 – EPDM (EPDM)			
	Diameter Designation	Number of Cells	Configuration	Material	Gasket Material	Package	Grade
	Z8FA -Plug-in	2 - 2 cell 4 - 4 cell	N - None	P - Polypropylene	C – EPDM (EPDM) D – Nitrile (NBR)	2 - Standard	30LA 50LA 60LA 90LA
Poland	Diameter Designation		Cartridge Construction		Gasket Material		Grade
	Z08		D - Standard 8 cells		C – EPDM (EPDM) D – Nitrile (NBR)		30LA 50LA 60LA 90LA

3M™ Zeta Plus™ 12-Inch Filter Cartridges

Table 2. 3M™ Zeta Plus™ 12-Inch Filter Cartridge Product Descriptions: Single Layer Media					
Manufacturing Facility	Product Description Examples: 4511515 60LA, 4523701D50LA, Z12DD90LA				
United States	Diameter Designation	Material	Gasket Material	Grade	
	45116 – 9 cell 45115 – 16 cell	Not included in description	12 – Nitrile 15 – EPR (EPDM) 17 – Silicone	30LA 50LA 60LA 90LA	
	45244 – 9 cell 45237 – 12 cell 45230 – 15 cell 45245 – 16 cell	01 – Polypropylene (PP)	C – EPR (EPDM) D – Nitrile (NBR)	30LA 50LA 60LA 90LA	
Poland	Diameter Designation	Cartridge Construction	Gasket Material	Grade	Optional Material
	Z12	C – 9 cells B – 12 cells D – 16 cells ¹ M – 15 cells, Netting S – 7 cells	C – EPR (EPDM) D – Nitrile (NBR)	30LA 50LA 60LA 90LA	H ¹ – Hastelloy Bands

1 "H" for Hastelloy® bands. Omit "H" for Stainless Steel Bands.

3M™ Zeta Plus™ 16-Inch Filter Cartridges

Table 3. 3M™ Zeta Plus™ 16-Inch Filter Cartridge Product Descriptions: Single Layer Media					
Manufacturing Facility	Product Description Examples: Z16PD90LA, Z16MD90LA				
United States	Diameter Designation	Configuration	Gasket Material	Grade	Lifting Handle
	Z16	P – 14 cell H – High Area ¹ R – 14 cell (Hastelloy® Bands) T – High Area (Hastelloy® Bands)	C – EPR (EPDM) D – Nitrile (NBR)	30LA 50LA 60LA 90LA	H – with Handle ²
Poland	Diameter Designation	Cartridge Construction	Gasket Material	Grade	Optional Material
	Z16	M – 14 cell, Netting P – 14 cell, Netting D – 15 cell S – 9 cell H – High Area ³ , Netting, Stainless Steel Bands	C – EPR (EPDM) D – Nitrile (NBR)	30LA 50LA 60LA 90LA VR06	H ⁴

1 High Area Cell Count – 16 cells for grades 30LA & 50LA; 17 cells for grades 60LA & 90LA. Bodyfeed cartridge available, please order 45802 (16", 9 cells).

2 Omit "H" from product description if film lifting handle is not required.

3 16 cells for 30LA and 50LA, 17 cells for 60LA and 90LA.

4 "H" for Hastelloy bands. Omit "H" for Stainless Steel Bands.

The following special part numbers (p/n) have customized filter configurations with the corresponding part numbers.

Table 4. Special Part Numbers (p/n)		
Poland Part Number (p/n)	Filter Configuration	Design Variation Description
7100102733	Z16M6D	Special spacer ring, 6 cells
7100102733	Z12XD50LA	Special spacer ring, 6 cells
7100102719	Z083CA30LA	Special spacer ring, 3 cells

3M™ Zeta Plus™ Encapsulated Series Scale-Up Filter Capsules

Table 5. 3M™ Zeta Plus™ Encapsulated Series Scale-Up Filter Capsule Product Descriptions: Single Layer Media			
Manufacturing Facility	Product Description Example: 4583602VR06		
United States	Diameter Designation	EFA (cm²)	Grade
	45836	01 - 0170 02 - 0340 03 - 1020	VR02 VR06

Media Release Specifications

The product specifications verified during filter manufacturing and prior to the release of media lots include but are not limited to the following.

- 1) Pressure Drop at constant air flow – Determined by testing a 5-inch diameter disc of media sheet when challenged at a specific air flow rate.
- 2) Wet Tensile Strength - Determined by soaking a media coupon in water for two minutes then measuring the peak force (in kilograms) to break the sample. The result is normalized for the cross-sectional width and length.
- 3) Calcium Extraction - Determined after completing a pre-conditioning flush with deionized (DI) water, then soaking media in DI water at a ratio of 1 gram of media to 10 mL of water for 24 hours at ambient temperature and analyzing the water for soluble calcium. The result is normalized as mg of calcium per gram of media.
- 4) Iron Extraction - Determined after completing a pre-conditioning flush with DI water, then soaking media in DI water at a ratio of 1 gram of media to 10 mL of water for 24 hours at ambient temperature and analyzing the water for soluble iron. The result is normalized as mg of iron per gram of media.
- 5) Aluminum Extraction - Determined by flushing media with DI water followed by a flush of lactic acid solution. After flushing the media is allowed to sit in the lactic acid solution for 1hr. After 1hr the housing is drained of fluid and the solution is analyzed for soluble aluminum.
- 6) Color Extraction - Determined by flushing a media sample with 100 mL of 0.4% w/v 180° F sodium citrate solution through a 45 mm disc sample of the media. The pooled effluent is analyzed for percent transmittance at 420 nm.
- 7) Total Nitrogen (TN) - Determined by autoclaving media in deionized (DI) water at a ratio of 1 gram of media to 12 mL of water for 1 hour at 121 °C. The extract is analyzed for Total Nitrogen content.
- 8) Endotoxin Extraction - *Limulus* Amebocyte Lysate (LAL) bacterial endotoxin reactivity - Determined by filtering sterile water through a 45 mm disc of media at a flow rate of 18-20 mL/min then collecting a 2 mL effluent sample after 49 mL. The effluent sample is tested for endotoxins using a Kinetic Turbidimetric LAL Assay.
- 9) Metanil Yellow Dye (MYD) Capacity (3M™ Zeta Plus™ VR02 and VR06 Grade Filter Media only) - Charge capacity is measured by challenging the media with a solution of the negatively charged Metanil Yellow dye and measuring the volume required for dye breakthrough.

The above specification limits for each 3M™ Zeta Plus™ LA Series Filter Media Grade are presented in Table 6 below.

3M™ Zeta Plus™ 50LA and 90LA Grade Filter Media can have the designations of 3M™ Zeta Plus™ VR02 and VR06 Grade Filter Media, respectively, after dynamic binding capacity qualification with Metanil Yellow Dye (MYD).

Table 6. Product Release Properties for 3M™ Zeta Plus™ LA Series Filter Media					
Product Release Properties	Single Layer Media Specifications				
	30LA	50LA / VR02	60LA/60LAC	90LA / VR06	Units
Pressure Drop at Air Flow	16.0 – 26.0	50.0 – 68.0	81.0 – 107.0	120.0 – 164.0	Inch H ₂ O
Wet Tensile Strength	≥ 2.0	≥ 2.5	≥ 2.5	≥ 2.5	Kg/in
Ca Extraction	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Fe Extraction	≤ 0.010	≤ 0.010	≤ 0.010	≤ 0.010	mg/g
Al Extraction	≤ 25	≤ 25	≤ 25	≤ 25	ppb
Color Extraction	≤ 8.0	≤ 6.0	≤ 6.0	≤ 6.0	Color Units
Total Nitrogen	≤ 60	≤ 60	≤ 60	≤ 60	ppm
Endotoxin Extraction	≤ 0.05	≤ 0.05	60LA: ≤ 0.05 60LAC: ≤ 0.03	≤ 0.05	EU/mL
MYD Capacity (3M™ Zeta Plus™ VR Grade Filter Media Only)	N/A	50LA: N/A VR02: ≥ 1.5	N/A	90LA: N/A VR06: ≥ 1.5	mg/g

The 3M™ Zeta Plus™ 60LAC Grade Filter Media is manufactured in Stafford Springs, CT, USA and has the same specifications as the 3M™ Zeta Plus™ 60LA Grade Filter Media, except the LAL specification is ≤ 0.03 E.U./ml.

Intended Use(s): 3M™ Zeta Plus™ Filters with LA Series Media are single-use filter products intended for use in biopharmaceutical processing applications of aqueous and chemical based pharmaceuticals (drugs) and vaccines in accordance with the product instructions and specifications, and cGMP requirements, where applicable.

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