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3M Separation and Purification Sciences Division

3M™ Zeta Plus™ Filters with SP Series Media

Regulatory Support File Supplement

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This document is a supplement to the 3M™ Zeta Plus™ Filters with SP 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 construction and filter performance are covered by the 3M™ Zeta Plus™ Filters with SP Series Media Regulatory Support File.

This supplemental document includes a special filter configuration for 3M™ Zeta Plus™ Filters with 30SP Grade Media produced in Mazerès, France. The Mazerès, France facility has quality systems registered to the ISO 9001 quality system standard.

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: 451091160SP, Z8FA4NPC260SP, Z08DD60SP				
United States	Diameter Designation		Gasket Material		Grade
	45109 - 8 cell		11 – Nitrile (NBR) 12 – Neoprene		05SP 10SP 30SP 50SP 60SP 90SP
	45167 - 7 cell Plug-in		01 – Nitrile (NBR) 02 – EPR (EPDM)		
Poland	Diameter Designation	Cartridge Construction	Gasket Material	Grade	Optional Material
	Z08	D – 8 cells	C – EPR (EPDM) D – Nitrile (NBR) E – Teflon (PTFE)	05SP 10SP 30SP 50SP 60SP 90SP	H ¹ – Hastelloy Bands
	Diameter Designation	Cartridge Construction	Gasket Material	Grade	Optional Material
	Z08	P – 7 cell Plug-in P2 – 2 cell Plug-in	C - EPR (EPDM) FEP K – Teflon Encap. Viton	05SP 30SP 50SP	H ¹ – Hastelloy Bands

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

3M™ Zeta Plus™ 12-Inch Filter Cartridges

Table 2a. 3M™ Zeta Plus™ 12-Inch Filter Cartridge Product Descriptions: Single Layer Media					
Manufacturing Facility	Product Description Examples: 4511512 90SP, 4523701 D60SP, Z12DD30SP				
United States	Diameter Designation	Material	Gasket Material	Grade	
	45115 – 16 cell	Not included in description	12 – Nitrile 15 – EPR (EPDM) 17 – Silicone	30SP 50SP 60SP 90SP	
	45207 – 7 cell 45244 - 9 cell 45237 - 12 cell 45230 - 15 cell 45245 - 16 cell	01 - Polypropylene (PP) 03 – PP, Hastelloy® Bands	C – EPR (EPDM) D – Nitrile (NBR) E – Teflon (PTFE)	05SP 10SP 30SP 50SP 60SP 90SP	
Poland	Diameter Designation	Cartridge Construction	Gasket Material	Grade	Optional Material
	Z12	C – 9 cells B – 12 cells D – 16 cells M – 15 cells, Netting S – 7 cells	C – EPR (EPDM) D – Nitrile (NBR) E – Teflon (PTFE)	05SP 10SP 30SP 50SP 60SP 90SP	H ¹ – Hastelloy Bands

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

Table 2b. 3M™ Zeta Plus™ 12-Inch Filter Cartridge Product Descriptions: Dual Layer (EXT) Media						
Manufacturing Facility	Product Description Example: Z12E11AA60SP05A					
Poland	Diameter Designation	Cartridge Construction	Number of Cells	Cartridge Construction	Gasket Material	Grade
	Z12	E	11 – 11 cell	A - Stainless Steel Bands	C – EPR (EPDM)	10SP02A

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: Z16PD30SP, Z16MD30SP, Z16PA30SP1				
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)	05SP 10SP 30SP 50SP 60SP 90SP	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 – 17 cell ³ , netting X – 14 cells	C – EPR (EPDM) D – Nitrile (NBR) E – Teflon (PTFE)	05SP 10SP 30SP 50SP 60SP 90SP	H ⁴
Mazeres	Z16	P – 14 cell, Netting	A – Silicone (VMQ)	30SP	N/A

¹ High Area Cell Count – 16 cells for grades 30SP & 50SP; 17 cells for grades 60SP & 90SP; not available for 05SP & 10SP. Bodyfeed cartridge available, please order 45802 (16", 9 cell).

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

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

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

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 deionized (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 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 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.

The above specification limits for each grade of 3M™ Zeta Plus™ SP Series Filter Media are presented in Table 4. The dual layer (EXT) media specifications represent the specifications of the tighter media layer. The tighter media layer has the smaller nominal pore size of the two layers; the larger the grade number, the tighter or smaller the nominal media pore size. In the Dual Layer (EXT) Media section of Table 4, the dual layer configuration is shown in parentheses beneath the media grade; the upstream layer is shown first, followed by the downstream layer. Each layer is released according to the single layer media specification, and then assembled into dual layer products.

The product release specifications for 3M™ Zeta Plus™ 30SP Grade Filter Media manufactured in Mazerès, France are indicated in the table below. They are the same as the release specification for 3M™ Zeta Plus™ 30SP Grade Filter Media manufactured in the US, Poland and Australia except as noted in parentheses.

Table 4. Product Release Properties for 3M™ Zeta Plus™ SP Series Filter Media								
Product Release Properties	Single Layer Media Specifications¹							Units
	01SP	05SP	10SP	30SP	50SP	60SP	90SP	
Pressure Drop at Air Flow	≤ 2.8	2.7 – 5.0	8.5 – 13.0	16.0 – 26.0 (FR: 13.5-33.0)	50.0 – 68.0	81.0 – 107.0	148.0 - 202.0	Inch H ₂ O
Wet Tensile Strength	≥ 1.5	≥ 3.0	≥ 3.0	≥ 4.0 (FR: ≥ 3.5)	≥ 5.0	≥ 5.5	≥ 6.5	Kg/in
Ca Extraction	≤ 0.040 (PL ≤ 0.080)	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Fe Extraction	≤ 0.010	≤ 0.010	≤ 0.010	≤ 0.010	≤ 0.010	≤ 0.010	≤ 0.010	mg/g
Color Extraction	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	Color Units
Total Nitrogen	≤ 60	≤ 60	≤ 60	≤ 60	≤ 60	≤ 60	≤ 60	ppm
Endotoxin Extraction	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	EU/mL
Product Release Properties	Dual Layer (EXT) Media Specifications¹ (Specification of Tighter Media Layer)						Units	
	05SP01 (01SP/05SP)	10SP01 (01SP/10SP)	10SP02 (05SP/10SP)	30SP02, 30SP03 (05SP/30SP, 10SP/30SP)	60SP02, 60SP03, 60SP05 (05SP/60SP, 10SP/60SP, 30SP/60SP)	90SP05, 90SP08 (30SP/90SP, 60SP/90SP)		
Pressure Drop at Air Flow	2.7 – 5.0	8.5 – 13.0	8.5 – 13.0	16.0 – 26.0	81.0 – 107.0	148.0 - 202.0	Inch H ₂ O	
Wet Tensile Strength	≥ 3.0	≥ 3.0	≥ 3.0	≥ 4.0	≥ 5.5	≥ 6.5	Kg/in	
Ca Extraction	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g	
Fe Extraction	≤ 0.010	≤ 0.010	≤ 0.010	≤ 0.010	≤ 0.010	≤ 0.010	mg/g	
Color Extraction	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	Color Units	
Total Nitrogen	≤ 60	≤ 60	≤ 60	≤ 60	≤ 60	≤ 60	ppm	
Endotoxin Extraction	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	EU/mL	

¹ Manufacturing facilities have the same specification except as noted in parentheses. (US: USA; PL: Poland, AU: Australia; FR: France)

Intended Use(s): 3M™ Zeta Plus™ Filters with SP 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.

Since there are many factors that can affect a product's use, the customer and user remain responsible for determining whether the 3M product is suitable and appropriate for the user's specific application, including user conducting an appropriate risk assessment and evaluating the 3M product in user's application.

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3M Purification Inc.
3M Separation and Purification Sciences Division
400 Research Parkway, Meriden, CT 06450 USA

Phone 1-800-243-6894 1-203-237-5541

Web 3M.com/bioprocessing

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