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3M Separation and Purification Sciences Division

# 3M™ Zeta Plus™ Filters with ZB Series Media

Regulatory Support File Supplement

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

This document is a supplement to the 3M™ Zeta Plus™ Filters with ZB 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 the 3M™ Zeta Plus™ Filters with ZB Series Media Regulatory Support File. However, the USP <87> statement that is in the RSF does not apply to products containing the Nitrile (NBR) or EPR (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

<b>Table 1. 3M™ Zeta Plus™ 8-Inch Filter Cartridge Product Descriptions: Single Layer Media</b>							
<b>Manufacturing Facility</b>	<b>Product Description Examples: 451091160ZB , Z8FA4NPC260ZB, Z08DD60ZB</b>						
United States	<b>Diameter Designation</b>				<b>Gasket or O-ring Material</b>		<b>Grade</b>
	45109 - 8 cell				11 – Nitrile (NBR) 14 – EPR (EPDM)		30ZB 60ZB 90ZB
	45167 - 7 cell Plug-in				01 – Nitrile (NBR) 02 – EPR (EPDM)		
	<b>Diameter Designation</b>	<b>Number of Cells</b>	<b>Configuration</b>	<b>Material</b>	<b>Gasket Material</b>	<b>Package</b>	<b>Grade</b>
	Z8FA -Plug-in	2 - 2 cell 4 - 4 cell	N - None	P - Polypropylene	C – Nitrile (NBR) D – EPR (EPDM)	2 - Standard	30ZB 60ZB 90ZB
Poland	<b>Diameter Designation</b>	<b>Cartridge Construction</b>		<b>O-Ring Material</b>			<b>Grade</b>
	Z08	D - Standard 8 cells		D – EPR (EPDM)			30ZB 60ZB 90ZB

### 3M™ Zeta Plus™ 12-Inch Filter Cartridges

<b>Table 2. 3M™ Zeta Plus™ 12-Inch Filter Cartridge Product Descriptions: Single Layer Media</b>				
<b>Manufacturing Facility</b>	<b>Product Description Examples: 4524501D30ZB, Z12CC60ZB</b>			
<b>United States</b>	<b>Diameter Designation</b>	<b>Material</b>	<b>Gasket Material</b>	<b>Grade</b>
		45237 - 12 cell 45230 - 15 cell 45245 - 16 cell	01 - Polypropylene (PP)	C – EPR (EPDM) D – Nitrile (NBR)
<b>Poland</b>	<b>Diameter Designation</b>	<b>Cartridge Construction</b>	<b>Gasket Material</b>	<b>Grade</b>
	Z12	C - 9 cells D - 16 cells	C – Nitrile (NBR) D – EPR (EPDM)	30ZB 60ZB 90ZB

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

### 3M™ Zeta Plus™ 16-Inch Filter Cartridges

<b>Table 3. 3M™ Zeta Plus™ 16-Inch Filter Cartridge Product Descriptions: Single Layer Media</b>				
<b>Manufacturing Facility</b>	<b>Product Description Examples: Z16PC30ZB</b>			
<b>United States</b>	<b>Diameter Designation</b>	<b>Configuration</b>	<b>Gasket Material</b>	<b>Grade</b>
		Z16	P - 14 cell	C – EPR (EPDM)

### 3M™ Zeta Plus™ Encapsulated Series Filter Capsules (Production Capsules)

<b>Table 4a. 3M™ Zeta Plus™ Encapsulated Series Filter Capsule (Production Capsule) Product Descriptions: Single Layer Media</b>					
<b>Manufacturing Facility</b>	<b>Product Description Example: E16E07A60ZB</b>				
<b>United States and Poland</b>	<b>Diameter Designation</b>	<b>Configuration</b>	<b>Number of Cells</b>	<b>Gasket Material</b>	<b>Grade</b>
		E16	E - Standard	07 - 7 cell	A – Silicone (VMQ)

## A. 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 normalised 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 analysing the water for soluble calcium. The result is normalised 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 analysing the water for soluble iron. The result is normalised 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 3M™ Zeta Plus™ ZB Series Filter Media Grade are presented in Table 5.

<b>Table 5. Product Release Properties for 3M™ Zeta Plus™ ZB Series Filter Media</b>					
<b>Product Release Properties</b>	<b>Single Layer Media Specifications</b>				<b>Units</b>
	<b>30ZB</b>	<b>60ZB</b>	<b>90ZB</b>	<b>120ZB</b>	
Pressure Drop at Air Flow	16.0 – 26.0	81.0 – 107.0	148.0 – 202.0	325.0 – 425.0	Inch H <sub>2</sub> O
Wet Tensile Strength	≥ 3.0	≥ 3.8	≥ 3.8	≥ 3.8	Kg/in
Ca Extraction	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Fe Extraction	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Al Extraction	≤ 60	≤ 60	≤ 60	≤ 60	ppb
Color Extraction	≤ 10.0	≤ 10.0	≤ 10.0	≤ 12.0	Color Units
Total Nitrogen	≤ 60	≤ 60	≤ 60	≤ 60	ppm
Endotoxin Extraction	≤ 0.12	≤ 0.12	≤ 0.12	≤ 0.12	EU/mL

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

**Restrictions on Use:** 3M advises against the use of these 3M products in any application other than the stated intended use(s), since other applications have not been evaluated by 3M and may result in an unsafe or unintended condition. Do not use in any manner whereby the 3M product, or any leachable from the 3M product, may become part of or remains 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 Regulation (MDR), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA) or in applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring food contact compliance.

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