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3M Separation and Purification Sciences Division

3M™ Zeta Plus™ ZB Series Filters

Regulatory Support File Supplement

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This document is a supplement to the 3M™ Zeta Plus™ ZB Series Filters 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™ ZB Series 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.

8” Diameter Cartridges

Table 1. 8” Cartridge Product Descriptions: Single Layer Media

Manufacturing Facility	Product Description Examples: 451091160ZB , Z8FA4NPC260ZB, Z08DD60ZB						
United States	Diameter Designation				Gasket or O-ring Material		Grade
	45109 - 8 cell				11 – Nitrile (NBR) 14 – EPR (EPDM)		30ZB 60ZB 90ZB
	45167 - 7 cell Plug-in				01 – Nitrile (NBR) 02 – EPR (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 – Nitrile (NBR) D – EPR (EPDM)	2 - Standard	30ZB 60ZB 90ZB
Poland	Diameter Designation	Cartridge Construction		O-Ring Material			Grade
	Z08	D - Standard 8 cells		D – EPR (EPDM)			30ZB 60ZB 90ZB

12” Diameter Cartridges

Table 2. 12” Cartridge Product Descriptions: Single Layer Media

Manufacturing Facility	Product Description Examples: 4524501D30ZB, Z12CC60ZB			
United States	Diameter Designation	Material	Gasket Material	Grade
	45237 - 12 cell 45230 - 15 cell 45245 - 16 cell	01 - Polypropylene (PP)	C – EPR (EPDM) D – Nitrile (NBR)	30ZB 60ZB 90ZB
Poland	Diameter Designation	Cartridge Construction	Gasket Material	Grade
	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.

16” Diameter Cartridges

Table 3. 16” Cartridge Product Descriptions: Single Layer Media				
Manufacturing Facility	**Product Description Examples: Z16PC30ZB**			
	Diameter Designation	**Configuration**	**Gasket Material**	**Grade**
United States	Z16	P - 14 cell	C – EPR (EPDM)	30ZB

Production Capsules

Table 4a. Production Capsule Product Descriptions: Single Layer Media					
Manufacturing Facility	**Product Description Example: E16E07A60ZB**				
	Diameter Designation	**Configuration**	**Number of Cells**	**Gasket Material**	**Grade**
United States and Poland	E16	E - Standard	07 - 7 cell	A – Silicone (VMQ)	60ZB

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 by 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 analysing the water for soluble calcium. The result is normalised as mg of calcium per gram of media.
4) Iron Extraction - Determined by 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 analysed 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 media grade are presented in Table 5.

Table 5. Product Release Properties for 3M™ Zeta Plus™ ZB Series Filters					
Product Release Properties	**Single Layer Media Specifications**				
	30ZB	**60ZB**	**90ZB**	**120ZB**	**Units**
Pressure Drop at Air Flow	16.0 – 26.0	81.0 – 107.0	148.0 – 202.0	325.0 – 425.0	Inch H_2O
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

Intended Use(s): 3M™ Zeta Plus™ single-use filter products are 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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