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3M Separation and Purification Sciences Division

3M™ Zeta Plus™ Activated Carbon Series Filters

Regulatory Support File Supplement

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This document is a supplement to the 3M™ Zeta Plus™ Activated Carbon Series Filters Regulatory Support File.

This supplemental document covers special media and filter configurations. The special media and filter configurations are summarized below. The filter materials of construction and filter performance are covered by 3M™ Zeta Plus™ Activated Carbon Series Filters Regulatory Support File. If you do not see your product configuration listed below, please contact 3M to determine if the 3M™ Zeta Plus™ Activated Carbon Series Filters Regulatory Support File is applicable to your product.

A. Special Media Configurations

The first special media configuration is “Hi-Flow” media series. The media has about 30% less activated carbon compared to their corresponding standard media grade as listed in the Regulatory Support File. The materials of construction and the manufacturing process for Hi-Flow media are the same as their corresponding standard grades.

The second special media configuration is “0” porosity rating media series. It is more open than the standard “1” or “3” or “5” rating media. The designations are R01, R02, R03, R04 and R05, where the first number “0” after “R” represents the porosity rating and the second number 1 – 5 represents each standard Type of activated carbon.

Another special media configuration includes other Types of powdered activated carbons than the standard 5 types incorporated in the media series. The designations are R00, R10, R30 and R50, where the first number after “R” represents the porosity rating and the second number “0” represents the non-standard activated carbon Types. There are multiple non-standard activated carbons.

Each media grade can have “SP” or “SLP” suffix that represents different release specification of Extractable Endotoxin.

The specification limits of above special 3M™ Zeta Plus™ Activated Carbon media series products are presented in Table 1. Certain modifications to Pressure Drop specifications may be made to non-standard Types of activated carbon media R00, R10, R30, R50, and R05 based on agreements with customers.

Table 1. Product Release Properties of Special 3M™ Zeta Plus™ Activated Carbon Series Filters					
Product Release Properties	Specifications – Std (SP) and Hi-Flow (SP and SLP)				
	R00 R01 R02 R03 R04 R05	R10 R11 R12 R13 R14 R15	R30 R31 R32 R33 R34 R35	R50 R51 R52 R53 R54 R55	Units
Pressure Drop at Air Flow	2.0 – 6.0	4.5 – 16.5	10.8 – 33.0	25.4 – 44.0	Inch H ₂ O
Wet Tensile Strength	≥ 1.0	≥ 1.0	≥ 2.5	≥ 4.0	Kg/in
Color Extraction	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	Color Units
Total Nitrogen	≤ 40	≤ 40	≤ 40	≤ 40	ppm
Endotoxin Extraction	≤ 0.5 (SP) ≤ 0.125 (SLP)	≤ 0.5 (SP) ≤ 0.125 (SLP)	≤ 0.5 (SP) ≤ 0.125 (SLP)	≤ 0.5 (SP) ≤ 0.125 (SLP)	EU/mL

B. Mass of Activated Carbon Raw Material in Special Media

A range of commercially available activated carbons are integrated into special 3M™ Zeta Plus™ Activated Carbon media series products.

Based on media formulation and specifications for these series, the average mass of activated carbon raw material in the media, inclusive of all grades, falls into this range.

Hi-Flow carbon media carbon mass: $0.073 \pm 0.004 \text{ g/cm}^2$

Non-standard carbon and “0” porosity rating media carbon mass: 0.101 ±0.013 g/cm²

This value does not account for any slight variation that may occur between the formulation and final media composition.

This value can be used to calculate the total amount of carbon contained in various product configurations, such as capsules or cartridges, based on their total effective surface area.

C. Special Filter Configurations

Table 1. 8” Cartridge Product Descriptions					
Product Description Examples: C08DDR55SP					
Diameter Designation	Cartridge Construction	Gasket Material		Grade ¹	Endotoxin Designation
C08	P - Plug-in 6 cells P2 - Plug-in 2 cells P4 - Plug-in 4 cells	A - Silicone (VMQ) B – Fluorocarbon (FPM) C – EPR (EPDM) D – Nitrile (NBR) FEP K – Teflon Encap. Viton		RX0 RX1 RX2 RX3 RX4 RX5	SP SLP
Diameter Designation	Cartridge Construction	Gasket Material	Binder Material	Grade ¹	Endotoxin Designation
C08	D - Standard 7 cells	A - Silicone (VMQ) B – Fluorocarbon (FPM) C – EPR (EPDM) D – Nitrile (NBR) E – Fluoropolymer (PTFE)	H ² - Hastelloy®	RX0 RX1 RX2 RX3 RX4 RX5	SP SLP

1. “X” should be “0” or “1” or “3” or “5” that represents different porosity rating from the most open to the tightest media grade
2. “H” for Hastelloy bands. Omit “H” for Stainless Steel Bands.

12” Diameter Cartridges

Table 2. 12” Cartridge Product Descriptions						
Product Description Examples: C12DDHR53SP						
Diameter Designation	Cartridge Construction	Gasket Material		Grade ¹	Endotoxin Designation	
C12	C – 9 cells	A - Silicone (VMQ) B – Fluorocarbon (FPM) C – EPR (EPDM) D – Nitrile (NBR) E – Fluoropolymer (PTFE)		RX1 RX2 RX3 RX4 RX5	SP SLP	
Diameter Designation	Cartridge Construction	Optional Handle	Gasket Material	Binder Material	Grade ¹	Endotoxin Designation
C12	D – 13 cells	H ²	A - Silicone (VMQ) B – Fluorocarbon (FPM) C – EPR (EPDM) D – Nitrile (NBR) E – Fluoropolymer (PTFE)	H ³ - Hastelloy®	RX1 RX2 RX3 RX4 RX5	SP SLP

- 1 “X” should be “0” or “1” or “3” or “5” that represents different porosity rating from the most open to the tightest media grade
- 2 “H” for handle, not available with Hastelloy band.
- 3 “H” Hastelloy bands are not available with handles.

16" Diameter Cartridges

Table 3. 16" Cartridge Product Descriptions						
Product Description Examples: C16MDR53SP, C16YHAR53SP						
Diameter Designation	Configuration	Optional Handle	Gasket Material	Binder Material	Grade ⁴	Endotoxin Designation
C16	M – 13 cell, netting R ¹ – 13 cell, netting	H	A – Silicone (VMQ) B – Fluorocarbon (FPM) C – EPR (EPDM) D – Nitrile (NBR) E – Fluoropolymer (PTFE)	H ³ - Hastelloy [®]	RX0 RX1 RX2 RX3 RX4 RX5	SP SLP
C16	Y ⁵ – 14 cell, netting	H ²	A – Silicone (VMQ) B – Fluorocarbon (FPM) C – EPR (EPDM) D – Nitrile (NBR) E – Fluoropolymer (PTFE)	H ³ - Hastelloy [®]	RX0 ⁶ RX1 ⁶ RX2 ⁶ RX3 ⁶ RX4 ⁶ RX5 ⁶	SP SLP

1 "R" for configurations with Hastelloy bands and no Handle at a different height specification from "M"

2 "H" for optional Handle for Stainless Steel Band configuration only.

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

4 "X" should be "1" or "3" or "5" that represents different porosity rating from the most open to the tightest media grade

5 "Y" for configuration with either Handle or Hastelloy bands options with Hi-Flow media grades.

6 High Flow Media Grades

Laboratory Capsules

Table 4. Laboratory Capsule Product Descriptions				
Manufacturing Facility	Product Description Example: BC0025SR35SP			
	Diameter Designation	Configuration	Grade ¹	Endotoxin Designation
France	BC0025	L - Luer S - Sanitary	RX0 RX1 RX2 RX3 RX4 RX5	SP

1 "X" should be "1" or "3" or "5" that represents different porosity rating from the most open to the tightest media grade

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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