Science.
Applied to Life.™

3M Separation and Purification Sciences Division

3M™ Zeta Plus™ Activated Carbon Series Filters

Regulatory Support File

Table of Contents

I. Regulatory Support Information

3M Separation and Purification Sciences Division is a leader in advanced filtration and purification solutions, offering a wide range of products and services for various stages of pharmaceutical and biologics manufacturing.

3M, a U.S. based multinational high technology company, has operations in more than 65 countries. Facilities that participate in the manufacturing of 3M™ Zeta Plus™ Activated Carbon Series products (collectively referred to as 3M™ Zeta Plus™ Activated Carbon Series herein) as shown below, have quality systems registered to quality system standards as noted below.

Mazeres, France
Registered to: ISO 9001

This Regulatory Support File provides information pertinent to the 3M™ Zeta Plus™ Activated Carbon Series filter products. Contained herein are detailed test methods, product specifications, product performance information and regulatory documentation related to pharmaceutical and biologics manufacturing processes. 3M supplied documentation can be used to support risk assessments and regulatory submissions, prepare standard operating procedures, and streamline testing requirements, all of which save time and cost for the manufacturer. The manufacturer of a pharmaceutical or biologic product is ultimately responsible for registration through regulatory authorities in each country or region where their product will be produced or used.

The U.S. Federal Food, Drug, and Cosmetics Act designated the United States Pharmacopeia (USP) and the National Formulary (NF) as official compendia for drugs marketed in the United States. USP-NF is a combination of two public compendia of pharmacopeia standards. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) brings together the regulatory authorities and pharmaceutical industry to discuss various aspects of drug registration and to achieve greater international harmonization. These standards form the primary basis for technical information provided in this product support document. 3M routinely completes a thorough review of the USP and ICH standards and this regulatory support file to ensure that the claims and data package are current.

Complementary product information, use and operating instructions and guidelines, and technical data can be found in the 3M™ Zeta Plus™ Activated Carbon Series filter product literature and product quality certifications. Further information can be obtained by contacting your local 3M representative.

The intended use(s), restrictions on use, and production selection and use for 3M™ Zeta Plus™ Activated Carbon Series products are stated below.

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.

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.

Product Selection and Use: Many factors beyond 3M's control and uniquely within user's knowledge and control can affect the use and performance of a 3M product in a particular application. As a result, end-user is solely responsible for evaluating the product and determining whether it is appropriate and suitable for end-user's application, including completing a risk assessment that considers the product leachable characteristics and its impact on drug safety, conducting a workplace hazard assessment and reviewing all applicable regulations and standards (e.g., OSHA, ANSI, etc.). Failure to properly evaluate, select, and use a 3M product and appropriate safety products, or to meet all applicable safety regulations, may result in injury, sickness, death, and/or harm to property.

II. Product Descriptions

3M™ Zeta Plus™ Activated Carbon Series filter products are a family of advanced depth filters designed for purification of various bioprocess, biological and pharmaceutical fluids.

3M™ Zeta Plus™ Activated Carbon Series filter media contains a mixture of powdered activated carbon, cellulose, and a crosslinking polymer binder resin.

The 3M™ Zeta Plus™ Activated Carbon Series filter media exhibits a combination of chemical specific adsorptive, mechanical and electrokinetic mechanisms for soluble and particulate contaminant reduction. A variety of powdered activated carbons with different raw material having various activation methods are used in 3M™ Zeta Plus™ Activated Carbon Series filters. The polymer binding resin used in this series of products is a polyamide epichlorohydrin (PAE) polymer that contains a balance of tertiary and quaternary amines, which imparts the anion exchange functionality of the media. The surface charge enhances the filtration effectiveness by attracting negatively charged contaminates too small to be removed by mechanical sieving. Note that the adsorptive and charge capacity of the media is a general attribute but not a controlled qualification or release specification. Therefore, formal process validation of the targeted contaminant removal must be fully assessed as part of the customer's rigorous risk management process.

A range of product configurations are available including converted media sheets, lenticular cartridges and single-use Laboratory and Scale-up capsules.

Note that special configurations for current customers may not be covered by this RSF. Contact 3M to determine if a specific 3M™ Zeta Plus™ Activated Carbon Series filter configuration not listed below is covered by an RSF Supplement.

8" Diameter Cartridges

Table 1. 8" Cartridge Product Descriptions

Product Description Examples: C08DER55SLP					
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) K – PTFE-Encapsulated Fluorocarbon		RX1 RX2 RX3 RX4 RX5	SLP
Diameter Designation	**Cartridge Construction**	**Gasket Material**	**Binder Material**	**Grade[1]**	**Endotoxin Designation**
C08	D - Standard 7 cells	A - Silicone (VMQ) B – Fluorocarbon (FPM) E – Fluoropolymer (PTFE)	H[2] - Hastelloy®	RX1 RX2 RX3 RX4 RX5	SLP

1. "X" should be "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: C12DEHR53SLP

Diameter Designation	Cartridge Construction	Gasket Material	Binder Material	Grade[1]	Optional Material
C12	C – 9 cells	A - Silicone (VMQ) B – Fluorocarbon (FPM) E – Fluoropolymer (PTFE)	H[3] - Hastelloy®	RX1 RX2 RX3 RX4 RX5	H[1] – Hastelloy® Bands

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) E – Fluoropolymer (PTFE)	H[3] - Hastelloy®	RX1 RX2 RX3 RX4 RX5	H[1] – Hastelloy® Bands

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 optional handle. Handle option is not available with Hasteloy Bands.

3 “H” for Hastelloy bands. Omit “H” for Stainless Steel Bands.

16” Cartridges

Table 3. 16” Cartridge Product Descriptions

Product Description Examples: C16MER53SLP

Diameter Designation	Configuration	Optional Handle	Gasket Material	Binder Material	Grade[4]	Endotoxin Designation
C16	M – 13 cell, netting R[1] – 13 cell, netting	H[2]	A – Silicone (VMQ) B – Fluorocarbon (FPM) E – Fluoropolymer (PTFE)	H[3] - Hastelloy®	RX1 RX2 RX3 RX4 RX5	SLP

1 “R” for configurations with Hastelloy band 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

Laboratory Capsules

Table 4. Laboratory Capsule Product Descriptions

Product Description Example: BC0025SR35SP

Diameter Designation	Configuration	Grade[1]	Endotoxin Designation
BC0025	L - Luer S - Sanitary	RX1 RX2 RX3 RX4 RX5	SLP

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

III. Product Design

All components used in the manufacture of 3M™ Zeta Plus™ Activated Carbon Series filter products are traceable. Intermediate products are packaged and labeled throughout the manufacturing process to provide complete traceability from the raw materials to media batch to finished product.

All grades of the 3M™ Zeta Plus™ Activated Carbon Series filter media are composed of the same materials of construction at varying ratios. Therefore, the test results reported herein are generally applicable to all grades and product configurations.

A. Media

3M™ Zeta Plus™ Activated Carbon Series filter media contains a mixture of powdered activated carbon, cellulose, and a crosslinking polymer binder resin. The polymer binding resin used in this series of products is a polyamide epichlorohydrin (PAE) polymer that contains a balance of tertiary and quaternary amines. The media is produced by a wetlaid process.

Media or filter sheets may be die cut to various shapes and dimensions per customer specifications. Converted filter sheets are generally used in commercially available filter presses. Each distinct pattern is assigned a unique stock number.

B. Cartridges

The lenticular cells of cartridges are comprised of single layers of the filter media and an inner cell separator with a polymeric molded edge seal. The lenticular cells are sealed to one another by ring seals that are aligned to the inner fluid effluent core and rest on the media under predetermined compression by three 316 stainless steel or Hastelloy® binder bands or, in the case of certain 8'' cartridges that are designated as Plug-in, by "push-fit" between a plug-in post and a connector. Netting is added to 16" cartridges. Each cartridge has two gaskets, one at the top and one at the bottom. Depending on the cartridge configuration, three standard gasket materials may be offered: silicone (VMQ), fluorocarbon (FPM) or fluoropolymer (PTFE).

Filter cartridges are available in 8", 12" and 16" nominal diameters, with surface areas ranging from 0.26 m^2 to 3.2m^2 per cartridge. The cartridge lenticles have an outside-to-in flow path. The flow passes through the filter media and is directed to a central exit flow path along the separators.

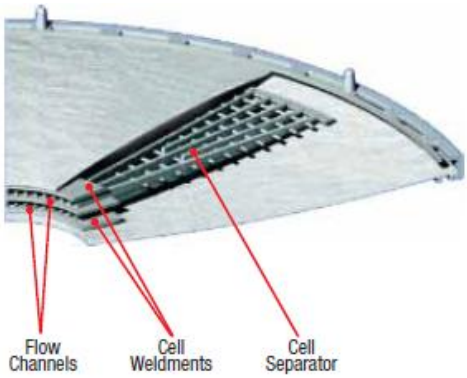


Figure 1a. 3M™ Zeta Plus™ Activated Carbon cartridge lenticle configuration with single media layer

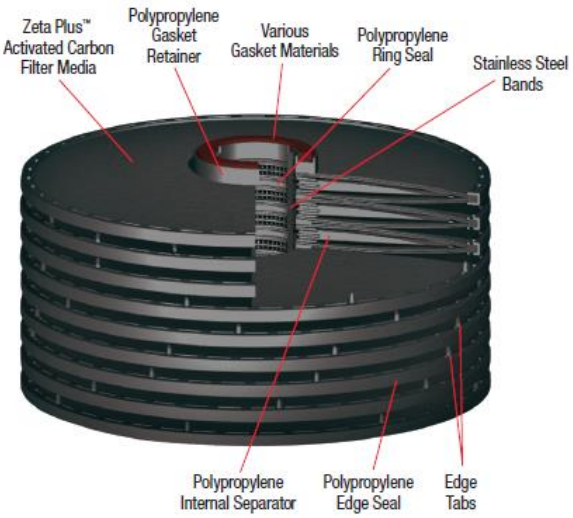


Figure 1b. 3M™ Zeta Plus™ Activated Carbon cartridge and components

Figure 1c. 3M™ Zeta Plus™ Activated Carbon cartridges shown with housings

Figure 1d. 3M™ Zeta Plus™ Activated Carbon 8” plug-in cartridge

Figure 1e. 3M™ Zeta Plus™ plug-in cartridge housing

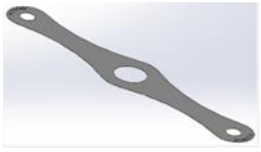


Figure 1f. Optional Film Lifting Handle for 16” cartridges

C. Capsules

The Laboratory capsule (BC0025) is constructed by compressing the single layer filter media between the inlet and outlet capsule components, then overmolding this entire unit with a glass fiber filled polypropylene. The Laboratory capsule is available with either luer lock or 1/2" mini sanitary matched inlet and outlet connections. The Laboratory capsule has a nominal surface area of 25 cm².

Figure 2. 3M™ Zeta Plus™ Activated Carbon capsules

Figure 3. Laboratory Capsules

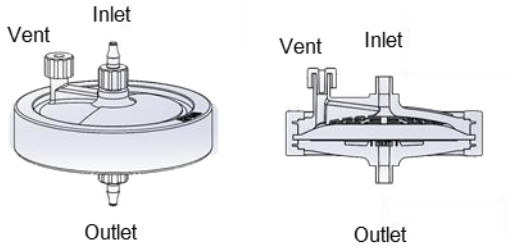


Figure 3a. BC0025 Capsule – Luer Style

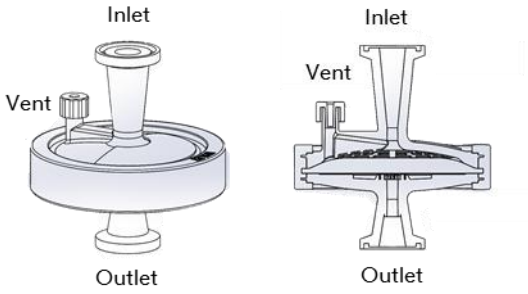


Figure 3b. BC0025 Capsule – Sanitary Style

D. Materials of Construction

Table 5. Materials of Construction – Filter Cartridges

Part Type	Materials
Filter Media	Activated Carbon, Cellulose, Polymer Resin
Separators	Polypropylene
Netting[1]	Polypropylene
Edge Seal	Polypropylene or Mineral-filled Polypropylene
Ring Seal	Polypropylene
Gasket Retainers	Polypropylene or Mineral-filled Polypropylene
Gaskets	Silicone, Fluorocarbon or PTFE
Optional Film Lifting Handle	Polypropylene
Binder Bands	316 Stainless Steel or Hastelloy®
8" Cartridge Plug-in Unitizing Post	Polypropylene

1 For 16" cartridges

Table 6. Materials of Construction – Laboratory Capsule	
Part Type	**Materials**
	BC0025
Nominal Surface Area	25 cm^2
Filter Media	Activated Carbon, Cellulose, Polymer Resin
Shells	Polypropylene
Edge Seal Overmold	Glass Fiber Filled Polypropylene
Edge Seal film	PTFE
Luer cap & luer-barb connector	Polypropylene

E. Wetted Surface Areas

The wetted surface areas of components in 3M™ Zeta Plus™ filter cartridges and capsules are listed in Tables 7-8. For O-rings, it is estimated that 50% of the surface area is wetted. Nominal media surface areas for capsules and cartridges are listed in Table 11.

Wetted surface area calculations are based on 3D models where all geometries are represented by a finely spaced discrete set of points; curves are approximated by linear interpolation between these points. A numerical quadrature algorithm is used to estimate the surface area and volume. The listed wetted surface areas represent the nominal values with tolerances allowed in component dimensions.

Table 7. Wetted Surface Areas of Cartridge Components			
Components	**Wetted Surface Area [cm^2]**		
	8" Cartridge	**12" Cartridge**	**16" Cartridge**
Separator (per lenticle)	415	1373	4361
Netting[1] (per lenticle)	-	5970	12900
Edge Seal (per lenticle)	174	312	426
Ring Seal (per lenticle)	23	12	22
Gasket Retainer (each)	46	57	57
Gasket (each)	28	37	37
Film Handle[2]	--	--	1245
Binder Bands	19	28	28
8" Plug-in Unitizing Post	397	--	--

1 16" cartridges

2 Specific 16" cartridges

Table 8. Wetted Surface Areas of Laboratory Capsule Components	
Components	**Wetted Surface Area [cm^2]**
	BC0025
Shell (Inlet – Luer)	41
Shell (Inlet – Sanitary)	48
Shell (Outlet - Luer)	54
Shell (Outlet – Sanitary)	58
Edge Seal	Non-wetted Surface

F. Mass of Activated Carbon Raw Material

A range of commercially available activated carbons are integrated into standard and special sub-families of the 3M™ Zeta Plus™ Activated Carbon Series products portfolio. The product configurations include media sheets, lenticular cartridges and single-use capsules.

Based on media formulation and specifications for all standard grades in this product family, the average mass of activated carbon raw material in the media, inclusive of all grades, falls into this range: 0.101 ±0.013 g/cm^2.

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.

IV. Product Specifications and Operation Parameters

A. Product 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) 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.
4) 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.
5) 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™ Activated Carbon media grade are presented in Table 9.

There is a total of 5 standard Types of powdered activated carbon incorporated in 3M™ Zeta Plus™ Activated Carbon media. For each Type of activated carbon, there are 3 porosity ratings of media – designated 1, 3 and 5 – from the most open to the tightest grade. The designation of R53SLP, for example, represents 3M™ Zeta Plus™ Activated Carbon media that has a porosity rating of 5, uses Type 3 activated carbon, and meets the SLP grade endotoxin specification.

Table 9. Product Release Properties of 3M™ Zeta Plus™ Activated Carbon Series Filters

Product Release Properties	Specifications			
	R11 R12 R13 R14 R15	R31 R32 R33 R34 R35	R51 R52 R53 R54 R55	Units
Pressure Drop at Air Flow	4.5 – 16.5	10.8 – 33.0	25.4 – 44.0	Inch H_2O
Wet Tensile Strength	≥ 1.0	≥ 2.5	≥ 4.0	Kg/in
Color Extraction	≤ 8.0	≤ 8.0	≤ 8.0	Color Units
Total Nitrogen	≤ 40	≤ 40	≤ 40	ppm
Endotoxin Extraction	≤ 0.125 (SLP)	≤ 0.125 (SLP)	≤ 0.125 (SLP)	EU/mL

B. Minimum Required Preconditioning Flush

3M™ Zeta Plus™ depth filters are comprised primarily of natural products and are considered fiber-releasing filters. Trace amounts of polymer resin, cellulosic fibers and natural extractables such as endotoxin, beta glucan, and inorganic ions, are released by these filters during use. Therefore, customers must flush the filters before exposure to their product. 3M™ Zeta Plus™ Activated Carbon Series products can be flushed with water or buffer at temperature and pressure not to exceed the maximum product specification. The required minimum preconditioning flush volume for all products is 54 L/m². Pressure drop across the filter should not exceed 2.4 bar [35 psid]. The maximum recommended flux for the required preconditioning flush is 1200 L/m²/hour (LMH) for cartridges. The maximum recommended flux for the required preconditioning flush is 210

LMH for capsules. If the filter is autoclaved or steam sterilized *in-situ* prior to use, the product must be flushed after sterilization using the required preconditioning flush.

Based on the required minimum preconditioning flush of 54 L/m² and the nominal surface area for each filter, flush volumes for each filter configuration are provided in Table 11.

The data package of effluent quality presented in this Regulatory Support File is developed based on the recommended flux of the required preconditioning flush for cartridges.

Table 10. Minimum Required Preconditioning Flush Volume and Recommended Flux		
Minimum Required Preconditioning Flush Volume	All Products	54 L/m²
Maximum Recommended Flux of Required Preconditioning Flush	Cartridges	1200 LMH
	Capsules	210 LMH

Table 11. Minimum Required Preconditioning Flush Volume & Nominal Surface Area		
Cartridge Configuration	**Nominal Surface Area**	**Minimum Required Preconditioning Flush Volume [L]**
C08P, 45167 (8" diameter cartridge, 6-cell plug-in)	0.19 m²	10
C08D, 45109 (8" diameter cartridge, 7-cell)	0.23 m²	12
C12C, 45158 (12" diameter cartridge, 9-cell)	0.9 m²	49
C12D, 45159 (12" diameter cartridge, 13-cell)	1.2 m²	65
C16M, C16R (16" diameter cartridge, 13-cell)	3.0 m²	162
C16Y (16" diameter cartridge, 14-cell)	3.2 m²	173
Capsule Configuration	**Nominal Surface Area**	**Minimum Required Preconditioning Flush Volume [L]**
BC0025 Laboratory Capsule	25 cm²	0.14

C. Operating Conditions

Table 12. Operating Conditions		
Maximum Operating Pressure	Laboratory Capsule	2.8 bar (40 psig) maximum inlet pressure
	Scale-Up Capsule	3.1 bar (45 psig)
Maximum Differential Pressure Forward	All Products	2.4 bar (35 psig)
Maximum Operating Temperature	Cartridge	80 °C (176 °F)
	Laboratory Capsules	40 °C (104 °F)
	Scale-up Capsule	60 °C (140 °F)
Minimum Required Preconditioning Flush Volume	All Products	See Section V. B.
Maximum Recommended Flux of Required Preconditioning Flush	Cartridges	
	Capsules	
Autoclave or *in-situ* Steam Sterilization	Cartridges	See Section V. D.
	Capsules	

D. Autoclave or *in-situ* Steam Sterilization

3M™ Zeta Plus™ Activated Carbon Series products are not bioburden controlled. They can be autoclaved or *in-situ* steam sterilized per recommended conditions listed in Table 13. If the filter is autoclaved or steam sterilized *in-situ* prior to use, it must be flushed after sterilization using the required preconditioning flush.

Table 13. Pre-Use Sterilization Conditions

Product Class	Autoclave / Steam-in-Place Parameters[1]
Cartridges	*in situ* steam sterilization, 30 minutes @ 126 °C (259 °F) maximum (3 cycles Max)
Laboratory Capsules	Autoclave only, 30 minutes @ 121 °C (250 °F) maximum (1 cycle)

1 Do not exceed maximum pressure and temperature ratings during sterilization.

V. Effluent Quality

Various regulatory organizations require that equipment used in pharmaceutical manufacturing that is in direct contact with the drug product should not add to or change the drug in any way other than what is intended by the manufacturer.

Distribution of Responsibility

3M Separation and Purification Sciences Division has adopted the following supplier collaborative model (D. Jenke, Pharma Ed Conference on Extractables & Leachables, keynote address Oct 2011) relative to Extractable and Leachable evaluation.

Shared Responsibility of Supplier and Producer

1. It is the responsibility of suppliers of plastic materials or systems to provide users with a full and complete composition of their material or system.

2. It is the responsibility of the producer to supply regulators with a full and complete leachables assessment for their finished therapeutic product.

3. It is the shared responsibility of the producer and supplier to collaborate on obtaining extractables information and in so doing increases the effectiveness and efficiency of extractables studies.

In this Regulatory Support File, 3M provides effluent quality data relating to the required preconditioning flush based on the requirements listed in Table 29. As of August 2020, the USP chapter <665> outlining guidance for extractables/leachables of polymers in pharmaceutical manufacturing is still in draft form. It is 3M's commitment to comply with all regulatory requirements, as well as provide data for our customers to make appropriate risk assessments. To this end, an Extractable Profile Report is available upon request that follows current USP draft guidance for reporting extractables/leachables.

Table 14. Reference Industry Standards

USP Standards	Applicable Methods
<643>	Total Organic Carbon
<645>	Water Conductivity
<791>	pH
<232>, <233>, ICH* Q3D	Elemental Impurities
<788>	Particulate Matter in Injections
<85>	Bacterial Endotoxin Test
<88>	Biological Reactivity

* ICH – International Conference for Harmonisation, Guideline for Elemental Impurities, Q3D

A. USP <643> Total Organic Carbon (TOC) and Total Nitrogen (TN)

The 90-mm discs of various 3M™ Zeta Plus™ Activated Carbon media were challenged with 18 Megohm water (25°C) at a constant flux of 1200 LMH to a total volume of two times the minimum required preconditioning flush volume of 54 L/m². Effluent samples were collected at 10%, 20%, 30%, 40%, and so on at 10% increments to 200% of the preconditioning flush volume. The effluent samples were then analyzed for TOC and TN. The TOC data at selected preconditioning flush volume percentages is shown in Table 15 and Figure 4. The TN data at selected preconditioning flush volume percentages is shown in Table 16 and Figure 5.

Table 15. Effluent TOC [ppm] vs. Preconditioning Flush Volume % of various 3M™ Zeta Plus™ Activated Carbon Media

	R11SLP			R32SLP			R53SLP			R54SLP			R55SLP		
Flush Vol %	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 6			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 8		
[%]	Average	Max	Min	Average	Max	Min	Average	Max	Min	Average	Max	Min	Average	Max	Min
10%	4.6	4.9	4.3	3.3	3.9	2.7	10.2	18.6	2.1	1.2	1.3	1.2	14.0	22.0	4.3
20%	2.2	2.3	2.0	2.0	2.3	1.6	5.9	11.3	1.9	0.8	0.9	0.7	6.7	10.4	2.9
30%	1.3	1.5	1.1	1.4	1.7	1.1	2.8	4.1	1.1	0.7	0.8	0.6	4.3	7.6	2.0
40%	1.1	1.2	1.0	1.1	1.3	0.9	2.2	3.0	1.1	0.5	0.6	0.5	3.2	6.7	1.7
50%	0.9	1.0	0.8	1.0	1.1	0.8	1.9	2.5	0.8	0.6	0.7	0.5	2.6	5.6	1.3
60%	0.8	0.9	0.7	0.9	1.0	0.7	1.8	2.5	0.7	0.6	0.7	0.4	2.1	4.7	1.3
100%	**0.6**	**0.7**	**0.5**	**0.6**	**0.7**	**0.5**	**1.3**	**1.7**	**0.7**	**0.4**	**0.5**	**0.4**	**1.3**	**2.2**	**1.0**
150%	0.4	0.5	0.4	0.5	0.5	0.4	1.1	1.6	0.8	0.4	0.5	0.4	1.1	2.0	0.8
200%	0.3	0.3	0.3	0.4	0.5	0.4	0.9	1.1	0.6	0.5	0.6	0.3	1.0	1.4	0.8

Figure 4. Average TOC vs. Flush Volume % of 3M™ Zeta Plus™ Activated Carbon Media R11SLP, R32SLP, R53SLP, R54SLP and R55SLP

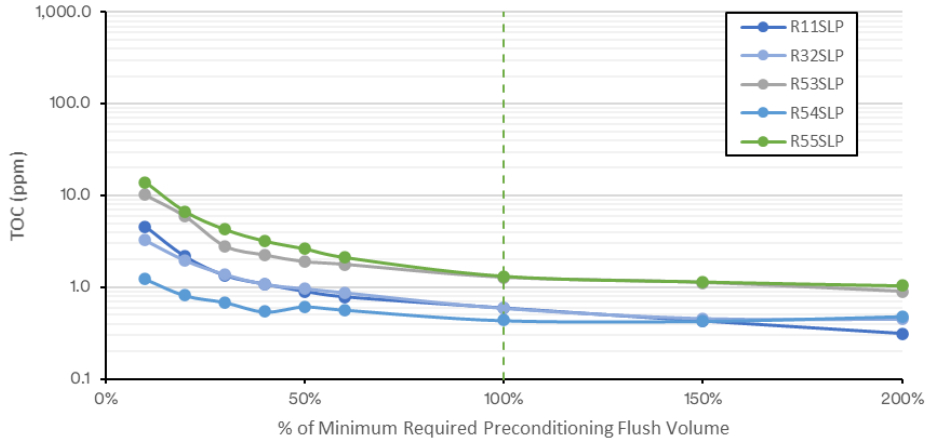
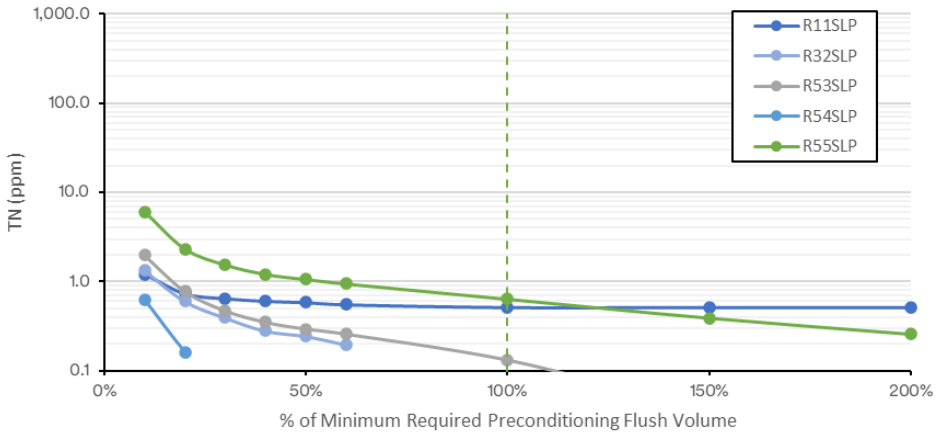


Table 16. Effluent TN [ppm] vs. Preconditioning Flush Volume % of various 3M™ Zeta Plus™ Activated Carbon Media															
	R11SLP			R32SLP			R53SLP			R54SLP			R55SLP		
Flush Volume	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 6			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 8		
[%]	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min
10%	1.2	1.3	1.1	1.3	1.6	1.0	2.0	5.6	0.7	0.6	0.6	0.6	6.1	9.4	3.8
20%	0.7	0.8	0.7	0.6	0.7	0.5	0.8	2.0	0.3	0.2	0.2	0.2	2.3	3.2	1.2
30%	0.6	0.7	0.6	0.4	0.5	0.3	0.5	1.2	0.2	0.1	0.1	0.0	1.5	2.1	0.8
40%	0.6	0.6	0.6	0.3	0.4	0.2	0.3	0.9	0.1	0.0	0.0	0.0	1.2	1.8	0.7
50%	0.6	0.6	0.6	0.2	0.3	0.2	0.3	0.7	0.1	0.0	0.0	0.0	1.1	1.6	0.6
60%	0.6	0.6	0.5	0.2	0.2	0.1	0.3	0.6	0.1	0.0	0.0	0.0	0.9	1.5	0.6
100%	**0.5**	**0.5**	**0.5**	**0.1**	**0.1**	**0.0**	**0.1**	**0.4**	**0.0**	**0.0**	**0.0**	**0.0**	**0.6**	**0.9**	**0.4**
150%	0.5	0.5	0.5	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.4	0.7	0.2
200%	0.5	0.5	0.5	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.3	0.5	0.1

Figure 5. Average TN vs. Flush Volume % of 3M™ Zeta Plus™ Activated Carbon Media R11SLP, R32SLP, R53SLP, R53SLP and R55SLP



Additional 90-mm discs of 3M™ Zeta Plus™ Activated Carbon media R53SLP were autoclaved using a pre-vac cycle at 126°C for 60 minutes prior to the preconditioning flush. The same preconditioning flush sampling and test procedures which were used for the non-autoclaved samples were followed for the autoclaved samples. The TOC data for autoclaved samples is shown in Table 17 and Figure 6. The TN data for autoclaved samples is shown in Table 18 and Figure 7.

Table 17. Effluent TOC [ppm] vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ Activated Carbon Media R53SLP – Post Autoclave			
	Single Layer Media		
	R53SLP		
Flush Volume	Number of Manufacturing Lots: 2		
[%]	Average	Max	Min
10%	3.8	4.0	3.7
20%	2.7	2.9	2.6
30%	2.2	2.5	2.0
40%	1.8	1.9	1.8
50%	1.7	1.8	1.7
60%	1.6	1.7	1.5
100%	**1.3**	**1.3**	**1.3**
150%	1.2	1.3	1.2
200%	1.2	1.2	1.1

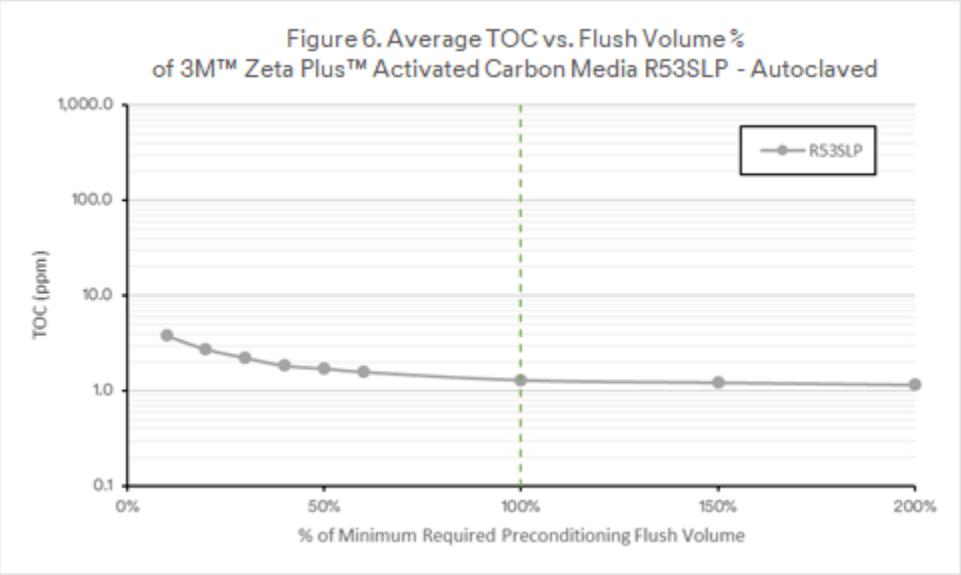
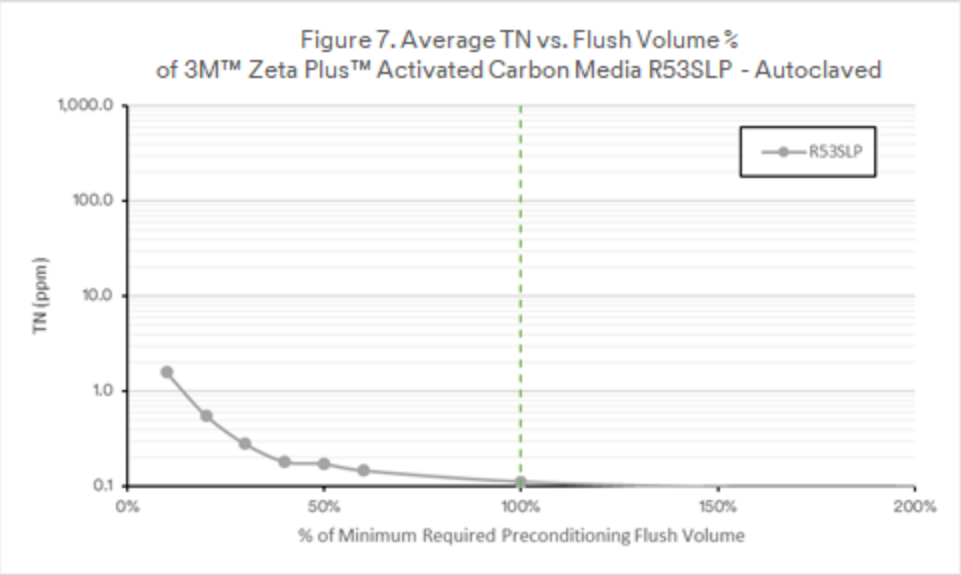


Table 18. Effluent TN [ppm] vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ Activated Carbon Media R53SLP – Post Autoclave			
	Single Layer Media		
	R53SLP		
Flush Volume	Number of Manufacturing Lots: 2		
[%]	Average	Max	Min
10%	1.6	1.7	1.5
20%	0.6	0.6	0.5
30%	0.3	0.3	0.3
40%	0.2	0.2	0.2
50%	0.2	0.2	0.2
60%	0.1	0.2	0.1
100%	**0.1**	**0.1**	**0.1**
150%	0.1	0.1	0.1
200%	0.1	0.1	0.1

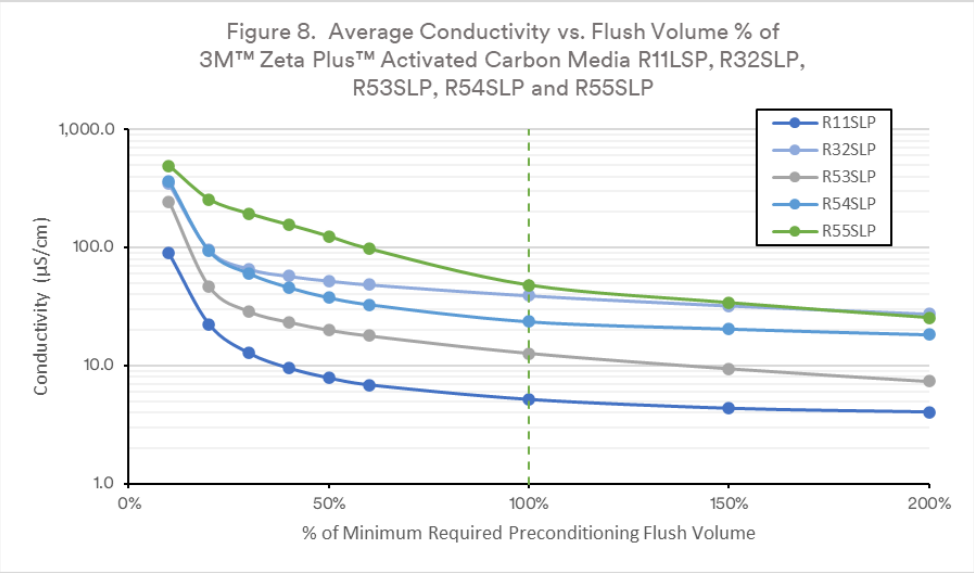


B. USP <645> Water Conductivity

The 90-mm discs of various 3M™ Zeta Plus™ Activated Carbon media were challenged with 18 Megohm water (25°C) at a constant flux of 1200 LMH to a total volume of two times the minimum required preconditioning flush volume of 54 L/m². Effluent samples were collected at 10%, 20%, 30%, 40%, and so on at 10% increments to 200% of the preconditioning flush volume. The effluent samples were then analyzed for conductivity. The conductivity at selected preconditioning flush volume percentages are shown in Table 19 and Figure 8.

Table 19. Effluent Conductivity [µS/cm] vs. Preconditioning Flush Volume % of various grades of 3M™ Zeta Plus™ Activated Carbon Media

	R11SLP			R32SLP			R53SLP			R54SLP			R55SLP		
Flush Volume	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 6			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 8		
[%]	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min
10%	89.6	90.9	88.2	349.1	356.3	341.9	245.6	494.0	107.4	365.1	372.5	357.7	491.0	922.3	361.1
20%	22.4	25.8	19.1	95.6	99.2	92.1	46.9	86.8	23.5	93.4	96.3	90.5	255.7	632.8	118.8
30%	12.7	14.2	11.2	65.9	69.7	62.0	28.7	50.3	14.9	60.1	62.8	57.4	192.9	441.9	76.1
40%	9.5	10.6	8.4	57.3	61.2	53.3	23.3	39.6	11.8	45.7	46.5	44.9	155.0	281.6	63.7
50%	7.8	8.6	7.1	52.2	56.9	47.6	20.0	32.9	10.9	37.6	38.2	36.9	124.0	181.7	63.0
60%	6.8	7.6	6.1	48.5	53.0	44.0	17.9	28.4	10.1	32.8	32.9	32.8	97.3	140.1	57.0
100%	**5.1**	**5.8**	**4.5**	**39.1**	**44.2**	**34.1**	**12.7**	**18.9**	**9.1**	**23.5**	**24.1**	**22.9**	**47.9**	**93.7**	**29.4**
150%	4.3	4.9	3.7	32.2	35.7	28.6	9.4	12.9	5.6	20.4	20.7	20.2	34.0	62.4	19.8
200%	4.0	4.9	3.1	27.3	29.5	25.1	7.3	9.6	3.9	18.3	18.7	17.9	25.4	41.6	14.6



C. USP <791> pH

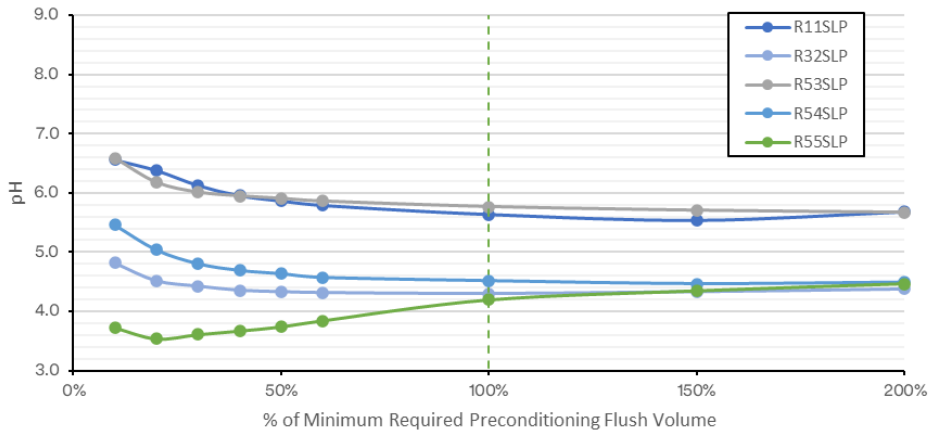
The 90-mm discs of various 3M™ Zeta Plus™ Activated Carbon media were challenged with 18 Megohm water (25°C) at a constant flux of 1200 LMH to a total volume of two times the minimum required preconditioning flush volume of 54 L/m². Effluent samples were collected at 10%, 20%, 30%, 40%, and so on at 10% increments to 200% of the preconditioning flush volume. The effluent samples were then measured for pH.

The effluent pH at selected preconditioning flush volume percentages, along with pH of DI water controls, are shown in Table 20 and Figure 9. Note that the DI water used as the flush solution is not buffered. Its low resistance to pH change due to small amount of acid or base is reflected in the extract pH difference shown here.

Table 20. Effluent pH vs. Preconditioning Flush Volume % of various 3M™ Zeta Plus™ Activated Carbon Media

	R11SLP			R32SLP			R53SLP			R54SLP			R55SLP		
Flush Volume	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 6			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 8		
[%]	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min
DI Water Control	5.2	5.3	5.2	5.6	5.9	5.2	5.6	5.9	5.1	5.2	5.3	5.4	5.5	5.9	5.1
10%	6.6	6.7	6.4	4.8	5.0	4.6	6.6	8.0	4.6	5.5	5.5	5.4	3.7	4.4	3.0
20%	6.4	6.5	6.3	4.5	4.7	4.4	6.2	7.6	4.9	5.0	5.1	5.0	3.5	4.2	3.0
30%	6.1	6.2	6.1	4.4	4.5	4.3	6.0	7.4	4.8	4.8	4.9	4.8	3.6	4.2	3.2
40%	6.0	6.0	5.9	4.4	4.5	4.3	5.9	7.4	4.7	4.7	4.7	4.7	3.7	4.3	3.3
50%	5.9	5.9	5.8	4.3	4.4	4.2	5.9	7.3	4.7	4.6	4.7	4.6	3.7	4.2	3.5
60%	5.8	5.8	5.8	4.3	4.4	4.2	5.9	7.2	4.7	4.6	4.6	4.6	3.8	4.2	3.7
100%	**5.6**	**5.7**	**5.5**	**4.3**	**4.4**	**4.2**	**5.8**	**7.1**	**4.7**	**4.5**	**4.5**	**4.5**	**4.2**	**4.5**	**3.9**
150%	5.5	5.7	5.4	4.3	4.4	4.3	5.7	6.9	4.8	4.5	4.5	4.5	4.3	4.6	4.1
200%	5.7	5.9	5.4	4.4	4.4	4.3	5.7	6.8	4.9	4.5	4.5	4.5	4.5	4.7	4.2

Figure 9. Average pH vs. Flush Volume % of 3M™ Zeta Plus™ Activated Carbon Media R11SLP, R32SLP, R53SLP, R54SLP, R55SLP



D. USP <232>/<233> and ICH Q3D Elemental Impurities

The 90-mm discs of 3M™ Zeta Plus™ Activated Carbon media R32SLP, R53SLP, and R55SLP were challenged with 18 Megohm DI water (25°C) at a constant flux of 1200 LMH to a total volume of two times the minimum required preconditioning flush volume of 54 L/m². Effluent samples were collected at 10%, 20%, 30%, 40%, and so on at 10% increments to 200% of the preconditioning flush volume. The 10%, 100% and 200% effluent samples were then analyzed for extractable elements.

Elemental profiles for effluent samples are shown in Table 21. The designation "<LOQ" indicates that the measured value is below the Limit of Quantification (LOQ). 3M™ Zeta Plus™ Activated Carbon Media contains natural products; naturally variability is anticipated, and the values below should be taken as representative.

Table 21. Flush Effluent Elemental Impurities for 3M™ Zeta Plus™ ActivatedCarbon Media R32SLP, R53SLP, R55SLP (ppb)											
ICH Class	Element	LOQ [ppb]	R32SLP*			R53SLP*			R55SLP*		
At % of Flush Volume			10%	**100%**	200%	10%	**100%**	200%	10%	**100%**	200%
1	**As**	0.01	14.03	**0.85**	0.29	6.36	**0.29**	0.08	0.57	**0.05**	0.02
	Cd	0.01	<LOQ	**<LOQ**	<LOQ	0.02	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Hg	0.2	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Pb	0.3	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	0.33	**<LOQ**	<LOQ
2A	**Co**	0.01	18.79	**1.84**	0.80	0.40	**0.05**	<LOQ	5.99	**<LOQ**	<LOQ
	Ni	1.8	452.2	**29.4**	13.5	5.8	**<LOQ**	<LOQ	16.9	**<LOQ**	<LOQ
	V	0.4	0.8	**0.1**	0.1	2.8	**0.4**	0.1	1.5	**0.12**	0.03
2B	**Ag**	0.02	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	0.02	**<LOQ**	<LOQ
	Au	0.071	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Ir	0.002	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Os	0.275	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Pd	0.017	0.31	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Pt	0.002	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Rh	0.001	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Ru	0.002	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Se	0.6	10.68	**0.98**	0.69	4.3	**0.15**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Tl	0.01	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
3	**Ba**	0.3	588.6	**405.0**	303.8	10.7	**0.8**	0.9	96.4	**2.9**	1.4
	Cr	0.6	20.1	**4.1**	1.4	4.2	**0.5**	0.2	3.6	**<LOQ**	<LOQ
	Cu	4	7	**11**	5	<LOQ	**0.5**	0.2	1	**<LOQ**	<LOQ
	Li	0.2	26.0	**<LOQ**	<LOQ	4.2	**<LOQ**	<LOQ	5.7	**<LOQ**	<LOQ
	Mo	0.01	<LOQ	**<LOQ**	<LOQ	6.92	**0.26**	0.07	<LOQ	**<LOQ**	<LOQ
	Sb	0.02	1.35	**0.13**	0.08	0.49	**0.03**	0.02	0.18	**0.03**	0.01
	Sn	0.2	<LOQ	**<LOQ**	<LOQ	0.07	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
Other Elements	**Al**	0.2	207.9	**58.7**	29.4	164.7	**45.1**	17.3	149.2	**10.2**	7.5
	B	0.6	540.7	**25.4**	11.3	25.5	**<LOQ**	<LOQ	74.3	**<LOQ**	<LOQ
	Ca	17	23371	**815**	301	5613	**321**	143	25720	**835**	208
	Fe	4	163	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	358	**<LOQ**	<LOQ
	K	65	976	**123**	59	1295	**59**	26	5059	**154**	21
	Mg	2	5868	**119**	36	2559	**123**	36	7360	**174**	45
	Mn	0.3	132.0	**4.7**	1.8	36.2	**2.3**	1.0	959.7	**38.7**	15.8
	Na	3	60184	**1120**	409	95716	**4108**	2098	73825	**1539**	694
	Si	10	1404	**129**	92	1512	**158**	91	534	**22**	7
	Sr	0.2	794.8	**39.5**	22.1	46.5	**2.0**	0.8	109.5	**2.9**	1.1
	W	0.01	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Zn	20	76.83	**120.43**	72.06	101	**108**	116	115	**74.04**	87.13
	Zr	0.01	<LOQ	**<LOQ**	<LOQ	2.72	**0.60**	<LOQ	<LOQ	**<LOQ**	<LOQ

*Contains Data from US, previous manufacturing facility, and Mazeres Media Lots

E. USP <788> Particulate Matter in Injections

90-mm discs of various 3M™ Zeta Plus™ Activated Carbon media were challenged with 18 Megohm water (25°C) at a constant flux of 1200 LMH to a total volume of two times the minimum required preconditioning flush volume of 54 L/m². Effluent samples were collected at 33%, 66%, 100% and 200% of the preconditioning flush volume. After the 200% extract sample was collected, the remaining extract was left to soak in the housing. After one hour, the static soak extract was then pushed through the filter and collected.

Additional 90-mm discs of 3M™ Zeta Plus™ activated carbon media R53SLP from a single plant were autoclaved using a pre-vac cycle at 121°C for 60 minutes prior to the preconditioning flush. The same preconditioning flush sampling and test procedures which were used for the non-autoclaved samples were followed for the autoclaved samples.

Samples were analyzed following USP <788> Method 1 (Light Obscuration Particle Count Test) for particulate release. Three to four aliquots of 5 mL each were measured from each sample, with particles counted and measured at the size ranges

specified in the USP chapter: particles greater than 10 µm but less than 25 µm; and particles > 25 µm. The solution meets the USP <788> requirement if it contains less than 25 particles/mL >10 µm and less than 3 particles/mL >25 µm.

The results of this analysis including results of control water samples are shown in Tables 22--24. The tests showed that minimum required preconditioning flush of the untreated and autoclaved 3M™ Zeta Plus™ Activated Carbon media reduced the particulate matter of effluent.

Table 22 – Particulate Matter of 3M™ Zeta Plus™ Activated Carbon Media R11SLP, R32SLP and R53SLP – No treatment

		R11SLP					R32SLP					R53SLP				
Particulate Size	18 Megohm Water (25°C)	Number of Manufacturing Lots: 2					Number of Manufacturing Lots: 4					Number of Manufacturing Lots: 4				
		Flush Volume				Static Soak	Flush Volume				Static Soak	Flush Volume				Static Soak
		33%	66%	100%	200%		33%	66%	100%	200%		33%	66%	100%	200%	
>10 µm	4.1	12.8	86.5	**6.7**	10.5	116.3	8.9	30.4	**35.4**	25.8	108.0	17.2	5.6	**9.2**	14.4	263.0
>25 µm	0.1	0.9	0.4	**0.5**	0.4	1.8	0.2	0.4	**0.5**	0.8	3.9	1.6	0.4	**0.3**	1.1	7.9

Table 23 – Particulate Matter of 3M™ Zeta Plus™ Activated Carbon Media R54SLP and R55SLP – No treatment

		R54SLP					R55SLP				
Particulate Size	18 Megohm Water (25°C)	Number of Manufacturing Lots: 2					Number of Manufacturing Lots: 4				
		Flush Volume				Static Soak	Flush Volume				Static Soak
		33%	66%	100%	200%		33%	66%	100%	200%	
>10 µm	4.1	14.4	11.9	**26.4**	50.2	421.4	21.5	9.8	**96.8**	78.7	512.8
>25 µm	0.1	0.6	0.4	**0.8**	1.2	9.9	0.6	0.3	**1.5**	1.3	11.9

Table 24 – Particulate Matter of 3M™ Zeta Plus™ Activated Carbon Media R53SLP – Post-Autoclave

	R53SLP					
	Number of Manufacturing Lots: 2					
Particulate Size	18 Megohm Water (25°C)	Flush Volume				Static Soak
		33%	66%	100%	200%	
>10 µm	4.1	3.8	1.0	**2.6**	11.9	66.7
>25 µm	0.1	0.5	0.1	**0.2**	0.4	1.6

F. USP <85> Bacterial Endotoxin Test

As part of the product release tests for every media lot, a 45-mm disc of 3M™ Zeta Plus™ Activated Carbon media produced is challenged with Sterile Water For Injection (SWFI) at a constant flux of 1200 LMH to a total volume equivalent to the minimum required preconditioning flush volume of 54 L/m^2. A 2 mL filtrate sample collected at the end of flush is analyzed per USP <85> for extractable endotoxin concentration by a *Limulus Amebocyte Lysate* (LAL) reactivity method. The extractable endotoxin release specification for SLP grades of 3M™ Zeta Plus™ Activated Carbon media is ≤0.125 EU/mL. Therefore, the 3M™ Zeta Plus™ Activated Carbon media flush effluent as prepared per above conditions meets the bacterial endotoxin limits for WFI of <0.25 EU/mL.

Note the release specification is based on a dynamic flush protocol that does not necessarily reflect the total endotoxin amount in the media. Therefore, the extractable endotoxin amount may be impacted if using a different challenge fluid under different test conditions (*i.e.*, pH, conductivity, protein, *etc.*).

Cellulose is a raw material used in 3M™ Zeta Plus™ media. Cellulose may contain β-Glucan, which is a non-endotoxin LAL-reactive material. The presence of β-Glucan in any 3M™ Zeta Plus™ media flush effluent may cause an interference or enhancement of endotoxin measurement. Thus, a β-Glucan blocking buffer or LAL reagent may be used to minimize interference in the product release test. USP <85> "Bacterial Endotoxins Tests" supports these strategies during extractable endotoxin measurement in the presence of β-Glucan.

VI. Shelf Life

Shelf Life of 3M™ Zeta Plus™ Activated Carbon Series Converted Media Sheets, Cartridges, and Capsules:
3 years at a recommended storage temperature of 5°C - 30°C, stored in original package

All 3M™ Zeta Plus™ Activated Carbon products should be stored in a controlled environment with an average temperature between 5°C and 30°C with short term excursions to 50°C, and relative humidity less than 90%. All 3M™ Zeta Plus™ Activated Carbon products should be inspected before use to determine if any unanticipated damage has occurred during shipping and storage. This includes an inspection of the O-rings to confirm that they have no nicks or cuts, are not cracked or do not exhibit a loss of elasticity that would prevent a normal sealing operation.

VII. Regulatory Compliance

A. USP <88> Class VI - 70°$C_{minimum}$ Biological Reactivity Tests, *In Vivo*

Representative media grade samples and wetted components or wetted component materials of 3M™ Zeta Plus™ Activated Carbon Series products were tested and met the requirements of USP <88> Class VI, Biological Reactivity Tests, *In Vivo* at either 121˚C or 70˚C extraction temperature.

B. BSE/TSE (animal derived materials)

3M understands the continued public interest and the increased regulatory scrutiny concerning the transmission of bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSE).

In order to address these issues, the following statement is offered: In order to assess the BSE/TSE risk associated with the above products, we have contacted our suppliers of raw materials and performed an evaluation of our production processes to determine if any of the materials used are of animal origin. The result of our survey and inquiries of our raw material suppliers has revealed that the resins used in the molded parts and over-molds may contain tallow derivatives and certain elastomer gaskets could contain a stearic acid that is used as an activator in the vulcanization process. We can state, however, that our suppliers have indicated that these parts which use tallow derivatives and stearic acid are processed at conditions conforming to the requirements of the European Medicines Agency note for guidance EMEA/410/01 rev.3.

VIII. Quality Assurance

Pharmaceutical and Biological products manufacturers routinely visit 3M manufacturing sites to audit production quality management systems and documentation. The ISO certifications for 3M Separation and Purification Sciences Division global plants are available on request.

Certificates are provided in support of the release of the 3M™ Zeta Plus™ Activated Carbon Series filter products.

The 3M™ Zeta Plus™ Activated Carbon Series filter products are defined as non-hazardous articles under REACH and do not require a Safety Data Sheet under Article 31 of Regulation (EC) No. 1907/2006.

The 3M™ Zeta Plus™ Activated Carbon Series filter products are not regulated under the OSHA Hazard Communication Standard (CFR Title 29 1910.1200). A Safety Data Sheet (SDS) is not required for these products.

Article Information Sheets for 3M™ Zeta Plus™ Activated Carbon Series filter products are available in the US as courtesy.

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.

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.

Technical Information: The technical information, guidance, and other statements contained in this document or otherwise provided by 3M are based upon records, tests, or experience that 3M believes to be reliable, but the accuracy, completeness, and representative nature of such information is not guaranteed. Such information is intended for people with knowledge and technical skills sufficient to assess and apply their own informed judgment to the information. No license under any 3M or third party intellectual property rights is granted or implied with this information.

Product Selection and Use: Many factors beyond 3M's control and uniquely within user's knowledge and control can affect the use and performance of a 3M product in a particular application. As a result, end-user is solely responsible for evaluating the product and determining whether it is appropriate and suitable for end-user's application, including completing a risk assessment that considers the product leachable characteristics and its impact on drug safety, conducting a workplace hazard assessment and reviewing all applicable regulations and standards (e.g., OSHA, ANSI, etc.). Failure to properly evaluate,select, and use a 3M product and appropriate safety products, or to meet all applicable safety regulations, may result in injury, sickness, death, and/or harm to property.

Warranty, Limited Remedy, and Disclaimer: Unless a different warranty is expressly identified on the applicable 3M product literature or packaging (in which case such express warranty governs), 3M warrants that each 3M product meets the applicable 3M product specification at the time 3M ships the product. 3M MAKES NO OTHER WARRANTIES OR CONDITIONS, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ARISING OUT OF A COURSE OF DEALING, CUSTOM, OR USAGE OF TRADE. If a 3M product does not conform to this warranty, then the sole and exclusive remedy is, at 3M's option, replacement of the 3M product or refund of the purchase price.

Limitation of Liability: Except for the limited remedy stated above, and except to the extent prohibited by law, 3M will not be liable for any loss or damage arising from or related to the 3M product, whether direct, indirect, special, incidental, or consequential (including, but not limited to, lost profits or business opportunity), regardless of the legal or equitable theory asserted, including, but not limited to, warranty, contract, negligence, or strict liability.

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

70020188309 REV 0222