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3M Separation and Purification Sciences Division

3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media

Regulatory Support File

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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™ Filters with 01AP Grade and CP Series Media, as shown below, have quality systems registered to ISO 9001:2015.

Stafford Springs, CT, USA	**Mazeres, France**	**Blacktown, Australia**
Registered	Registered	Registered

This Regulatory Support File provides information pertinent to the 3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media. 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™ Filters with 01AP Grade and CP Series Media 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™ Filters with 01AP Grade and CP Series Media are stated below.

Intended Use(s): 3M™ Zeta Plus™ Filters with 01AP Grade and CP 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.

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. 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. Drug Master File Reference

3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media are listed in a Drug Master File (DMF) registered with the United States Food and Drug Administration (FDA).

The information contained in the DMF may be utilized by regulatory reviewers to support a New Drug Application (NDA), Investigational New Drug Application (INDA), Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or supplements to any of these.

Permission by 3M for review of a DMF is granted only to appropriate United States Food and Drug Administration (FDA) or similar regulatory agency personnel as the document contains 3M proprietary information. Following the FDA Code of Federal Regulations (CFR) Title 21 Section 314.420, before FDA may review the DMF in support of an application, 3M Purification Inc. must provide a letter of authorization permitting FDA to reference the DMF. The applicant is required to include a copy of the letter of authorization in their application. Contact 3M Separation and Purification Sciences Division to initiate a review of the DMF. 3M will update this Regulatory Support File as a routine aspect of product maintenance.

III. Product Descriptions

3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media are a family of advanced depth filters designed for optimal clarification of various bioprocess, biological and pharmaceutical fluids. 3M™ Zeta Plus™ 01AP Grade Filter Media contains a mixture of cellulose and a melamine formaldehyde crosslinking binder resin and 3M™ Zeta Plus™ CP Series Filter Media contain a mixture of inorganic filter aids, cellulose and a melamine formaldehyde crosslinking binder resin. They offer a combination of mechanical and electrokinetic particulate removal mechanisms with an intermediate charge level relative to other 3M™ Zeta Plus™ Filter Media offerings.

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

3M has global manufacturing and supply chain capabilities. The products described below may be produced at multiple global locations. 3M assigns a unique ID number to each product specific to its country of origin and will ensure lot traceability to each manufacturing facility.

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. 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: 4510922 60CP, 4516701 50CP, Z08DA01CP			
United States	**Diameter Designation**		**Gasket Material**	**Grade**
	45109 - 8 cell		22 – Silicone (VMQ)	10CP 30CP 50CP 60CP 70CP
	45167 - 7 cell Plug-in		01 – Nitrile (NBR) 04 – Silicone (VMQ)	
France	**Diameter Designation**	**Number of Cells**	**Gasket Material**	**Grade**
	Z08	D – 9 cell	A – Silicone (VMQ) D – Nitrile (NBR)	01CP

3M™ Zeta Plus™ 12-Inch Filter Cartridges

Table 2. 3M™ Zeta Plus™ 12-Inch Filter Cartridge Product Descriptions: Single Layer Media				
Manufacturing Facility	**Product Description Examples: 4511301 01AP, 4511517 10CP, 4524501A50CP**			
United States	**Diameter Designation**	**O-Ring Material**		**Grade**
	45113 – 18 cell	01 – Nitrile (NBR) 11 – Silicone (VMQ)		01AP
	Diameter Designation	**O-Ring Material**		**Grade**
	45115 – 16 cell 45116 – 9 cell	14 - Fluorocarbon (FPM) 17 – Silicone (VMQ)		10CP 30CP 50CP 60CP 70CP
	Diameter Designation	**Material**	**O-Ring Material**	**Grade**
	45245 – 16 cell	01 - Polypropylene (PP)	A – Silicone (VMQ) B – Fluorocarbon (FPM)	50CP

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: Z16PA70CP**			
United States	**Diameter Designation**	**Configuration**	**Gasket Material**	**Grade**
	Z16	P - 14 cell H - 16 cell	A – Silicone (VMQ)	01AP 30CP 50CP
France	**Diameter Designation**	**Configuration**	**Gasket Material**	**Grade**
	Z16	M – 14 cell, FR height P - 14 cell, US height D - 15 cell S - 9 cell	A – Silicone (VMQ) D – Nitrile (NBR)	01CP 10CP 30CP 50CP 70CP

3M™ Zeta Plus™ BC Series Filter Capsules (Laboratory Capsules)

Table 4. 3M™ Zeta Plus™ BC Series Filter Capsule (Laboratory Capsule) Product Descriptions: Single Layer Media			
Manufacturing Facility	**Product Description Example: BC0025L70CP**		
United States	**Diameter Designation**	**Configuration**	**Grade**
	BC0025	L - Luer S - Sanitary	01AP 10CP 30CP 50CP 60CP 70CP

IV. Product Design

All components used in the manufacture of 3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media 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™ 01AP Grade and CP 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.

3M™ Zeta Plus™ Filters with CP Series Media are produced in the United States, France and Australia and 3M™ Zeta Plus™ Filters with 01AP Grade Media are produced in the United States and Australia. Raw materials are purchased consistent with global specifications.

A. Media

3M™ Zeta Plus™ 01AP Grade Filter Media contains a mixture of cellulose and a melamine formaldehyde crosslinking binder resin and 3M™ Zeta Plus™ CP Series Filter Media contain a mixture of inorganic filter aids, cellulose and a melamine formaldehyde crosslinking binder resin. They offer a combination of mechanical and electrokinetic particulate removal mechanisms with an intermediate charge level relative to other 3M™ Zeta Plus™ Filter Media offerings. 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 3M™ Zeta Plus™ 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 binder bands. Netting is added to selected model numbers to maintain flow path between lenticles. Each cartridge has two gaskets one at the top and one at the bottom. Depending on the cartridge configuration, three gasket materials may be offered: silicone (VMQ) fluorocarbon (FPM) or nitrile (NBR).

Filter cartridges are available in 8-inch, 12-inch and 16-inch nominal diameters, with surface areas ranging from 0.26 m^2 to 3.9 m^2 per cartridge. The cartridge lenticles have an outside-to-in flow path. The flow passes through the 3M™ Zeta Plus™ Filter Media and is directed to a central exit flow path along the separators.

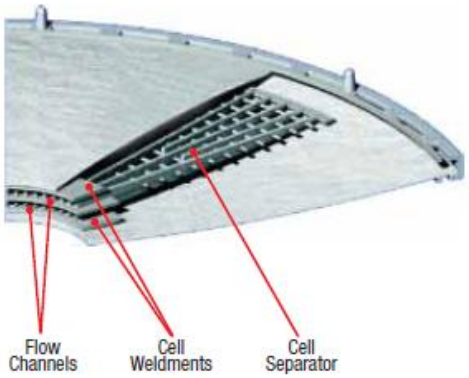


Figure 1a. 3M™ Zeta Plus™ Filter Cartridge lenticle configuration with single media layer

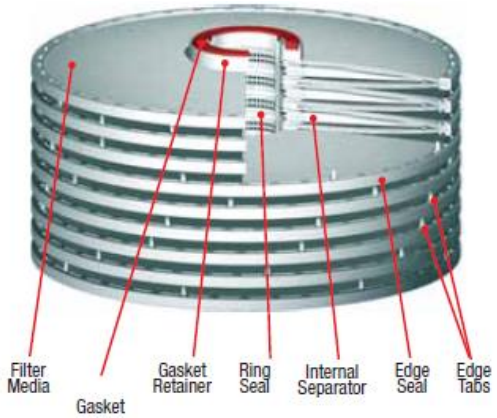


Figure 1b. 3M™ Zeta Plus™ Filter Cartridge and components

Figure 1c. 3M™ Zeta Plus™ Filter Cartridges shown with housings

Figure 1d. 3M™ Zeta Plus™ 8-Inch Plug-In Filter Cartridge

Figure 1e. 3M™ Zeta Plus™ Plug-In Filter Cartridge Housing

C. Capsules

There is one capsule category for 3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media: 3M™ Zeta Plus™ BC Series Filter Capsules (Laboratory 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 ½-inch mini sanitary matched inlet and outlet connections. The Laboratory capsule has a nominal surface area of 25 cm².

Figure 2. 3M™ Zeta Plus™ BC Series Filter Capsules (Laboratory Capsules)

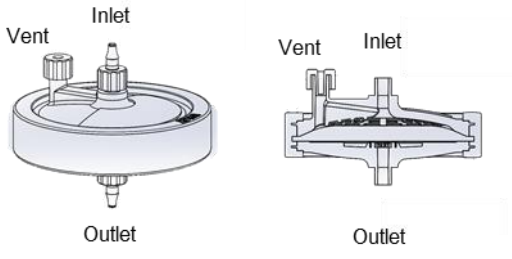


Figure 2a. 3M™ Zeta Plus™ BC Series Filter Capsule (BC0025 Laboratory Capsule) – Luer Style

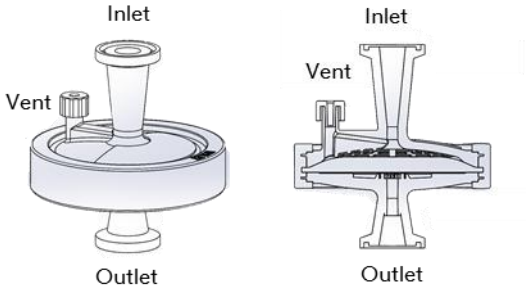


Figure 2b. 3M™ Zeta Plus™ BC Series Filter Capsule (BC0025 Laboratory Capsule) – Sanitary Style

D. Materials of Construction

Table 5. Materials of Construction – 3M™ Zeta Plus™ Filter Cartridges	
Part Type	**Materials**
3M™ Zeta Plus™ 01AP Grade Filter Media	Cellulose, Binding Resin
3M™ Zeta Plus™ CP Series Filter Media	Natural Filter Aids, Cellulose, Binding Resin
Retainers and separators	Polypropylene or Mineral-filled Polypropylene
Netting[1]	Polypropylene
Edge Seal	Polypropylene or Mineral-filled Polypropylene
Ring Seal	Polypropylene
Binder bands	316 stainless steel or Hastelloy®
Gaskets or O-rings	Silicone, Fluorocarbon or Nitrile
8" Plug-in Unitizing Post	Polypropylene

1 Specific 12-inch and 16-inch cartridges

Table 6. Materials of Construction – 3M™ Zeta Plus™ BC Series Filter Capsule (Laboratory Capsule)	
Part Type	**Materials**
	BC0025
Nominal Surface Area	25 cm^2
3M™ Zeta Plus™ 01AP Grade Filter Media	Cellulose, Binding Resin
3M™ Zeta Plus™ CP Series Filter Media	Natural Filter Aids, Cellulose, Binding Resin
Shells	Polypropylene
Edge Seal Overmold	Glass Fiber Filled Polypropylene
Luer cap & luer-barb connector	Polypropylene

E. Capsule Design Characteristics

Weights and Volumes shown in Table 7 below were experimentally determined from samples of various representative grades and families of 3M™ Zeta Plus™ Filter Media. **Please note that these values are presented for guidance only and are not specifications**; actual amounts depend upon individual capsule variability, exact blow-down conditions, media type in capsule, the number of capsules in the system, the process fluid, and loading level of the capsule.

1) Dry Weight – Weight of capsule prior to use.

2) Wet, Post Blow-down Weight - Liquid retained in the system, as measured by the differential between the capsule dry weight and the capsule weight after blow-down. This predominantly reflects the liquid left in the Filter Media. Actual amount depends upon exact blow-down conditions, media type in capsule, the number of capsules in the system, the process fluid, and loading level of the capsule.

3) Capsule Fill Volume - Amount of liquid necessary to fill the capsule from inlet to outlet, including media, calculated using the filled capsule weight and flush fluid density.

4) Post Blow-down Hold-Up Volume - Estimated volume of residual preconditioning flush liquid after air/gas blow-down using water as the flush fluid and calculated by post-blow-down weight and flush fluid density. Actual amount depends upon exact blow-down conditions, media type in capsule, the number of capsules in the system, the process fluid, and loading level of the capsule.

Table 7. Capsule Design Characteristics – Laboratory Capsules		
Product Name	**BC25, Luer**	**BC25, Sanitary**
Nominal Surface Area	25 cm²	25 cm²
Inlet/Outlet	Luer	½" - ¾" Sanitary Style
Nominal Dimensions		
Single Layer (height by diameter)	6.5 cm x 7.6 cm (2.6 inches x 3 inches)	7.9 cm x 7.6 cm (3.1 inches x 3 inches)
Weight		
Dry – Single Layer	≈ 60 g	≈ 64 g
Wet, post blow-down[1] – Single Layer	≈ 70 g	≈ 75 g
Volume		
Capsule Fill Volume[2] – Single Layer	≈ 17 mL	
Post blow-down Hold-Up Volume[3] – Single Layer	≈ 11 mL	

1 Post blow-down wet weight is defined as the experimentally measured weight of the capsule after air/gas blow-down using water as the flush fluid. Actual amount depends upon exact blow-down conditions, media type in capsule, the number of capsules in the system, the process fluid, and loading level of the capsule.

2 Capsule Fill Volume is defined as the volume of liquid required to fill the capsule (experimentally measured).

3 Post blow-down hold-up volume is defined as the estimated volume of the residual flush liquid after air/gas blow-down using water as the flush fluid and calculated by post-blow-down weight and flush fluid density. Actual amount depends upon exact blow-down conditions, media type in capsule, the number of capsules in the system, the process fluid, and loading level of the capsule.

F. Wetted Surface Areas

The wetted surface areas of components in 3M™ Zeta Plus™ Filter Cartridges and 3M™ Zeta Plus™ BC Series Filter Capsules are listed in Tables 8-9. 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 13.

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 8. Wetted Surface Areas of 3M™ Zeta Plus™ Filter Cartridge Components			
Components	**Wetted Surface Area [cm²]**		
	8-inch Cartridge	**12-inch Cartridge**	**16-inch 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
Molded Lifting Handle[2] on Gasket Retainer	-	181	-
Gasket (each)	28	37	37
Film Handle[3]	-	-	1245
Binder Bands	19	28	28

1 Specific 12-inch and 16-inch cartridges

2 Specific 12-inch cartridges

3 Specific 16-inch cartridges

Table 9. Wetted Surface Areas of 3M™ Zeta Plus™ BC Series Filter Capsule (Laboratory Capsule) Components	
Components	**Wetted Surface Area [cm²]**
	BC0025
Shell (Inlet – Luer)	41
Shell (Inlet – Sanitary)	48
Shell (Outlet - Luer)	54
Shell (Outlet – Sanitary)	58
Edge Seal	Non-wetted Surface

V. 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 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 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 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) 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.
6) Organic 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. The effluent sample is then filtered and 1 mL of filtered effluent sample is added to a cuvette with 49 mL of DI water. The final sample is analyzed for absorbance at 210 nm.
7) 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 specification limits for these test methods for the 3M™ Zeta Plus™ 01AP and 3M™ Zeta Plus™ CP Series Filter Media grades are presented in Table 10 for US and Australia manufactured media and Table 11 for France manufactured media.

Table 10. US and Australia Made Media Release Properties for 3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media

Product Release Properties	Specifications						
	01AP*	10CP	30CP	50CP	60CP	70CP	Units
Pressure Drop at Air Flow	≤ 2.0	8.5 – 13.0	15.0 – 26.0	50.0 – 68.0	80.0 – 104.0	148.0 – 202.0	Inch H_2O
Wet Tensile Strength	US: ≥ 1.5 AU: ≥ 2.0	≥ 4.0	≥ 4.5	≥ 5.5	≥ 6.0	≥ 7.0	Kg/in
Ca Extraction	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Fe Extraction	≤ 0.010	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Color Extraction	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	Color Units
Organic Extraction	≤ 0.37	≤ 0.37	≤ 0.37	≤ 0.37	≤ 0.37	≤ 0.37	Absorbance
Endotoxin Extraction	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	EU/mL

*Note: 01AP is only manufactured in US and AU

Table 11. France Made Media Release Properties for 3M™ Zeta Plus™ CP Series Filter Media							
Product Release Properties	**Specifications**						
	01CP	**10CP**	**30CP**	**50CP**	**60CP**	**70CP**	**Units**
Pressure Drop at Air Flow	0.4 – 1.1	5.4 – 10.5	13.5 - 33.0	45.0 - 68.0	68.0 – 112.0	112.5 – 220.0	Inch H_2O
Wet Tensile Strength	≥ 1.0	≥ 3.0	≥ 3.0	≥ 4.0	≥ 4.5	≥ 5.0	Kg/in
Ca Extraction	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Fe Extraction	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Color Extraction	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	Color Units
Organic Extraction	≤ 0.37	≤ 0.37	≤ 0.37	≤ 0.37	≤ 0.37	≤ 0.37	Absorbance
Endotoxin Extraction	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	EU/mL

B. Installation and Operation Instructions

The installation and operation of the 3M™ Zeta Plus™ 01AP Grade and CP Series Filter Products should follow the appropriate use instruction for each filter configuration. Always operate within the specified pressure and temperature limits.

Note: Installation and Operation Instructions are available upon request from your local representative.

Prior to filtration operation, end-users should verify that the housing for filter cartridges is integral and filter cartridges or capsules have been properly installed and sealed. Therefore, a pre-use Installation Qualification test (IQ) should be performed per recommended test procedure contained in 3M's Installation and Operating Procedures manuals (70-0201-8802-8 for cartridges, 70-0202-6945-5 for capsules).

C. Minimum Recommended Preconditioning Flush

3M™ Zeta Plus™ Filters with 01AP Grade or CP Series Media 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, 3M recommends that customers flush the filters before exposure to their product. 3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media can be flushed with water or buffer at temperature and pressure not to exceed the maximum product specification. The 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 preconditioning flush is 1200 L/m²/hour (LMH) for cartridges. The maximum recommended flux for the preconditioning flush is 210 LMH for capsules.

Detailed preconditioning flush protocols are provided in 3M Installation and Operating Instructions (see Section V.B.). Based on the 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 13.

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

Table 12. Minimum Preconditioning Flush Volume and Recommended Flux		
Minimum Preconditioning Flush Volume	All Products	54 L/m²
Maximum Recommended Flux of Preconditioning Flush	Cartridges	1200 LMH
	Capsules	210 LMH

Table 13. Minimum Preconditioning Flush Volume & Nominal Surface Area		
Cartridge Configuration	**Nominal Surface Area**	**Minimum Preconditioning Flush Volume [L]**
45109 & Z08 (8-inch diameter cartridge, 8-cell)	0.26 m^2	14
45167 (8-inch diameter cartridge, 7-cell O-ring plug-in)	0.23 m^2	12
Z8FA2NPX2 (8-inch diameter, 2-cell plug-in)	0.065 m^2	3.5
Z8FA4NPX2 (8-inch diameter, 4-cell plug-in)	0.13 m^2	7.0
45116 (12-inch diameter cartridge, 9-cell)	0.9 m^2	46
45115 & 45245 (12-inch diameter cartridge, 16-cell)	1.5 m^2	81
45113 (12-inch diameter cartridge, 18-cell)	1.8 m^2	92
Z16S (16-inch diameter cartridge, 9-cell)[1]	2.1 m^2	113
Z16P and Z16M (16-inch diameter cartridge, 14-cell)[1]	3.2 m^2	173
Z16D (16-inch diameter cartridge, 15-cell)	3.5 m^2	188
Z16H (16-inch diameter cartridge, 16-cell) 30CP & 50CP only[1]	3.7 m^2	200
Capsule Configuration	**Nominal Surface Area**	**Minimum Preconditioning Flush Volume [L]**
BC0025 Laboratory Capsule	25 cm^2	0.14

1 Wet weight (65 lb/ 29 kg) may require lifting assistance.

D. Operating Conditions

Table 14. Operating Conditions		
Maximum Operating Pressure	Laboratory Capsule	2.8 bar (40 psig) maximum inlet pressure
	Production Capsules	3.4 bar @40 °C (50 psig @104 °F)
Maximum Differential Pressure Forward	All Products	2.4 bar (35 psig)
Maximum Operating Temperature	Cartridge	82 °C (180 °F)
	Capsules	40 °C (104 °F)
Minimum Preconditioning Flush Volume	All Products	See Section V. C.
Recommended Flux of Preconditioning Flush	Cartridges	
	Capsules	

E. Pre-Use Sterilization

3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media are not intended for use with steam or autoclave sterilization.

VI. Performance Verification

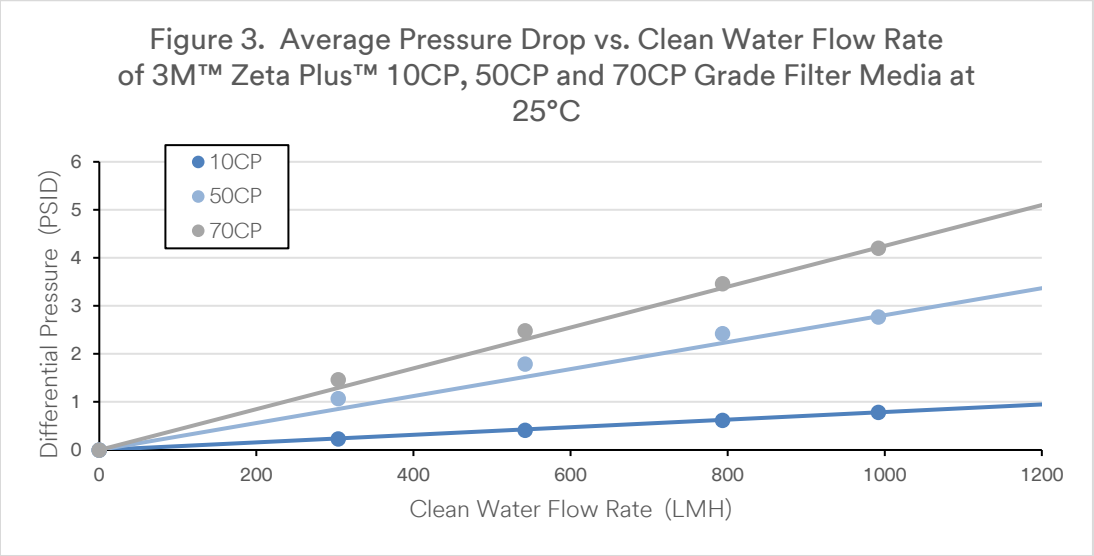
A. Media Pressure Drop vs. Water Flow Rate

The 90-mm discs of 3M™ Zeta Plus™ 10CP, 50CP and 70CP Grade Filter Media were tested for pressure drop as a function of water flow rate in liters/m²/hour (LMH) with 18 Megohm water (25°C), as shown in Table 15 and Figure 3.

3M™ Zeta Plus™ CP Series Filter Media has variations within each manufacturing lot and from lot-to-lot. The chart is based on test data for representative manufacturing lots from each global facility and should be considered typical values.

The water flow rate differentiation by grade of 3M™ Zeta Plus™ CP Series Filter Media indicated here is for guidance only. Factors that influence actual customer flow rates include fluid viscosity, density, flow restriction due to fluid path, and normal fouling of media by contaminant load.

Table 15. Pressure Drop vs. Clean Water Flow Rate of 3M™ Zeta Plus™ 10CP, 50CP and 70CP Grade Filter Media at 25°C									
	10CP			50CP			70CP		
	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2		
Flow Rate	Differential Pressure (PSID)								
LMH	Ave	Min	Max	Ave	Min	Max	Ave	Min	Max
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
304	0.2	0.2	0.3	1.1	1.0	1.2	4.2	3.3	6.4
542	0.4	0.4	0.4	1.8	1.6	2.0	6.2	5.1	8.8
794	0.6	0.6	0.6	2.4	2.2	2.7	7.7	6.2	11.1
992	0.8	0.8	0.8	2.8	2.6	3.0	8.5	6.5	10.9
1204	1.0	0.9	1.0	3.1	2.9	3.3	9.5	7.4	11.0



VII. 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.

In this Regulatory Support File, 3M provides effluent quality data relating to the required preconditioning flush based on the attributes listed in Table 16. 3M has also performed Extractable/Leachable studies consistent with guidance from the USP chapter <665> (draft) and the BioPhorum Operating Group (BPOG). The extractable/leachable data package is available as an addendum to this RSF upon request.

Table 16. Reference Industry Standards	
USP Standards	**Applicable Methods**
<643>	Total Organic Carbon
<645>	Conductivity
<791>	pH
<232>, <233>, ICH* Q3D	Elemental Impurities
<788>	Particulate Matter in Injections
<85>	Bacterial Endotoxin
<88>	Biological Reactivity

* ICH – International Conference for Harmonisation, Guideline for Elemental Impurities, Q3D, Dec. 16, 2014

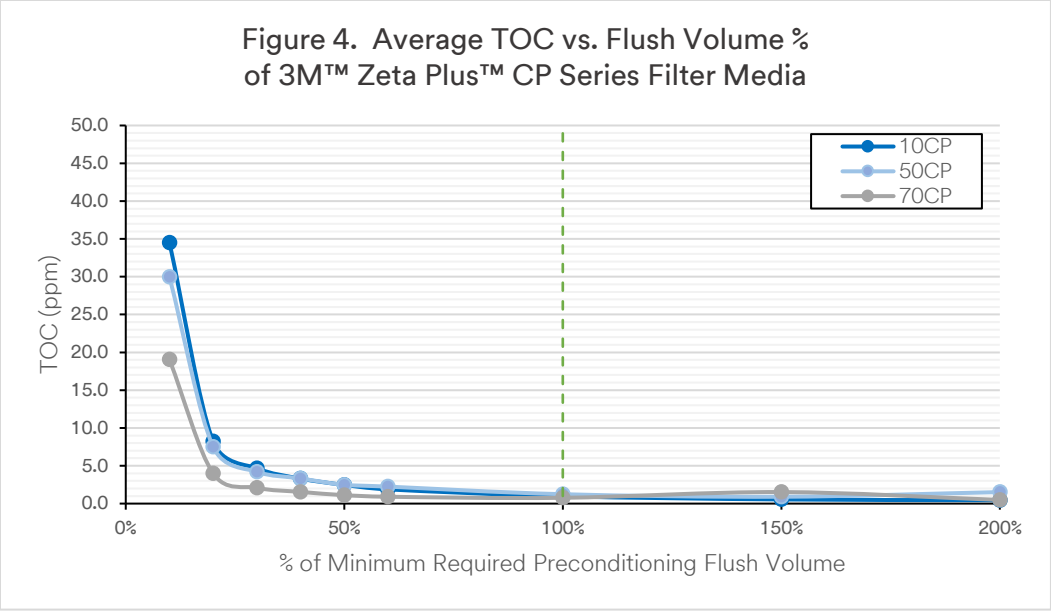
90-mm discs of 3M™ Zeta Plus™ 10CP, 50CP and 70CP Grade Filter Media were challenged with 18 Megohm water (25°C) at a constant flux of 1200 LMH to a total volume of two times the minimum recommended preconditioning flush volume of 54 L/m² . Effluent samples were collected at 10%, 20%, 30%, 40%, and so on at 10% increments to 200% of the preconditioning flush volume.

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

The effluent total organic carbon (TOC) at selected preconditioning flush volume percentages is presented in Table 17 and Figure 4. At 100% of the recommended preconditioning flush volume, the TOC of all tested 3M™ Zeta Plus™ CP Series Filter Media samples were less than 5 ppm.

Table 17. Effluent TOC [ppm] vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ 10CP, 50CP and 70CP Grade Filter Media

	10CP			50CP			70CP		
Flush Vol %	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2		
[%]	Average	Min	Max	Average	Min	Max	Average	Min	Max
10%	34.5	30.1	38.9	30.0	25.3	34.6	19.0	10.4	27.7
20%	8.2	7.4	9.0	7.5	5.9	9.1	4.0	2.7	5.3
30%	4.7	4.4	4.9	4.2	3.5	5.0	2.1	1.5	2.7
40%	3.3	3.3	3.3	3.3	2.7	3.9	1.5	1.4	1.7
50%	2.5	2.5	2.5	2.5	2.1	2.9	1.1	1.0	1.2
60%	1.9	1.8	1.9	2.2	2.0	2.5	0.9	0.9	0.9
100%	**1.0**	**0.9**	**1.0**	**1.2**	**1.2**	**1.2**	**0.8**	**0.7**	**0.8**
150%	0.5	0.5	0.6	0.9	0.8	1.0	1.5	1.0	2.1
200%	0.4	0.4	0.4	1.5	0.7	2.4	0.5	0.3	0.7



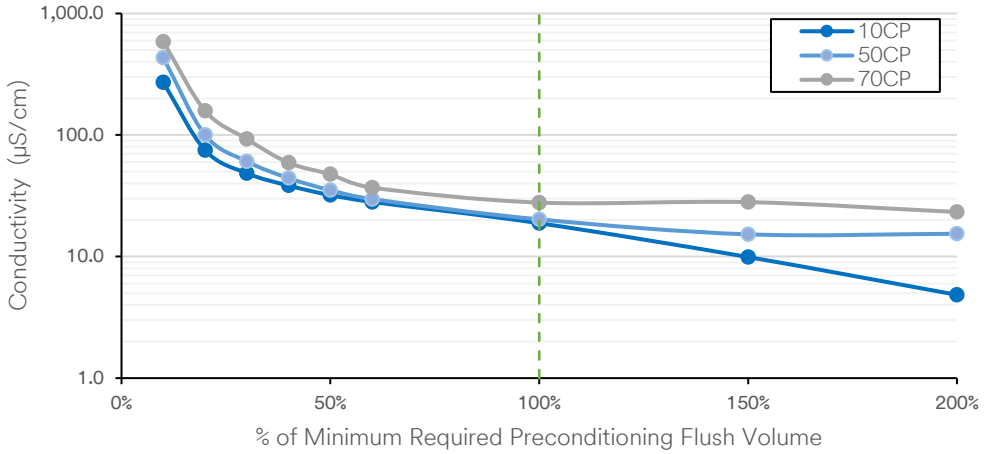
B. USP <645> Conductivity

The effluent conductivity at selected preconditioning flush volume percentages is presented in Table 18 and Figure 5. The data showed all media extracts had conductivity less than 40 µS/cm after 100% of the minimum recommended preconditioning flush volume.

Table 18. Effluent Conductivity [µS/cm] vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ 10CP, 50CP and 70CP Grade Filter Media

	10CP			50CP			70CP		
Flush Vol %	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2		
[%]	Average	Min	Max	Average	Min	Max	Average	Min	Max
10%	270.7	248.2	293.2	432.6	426.2	438.9	585.4	556.3	614.6
20%	75.1	71.0	79.2	100.3	93.6	106.9	158.5	158.4	158.6
30%	48.5	44.6	52.3	60.6	54.3	67.0	92.8	89.8	95.7
40%	38.4	37.5	39.3	44.2	38.5	49.9	59.2	56.5	61.9
50%	32.0	31.8	32.2	35.1	30.7	39.5	47.5	44.4	50.6
60%	28.1	27.9	28.3	29.7	27.0	32.4	36.9	33.7	40.2
100%	**18.8**	**18.5**	**19.1**	**20.2**	**19.9**	**20.6**	**27.8**	**21.0**	**34.6**
150%	9.9	9.6	10.2	15.2	14.7	15.7	28.0	17.7	38.4
200%	4.8	4.7	5.0	15.4	11.5	19.3	23.3	15.8	30.7

Figure 5. Average Conductivity vs. Flush Volume % of 3M™ Zeta Plus™ CP Series Filter Media



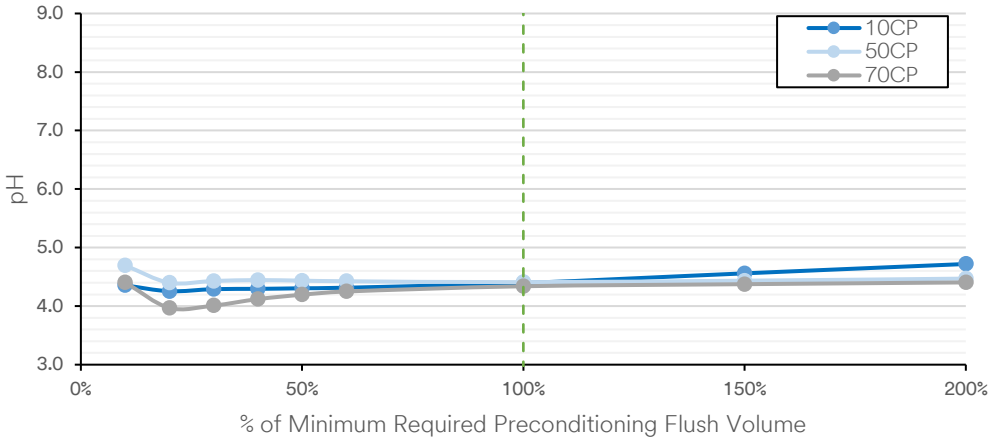
C. USP <791> pH

The effluent pH at selected preconditioning flush volume percentages, along with pH of the 18 Megohm water controls, are shown in Table 19 and Figure 6. Note that the 18 Megohm 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 19. Effluent pH vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ 10CP, 50CP and 70CP Grade Filter Media

	10CP			50CP			70CP		
Flush Vol %	**Number of Manufacturing Lots: 2**			**Number of Manufacturing Lots: 2**			**Number of Manufacturing Lots: 2**		
[%]	**Average**	**Min**	**Max**	**Average**	**Min**	**Max**	**Average**	**Min**	**Max**
18 MΩ Water Control	**5.2**	**5.2**	**5.2**	**5.2**	**5.2**	**5.2**	**5.4**	**5.2**	**5.6**
10%	4.4	4.3	4.4	4.7	4.5	4.9	4.4	4.3	4.5
20%	4.3	4.2	4.3	4.4	4.3	4.5	4.0	3.9	4.1
30%	4.3	4.3	4.3	4.4	4.4	4.5	4.0	4.0	4.0
40%	4.3	4.3	4.3	4.4	4.4	4.5	4.1	4.1	4.2
50%	4.3	4.3	4.3	4.4	4.4	4.5	4.2	4.2	4.2
60%	4.3	4.3	4.3	4.4	4.4	4.5	4.3	4.2	4.3
100%	**4.4**	**4.4**	**4.4**	**4.4**	**4.4**	**4.4**	**4.3**	**4.2**	**4.5**
150%	4.6	4.6	4.6	4.4	4.4	4.5	4.4	4.2	4.5
200%	4.7	4.7	4.7	4.5	4.5	4.5	4.4	4.3	4.6

Figure 6. Average pH vs. Flush Volume % of 3M™ Zeta Plus™ CP Series Filter Media



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

Aliquots were obtained at 10%, 100% and 200% of the recommended preconditioning flush volumes and tested for ICH Q3D class 1-3 elements, as well as selected others listed in Tables 20, by ICP-AES.

Table 20. Flush Effluent Elemental Impurities for 3M™ Zeta Plus™ 10CP, 50CP, and 70CP Grade Filter Media (ppb)											
ICH Class	Element	LOQ [ppb]	10CP			50CP			70CP		
At % of Flush Volume			10%	**100%**	200%	10%	**100%**	200%	10%	**100%**	200%
1	**As**	0.1	4.0	**0.2**	0.1	5.8	**0.6**	0.4	7.7	**0.5**	0.3
	Cd	0.9	<LOQ	**<LOQ**	<LOQ	1.1	**<LOQ**	<LOQ	4.4	**<LOQ**	<LOQ
	Hg	30	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Pb	0.12	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	0.55	**<LOQ**	<LOQ
2A	**Co**	0.010	1.17	**0.03**	0.01	2.48	**0.05**	0.01	2.54	**0.05**	0.02
	Ni	0.06	80	**2.60**	1.30	129	**3.10**	0.94	135	**2.67**	1.10
	V	0.05	17.80	**5.40**	4.37	59.40	**21.50**	18.80	45.90	**23.00**	22.50
2B	**Ag**	0.18	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Au	0.2	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Ir	0.18	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Os	0.4	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Pd	0.21	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Pt	0.3	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Rh	0.3	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Ru	0.3	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Se	*	*	*****	*	*	*****	*	*	*****	*
	Tl	0.1	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
3	**Ba**	0.30	24.90	**0.70**	0.30	147	**5.10**	2	200	**5.60**	2.50
	Cr	0.08	31.90	**1.90**	1.00	26.90	**1.90**	1.16	21.20	**1.30**	0.63
	Cu	0.05	4.41	**0.78**	0.32	5.40	**1.54**	0.65	4.20	**0.64**	0.27
	Li	2.6	<LOQ	**<LOQ**	<LOQ	5.0	**<LOQ**	<LOQ	9.0	**<LOQ**	<LOQ
	Mo	0.7	2.6	**<LOQ**	<LOQ	8.7	**1.4**	1.2	8.0	**1.3**	1.5
	Sb	0.3	<LOQ	**<LOQ**	<LOQ	0.9	**<LOQ**	<LOQ	1.0	**<LOQ**	<LOQ
	Sn	0.4	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
Other Elements	**Al**	1.7	856.8	**25.8**	12.8	3496.8	**171.8**	79.9	4096.8	**131.8**	58.8
	B	0.7	13.7	**3.1**	0.0	28.3	**5.4**	1.5	48.0	**0.0**	0.0
	Ca	1.5	1620.0	**43.1**	28.8	3080.0	**51.0**	16.0	3730.0	**67.0**	35.0
	Fe	0.1	576.0	**25.1**	8.8	560.0	**25.9**	12.5	524.0	**29.0**	14.4
	K	2	3910	**1280**	1920	23680	**850**	5390	74480	**1510**	2170
	Mg	0.7	930.0	**21.1**	12.0	2650.0	**37.5**	12.0	3080.0	**40.0**	28.6
	Mn	0.1	115.0	**2.8**	1.4	366.0	**8.4**	3.1	325.0	**5.0**	3.4
	Na	15	18200	**390**	231	27300	**370**	173	39800	**480**	310
	Si	1.5	169	**63**	<LOQ	575.00	**15.00**	11.00	929.00	**57.00**	25.00
	Sr	0.02	16.50	**0.38**	0.20	100.00	**1.83**	0.58	187.00	**3.39**	1.68
	W	0.21	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ	<LOQ	**<LOQ**	<LOQ
	Zn	0.1	19.3	**1.2**	0.8	73	**4**	1	69	**2.8**	3.1
	Zr	0.04	0.43	**0.14**	0.13	0.66	**0.13**	0.12	0.51	**0.17**	0.08

* Selenium was not measured

E. USP <788> Particulate Matter in Injections

90-mm discs of 3M™ Zeta Plus™ 10CP, 50CP and 70CP Grade Filter 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.

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 21-22.

Table 21. Particulate Matter of 3M™ Zeta Plus™ 10CP and 50CP Grade Filter Media [ppb]

		10CP					50CP				
		Number of Manufacturing Lots: 2					Number of Manufacturing Lots: 2				
Particulate Size	18 Megohm Water (25°C)	Flush Volume				Static Soak	Flush Volume				Static Soak
		33%	66%	100%	200%		33%	66%	100%	200%	
>10 µm	0.36	1256.5	17.9	7.5	17.9	143.0	682.8	123.7	166.0	249.2	460.0
>25 µm	0.08	43.4	0.6	0.2	0.6	6.8	21.2	3.7	5.2	8.5	21.4

Table 22. Particulate Matter of 3M™ Zeta Plus™ 70CP Grade Filter Media [ppb]

		70CP				
		Number of Manufacturing Lots: 2				
Particulate Size	18 Megohm Water (25°C)	Flush Volume				Static Soak
		33%	66%	100%	200%	
>10 µm	0.36	727.1	335.3	378.3	297.2	330.4
>25 µm	0.08	21.5	9.2	11.2	10.8	16.2

F. USP <85> Bacterial Endotoxin

The release of 3M™ Zeta Plus™ 01AP Grade and CP Series Filter Media includes the determination of filtrate bacterial endotoxins for each lot. Filter discs are challenged with Sterile Water for Injection (SWFI) at 25°C, in accordance to 3M's minimum recommended preconditioning flush of 5 L/ft² (54 L/m²) of effective area. The specification limit for bacterial endotoxins is <0.25 EU/mL for 3M™ Zeta Plus™ 01AP Grade and CP Series Filter Media manufactured in the US and Australia and ≤0.25 EU/mL for 3M™ Zeta Plus™ CP Series Filter Media manufactured in France.

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™ Filter Media. Cellulose may contain β-Glucan, which is a non-endotoxin LAL-reactive material. However, the presence of β-Glucan in any 3M™ Zeta Plus™ Filter 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.

VIII. Shelf Life

Shelf Life of 3M™ Zeta Plus™ Filter Sheets, Filter Cartridges, and BC Series Filter Capsules with 01AP Grade and CP Series Media:

3 years at a recommended storage temperature of 5ºC - 30ºC, stored in original package.

IX. 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™ Filters with CP Series Media 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.

C. FDA CFR Title 21

While 3M has evaluated 3M™ Zeta Plus™ CP Series Filter Media per the standards codified in the US Food and Drug Administration's (FDA) Code of Federal Regulations (CFR), Title 21 Parts 177.2260 Indirect Food Additive – Filters, resin-bonded, as described below, 3M does not intend the product for use in any food contact application. This information is being provided only to aid customer's evaluations, risk assessments and regulatory submissions specifically for uses and applications that are consistent with 3M's Intended Use statement. See also 3M's Restricted Use statement for this product.

The media present in 3M™ Zeta Plus™ Filters with CP Series Media meets US FDA 21 CFR Part 177.2260 Indirect Food Additive – Filters, resin-bonded Sections G, H and J. For details related to specific use conditions or limitations please contact your 3M Representative for more information.

Customer and user remain responsible for determining whether a 3M product is suitable and appropriate for their specific application, and for complying with all regulations applicable to their product in the countries where it will be produced, distributed or used, including any required registrations and/or certifications with governing regulatory authorities.

X. 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 upon request.

Certificates are provided in support of the release of the 3M™ Zeta Plus™ 01AP Grade and CP Series Media.

The 3M™ Zeta Plus™ Filters with 01AP Grade and CP Series Media 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™ Filters with 01AP Grade and CP Series Media 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™ Filters with 01AP Grade and CP Series Media are available in the US as courtesy.

Intended Use(s): 3M™ Zeta Plus™ Filters with 01AP Grade and CP 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.

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.

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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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