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3M Separation and Purification Sciences Division

3M™ Zeta Plus™ Filters with DELI Grade 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 DELI, DEL1, and DEL1LP Grade Media (herein collectively 3M™ Zeta Plus™ Filters with DELI Grade Media unless designated otherwise) with products as shown below, have quality systems registered to quality system standards as noted below.

Stafford Springs, CT, USA	Mazeres, France
Registered to: ISO 9001	Registered to: ISO 9001

This Regulatory Support File provides information pertinent to the 3M™ Zeta Plus™ Filters with DELI Grade 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 DELI Grade 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 DELI Grade Media are stated below.

Intended Use(s): 3M™ Zeta Plus™ Filters with DELI Grade 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 DELI Grade 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 DELI Grade Media are a family of advanced depth filters designed for optimal clarification of various bioprocess, biological and pharmaceutical fluids. 3M™ Zeta Plus™ DELI Grade Filter Media contains natural and precipitated silica and is designed to capture lipids and other hydrophobic contaminants.

3M™ Zeta Plus™ Filters with DELI Grade Media are a family of depth filter media which incorporates lipid-specific adsorbents for selective reduction of lipids, surfactants and biological hydrophobes from human blood plasma, serum-based products, recombinant proteins and other biological fluids.

3M™ Zeta Plus™ DELI Grade Filter Media contains a mixture of natural and precipitated silica, cellulose, nonionic surfactant, and a crosslinking polymer binder resin. The polymer resin has a mixed amine structure including a quaternary amine, which imparts the anion exchange functionality of the media. Precipitated silica is used to provide lipid reduction capacity and functionality.

Dual layer version of 3M™ Zeta Plus™ Filter Cartridges and 3M™ Zeta Plus™ Encapsulated System Filter Capsules with DELI Grade Media consist of two layers of 3M™ Zeta Plus™ DELI Grade Filter Media.

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 source of supply to enable traceability.

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: 4510913DELI, Z8FA4NPADELI, Z08PADEL1LP,					
United States	Diameter Designation			Gasket Material		Grade
	45109 - 8 cell			13 – Fluorocarbon 22 – Silicone (VMQ) 23 – Fluoropolymer (PTFE)		DELI
	45167 - 7 cell Plug-in			03- Fluorocarbon 04- Silicone (VMQ) 09-PTFE-Encapsulated Fluorocarbon		
	Diameter Designation	Number of Cells	Configuration	Material	Gasket Material¹	Grade
Z8FA -Plug-in	2 - 2 cell 4 - 4 cell	N - None	P - Polypropylene	A – Silicone (VMQ) B – Fluorocarbon (FPM) K – PTFE-Encapsulated Fluorocarbon	DELI	
France	Diameter Designation		Cartridge Construction		Gasket Material¹	Grade
	Z08		P2 - Plug-in 2 cells		A – Silicone (VMQ)	DEL 1
	Z08		P - Plug-in 7 cells		A – Silicone (VMQ)	DEL 1LP

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: 45805ADELI, Z12MDEL1LP				
United States	Diameter Designation	Material		O-Ring Material	Grade
	45805 - 9 cell 45211 - 15 cell	01 - Polypropylene (PP)		A – Silicone (VMQ) B – Fluorocarbon (FPM)	DELI
France	Diameter Designation	Configuration		Gasket Material	Grade
	Z12	M – 15 cells, Netting S – 7 cells		D – Nitrile E – Fluoropolymer (PTFE)	DEL 1LP

Table 2. 3M™ Zeta Plus™ 12-Inch Filter Cartridge Product Descriptions: Dual Layer Media					
Manufacturing Facility	Product Description Examples: Z12E11AADEL1DEL1A				
France	Diameter Designation	Configuration	Binder Wires	Gasket Material	Grade
	Z12	E11 – 11 cell, Netting	A – Stainless Steel	A - Silicone	DEL1DEL1A

3M™ Zeta Plus™ 16-Inch Cartridges

Table 3. 3M™ Zeta Plus™ 16-Inch Filter Cartridge Product Descriptions: Single Layer Media				
Manufacturing Facility	Product Description Examples: Z16PADELI, Z16MDEDEL1LP			
	Diameter Designation	Configuration	Gasket Material	Grade
United States	Z16	P - 14 cell	A - Silicone (VMQ) B - Fluorocarbon (FPM) E - Fluoropolymer (PTFE)	DELI
France	Z16	M - 14 cell, Netting	D - Nitrile	DEL 1LP

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

Table 4a. 3M™ Zeta Plus™ BC Series Filter Capsule (Laboratory Capsule) Product Descriptions: Single Layer Media			
Manufacturing Facility	Product Description Example: BC0025LDELI		
	Diameter Designation	Configuration	Grade
United States	BC0025	L - Luer S - Sanitary	DELI
France	BC0025	L - Luer	DEL 1

Table 4b. 3M™ Zeta Plus™ BC Series Filter Capsule (Laboratory Capsule) Product Descriptions: Dual Layer Media			
Manufacturing Facility	Product Description Example: BC0025LDELI		
	Diameter Designation	Configuration	Grade
United States	BC0025	L - Luer S - Sanitary	DELI08A
France	BC0025	S - Sanitary	DEL1DEL1

3M™ Zeta Plus™ Encapsulated System Scale-Up Filter Capsules

Table 5a. 3M™ Zeta Plus™ Encapsulated System Scale-Up Filter Capsule Product Descriptions: Single Layer Media				
Manufacturing Facility	Product Description Example: E0340FSADELI			
	Diameter Designation	EFA (cm²)	Capsule Material	Grade
United States	E	0170 0340 1020	FSA - Polysulfone	DELI

Table 5b. 3M™ Zeta Plus™ Encapsulated System Scale-Up Filter Capsule Product Descriptions: Dual Layer Media

Manufacturing Facility	Product Description Example: E0340FSADELI08A			
	Diameter Designation	EFA (cm ²)	Capsule Material	Grade
United States	E	0170 0340 1020	FSA - Polysulfone	DELI08A

3M™ Zeta Plus™ Encapsulated System Filter Capsules (Production Capsules)

Table 6a. 3M™ Zeta Plus™ Encapsulated System Filter Capsules (Production Capsule) Product Descriptions: Single Layer Media

Manufacturing Facility	Product Description Example: E16E01ADELI				
	Diameter Designation	Configuration	Number of Cells	Gasket Material	Grade
United States	E16	E - Standard	01 - 1 cell 11 - 11 cell	A – Silicone (VMQ)	DELI

Table 6b. 3M™ Zeta Plus™ Encapsulated System Filter Capsules (Production Capsule) Product Descriptions: Dual Layer Media

Manufacturing Facility	Product Description Example: E16E07ADELI08A				
	Diameter Designation	Configuration	Number of Cells	Gasket Material	Grade
United States	E16	E – Standard	01 - 1 cell 07 - 7 cell	A – Silicone (VMQ)	DELI08A

3M™ Manifolds

Table 7. 3M™ Manifold Product Description

Manufacturing Facility	Product Description Example: 6128901
	Product Description
United States	6128901 – Standard Set

IV. Product Design

All components used in the manufacture of 3M™ Zeta Plus™ Filters with DELI Grade Media 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 Filters with DELI Grade 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 DELI Grade Media are produced in the United States, while 3M™ Zeta Plus™ Filters with DEL1 and DEL1LP Grade Media are produced in France. Raw materials are purchased consistent with global specifications.

A. Media

3M™ Zeta Plus™ DELI Grade Filter Media contains a mixture of natural and precipitated silica, cellulose, nonionic surfactant, and a crosslinking polymer binder resin. The polymer binding resin used in 3M™ Zeta Plus™ DELI Grade Filter Media is a polyamide epichlorohydrin (PAE) polymer that contains a mixture of secondary, 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.

Dual layer versions of 3M™ Zeta Plus™ DELI Grade Filter Media consist of two layers of 3M™ Zeta Plus™ DELI Grade Filter Media.

B. Cartridges

The lenticular cells of cartridges are comprised of single or dual opposing 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-inch cartridges that are designated as Plug-in, by a plug-in post and a connector. 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 standard gasket materials may be offered: silicone (VMQ), fluorocarbon (FPM) or fluoropolymer (PTFE).

Filter cartridges are available in 8-inch, 12-inch and 16-inch nominal diameters, with surface areas ranging from 0.26 m² to 3.9 m² 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.

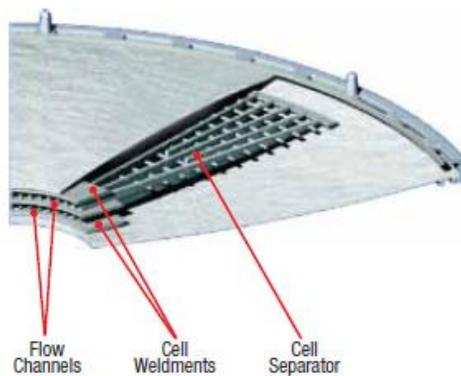


Figure 1a. 3M™ Zeta Plus™ Filter Cartridge lenticle configuration with single media layer

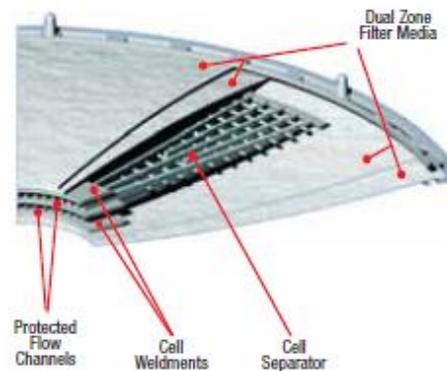


Figure 1b. 3M™ Zeta Plus™ Filter Cartridge lenticle configuration with dual media layers

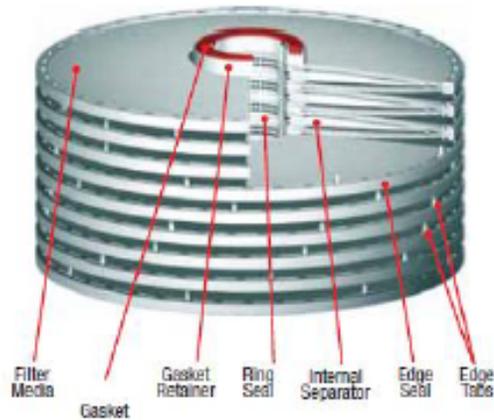


Figure 1c. 3M™ Zeta Plus™ Filter Cartridge and components



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



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



Figure 1f. 3M™ Zeta Plus™ Plug-In Filter Cartridge housing

C. Capsules

There are three capsule categories for the 3M™ Zeta Plus™ Encapsulated System Filter Capsules: Laboratory (BC Series), Scale-up and Production Capsules.

The Laboratory capsule (BC0025, 3M™ Zeta Plus™ BC Series Filter Capsule) is constructed by compressing the single or dual 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.

Scale-up capsules (3M™ Zeta Plus™ Encapsulated System Scale-Up Filter Capsules) are constructed from a lenticular media cell design with an 8-inch diameter. The lenticle comprises single or dual opposing layers of the filter media and an inner separator with a polymeric molded edge seal. This lenticle is first compressed and then held together by injection molding at the outer and inner diameter by a thermoplastic resin, which simultaneously seals all edges and forms the inner fluid outlet manifold. A polypropylene spacer is placed between the lenticles in 3-cell design capsule. The 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. Scale-up capsules have three configurations with nominal surface areas of 170 cm², 340 cm² and 1020 cm² per capsule. For the 170 cm² lenticle, one of the opposing filter media layers is replaced with an injection molded polypropylene disk, thereby, reducing the accessible surface area by a factor of two. The 1020 cm² capsules contain three stacked and sealed lenticles. The lenticles, or lenticle stack, are sealed to the outlet side of the capsule with a polypropylene support ring and fluorocarbon o-ring. The top and bottom pieces of the capsule are sealed together by a thermal bond. The Scale-up capsules have mini sanitary connections on the inlet and outlet.

Production capsules (3M™ Zeta Plus™ Encapsulated System Filter Capsules) are also constructed from a lenticular media cell design with a 16-inch diameter. Each lenticle has two opposing layers of the filter media and an inner separator with a polymeric molded edge seal. The lenticle is first compressed and then held together by injection molding at the outer and inner diameter by a thermoplastic resin, which simultaneously seals all edges and forms the inner fluid outlet manifold. A polypropylene spacer is placed between the lenticles in 7-cell and 11-cell capsules. The

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 separator. The production capsules have three single-use capsule configurations. The 0.23 m² capsule has one lenticle of single or dual layer media. The 1.6 m² capsule has seven (7) lenticles of dual layer media. The 2.5 m² capsule has eleven (11) lenticles of single layer media.

The outermost lenticles of the lenticle stack have respective male and female connectors thermally attached to provide connection to adjacent capsules or manifolds. The connectors use silicone o-rings. The top and bottom capsule shells are sealed together by a thermal bond. The multicell production capsule has a self-guiding locking mechanism for a robust capsule-to-capsule connection. The standard production capsule material is translucent polycarbonate. The multicell production capsules have two handles for convenient loading and unloading.

A set of 3M™ Manifolds is required for connecting the production capsules to external components of the purification train. The 3M™ Manifolds have 1.5-inch sanitary connections on the inlet and outlet. Manifold and capsule materials should always be the same; materials of construction should not be mixed. For example, polycarbonate capsules should only be used with polycarbonate manifolds.

The 3M™ Zeta Plus™ Encapsulated System Filter Capsules may be used in a multi-stage filtration or purification train with a single 3M™ Encapsulated System Holder. Production capsules of the same or different media configurations can be installed in a single 3M™ Encapsulated System Holder. Additionally, one of the stages may include 3M™ Emphaze™ AEX Hybrid Purifier. An extra pair of manifolds is required between each stage of the multi-stage train within the 3M™ Encapsulated System Holder.

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

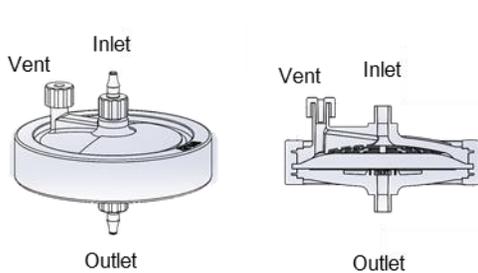


Figure 2a. 3M™ Zeta Plus™ BC Series Filter Capsule (BC0025 Laboratory Capsule) – Luer Style

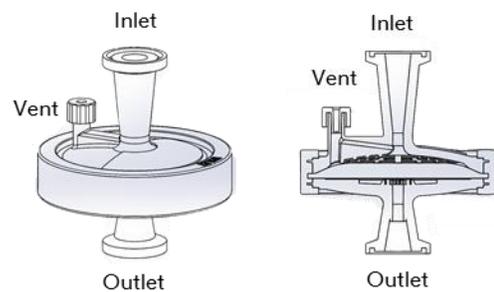


Figure 2b. 3M™ Zeta Plus™ BC Series Filter Capsule (BC0025 Laboratory Capsule) – Sanitary Style

Figure 3. 3M™ Zeta Plus™ Encapsulated System Scale-Up Filter Capsules

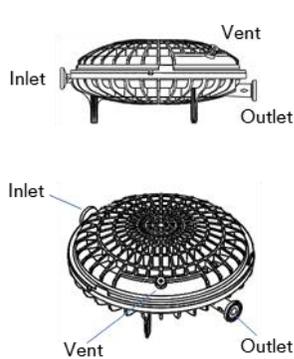


Figure 3a. 3M™ Zeta Plus™ Encapsulated System 170 cm² & 340 cm² Scale-Up Filter Capsules

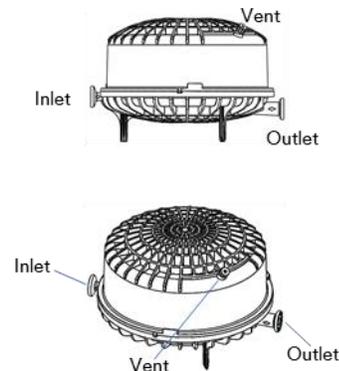


Figure 3b. 3M™ Zeta Plus™ Encapsulated System 1020 cm² Scale-Up Filter Capsule

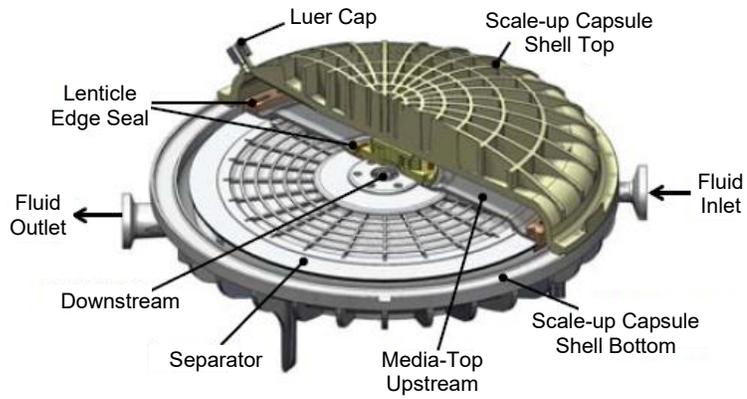


Figure 3c. 3M™ Zeta Plus™ Encapsulated System Scale-up Filter Capsule cross-section

Figure 4. 3M™ Zeta Plus™ Encapsulated System Filter Capsules (Production Capsules)

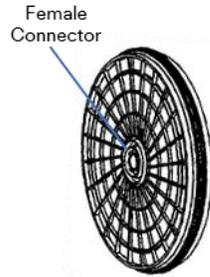


Figure 4a. 3M™ Zeta Plus™ Encapsulated System 0.23 m² Filter Capsule

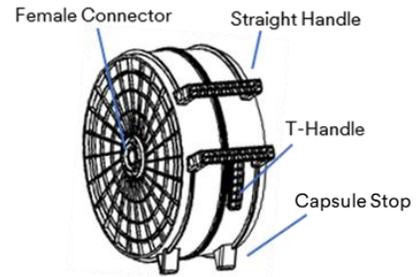


Figure 4b. 3M™ Zeta Plus™ Encapsulated System 1.6 m² & 2.5 m² Filter Capsules

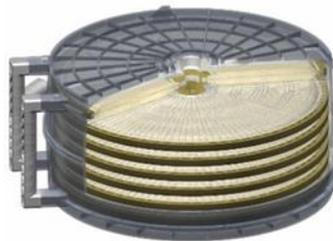


Figure 4c. 3M™ Zeta Plus™ Encapsulated System Filter Capsule (Production Capsule) cross-section

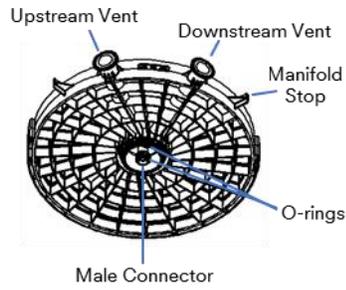


Figure 4d. 3M™ Manifolds – Top manifold

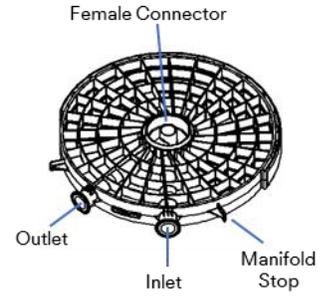


Figure 4e. 3M™ Manifolds – Bottom manifold



Figure 4f. 3M™ Zeta Plus™ Encapsulated System Filter Capsules (Production capsules) installed in 3M™ Encapsulated System Holders

D. Materials of Construction

Table 8. Materials of Construction – 3M™ Zeta Plus™ Filter Cartridges	
Part Type	Materials
Filter Media	Natural and Precipitated silica, cellulose, binding resin, nonionic surfactant
Separators	Polypropylene or Mineral-filled Polypropylene
Netting ¹	Polypropylene
Edge Seal	Polypropylene or Mineral-filled Polypropylene (single layer media) or Thermoplastic Elastomer (dual layer media)
Ring Seal	Polypropylene
Gasket Retainers	Polypropylene or Mineral-filled Polypropylene
Gaskets	Silicone, Fluorocarbon or PTFE
Binder Bands	316 Stainless Steel or Hastelloy®
8-inch Cartridge Plug-in Unitizing Post	Polypropylene

¹ Specific 12-inch and 16-inch cartridges

Table 9. Materials of Construction – 3M™ Zeta Plus™ BC Series Filter Capsule (Laboratory Capsule)

Part Type	Materials		
	BC0025		
Nominal Surface Area	25 cm ²		
Filter Media	Natural and Precipitated silica, cellulose, binding resin, nonionic surfactant		
Shells	Polypropylene		
Ring Seal (dual layer media)	Polypropylene		
Edge Seal Overmold	Glass Fiber Filled Polypropylene		
Luer cap & luer-barb connector	Polypropylene		

Table 10. Materials of Construction – 3M™ Zeta Plus™ Encapsulated System Scale-Up Filter Capsules

Part Type	Materials		
	E0170 Capsule	E0340 Capsule	E1020 Capsule
Nominal Surface Area	170 cm ²	340 cm ²	1020 cm ²
Filter Media	Natural and Precipitated silica, cellulose, binding resin, nonionic surfactant		
Separators	Polypropylene		
Spacers	N/A		Polypropylene
Flow Inhibitor Disc	Polypropylene	N/A	
Edge Seal	Thermoplastic Elastomer		
Inner Seal	Thermoplastic Elastomer		
Endcap	Thermoplastic Elastomer		
Shells	Polysulfone		
Back-up O-ring	Polypropylene		
O-ring	Fluorocarbon (FPM)		
Luer Cap	Polypropylene		

Table 11. Materials of Construction – 3M™ Zeta Plus™ Encapsulated System Filter Capsules (Production Capsules)

Part Type	Materials		
	E16E01 Capsules	E16E07 Capsules	E16E11 Capsules
Nominal Surface Area	0.23 m ²	1.6 m ²	2.5 m ²
Filter Media	Natural and Precipitated silica, cellulose, binding resin, nonionic surfactant		
Separators, Spacers	Polypropylene		
Edge Seal	Thermoplastic Elastomer		
Ring Seal	Thermoplastic Elastomer		
Connectors (Male & Female)	Polypropylene		
Shells	Polycarbonate		
O-ring Retainer	Polycarbonate		
O-rings	Silicone		
Handles	N/A	Nylon	
Manifold	Polycarbonate		

E. 3M™ Zeta Plus™ Encapsulated System Filter Capsule and 3M™ Manifold Design Characteristics

Weights and Volumes shown in Tables 12-15 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 12. Capsule Design Characteristics – 3M™ Zeta Plus™ BC Series Filter Capsules (Laboratory Capsules)		
Product Name	BC25, Luer	BC25, Sanitary
Nominal Surface Area	25 cm ²	25 cm ²
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)
Dual Layer (height by diameter)	6.9 cm x 7.6 cm (2.7 inches x 3 inches)	8.3 cm x 7.6 cm (3.3 inches x 3 inches)
Weight		
Dry – Single Layer	≈ 60 g	≈ 64 g
Dry – Dual Layer	≈ 69 g	≈ 75 g
Wet, post blow-down ¹ – Single Layer	≈ 70 g	≈ 75 g
Wet, post blow-down ¹ – Dual Layer	≈ 86 g	≈ 93 g
Volume		
Capsule Fill Volume ² – Single Layer	≈ 17 mL	
Capsule Fill Volume ² – Dual Layer	≈ 25 mL	
Post blow-down Hold-Up Volume ³ – Single Layer	≈ 11 mL	
Post blow-down Hold-Up Volume ³ – Dual Layer	≈ 17 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.

Table 13. Capsule Design Characteristics – 3M™ Zeta Plus™ Encapsulated System Scale-Up Filter Capsules

Product Name	E170	E340	E1020
Nominal Surface Area	170 cm ²	340 cm ²	1020 cm ²
Inlet/Outlet	½" Sanitary Style		
Nominal Dimensions			
Height by Diameter	10.3 cm x 21.6 cm (4.1 inches x 8.5 inches)		15.2 cm x 21.6 cm (6.0 inches x 8.5 inches)
Weight			
Dry – Single Layer	1.0 kg (2.2 lb)	1.0 kg (2.2 lb)	1.4 kg (3.0 lb)
Dry – Dual Layer	1.0 kg (2.2 lb)	1.0 kg (2.3 lb)	1.6 kg (3.5 lb)
Wet, post blow-down ¹ – Single Layer	1.1 kg (2.4 lb)	1.1 kg (2.5 lb)	1.8 kg (4.0 lb)
Wet, post blow-down ¹ – Dual Layer	1.2 kg (2.6 lb)	1.3 kg (2.9 lb)	2.4 kg (5.2 lb)
Volume			
Capsule Fill Volume ² – Single Layer	≈ 0.67 L (≈ 1.5 gal)	≈ 0.69 L (≈ 1.5 gal)	≈ 1.7 L (≈ 3.7 gal)
Capsule Fill Volume ² – Dual Layer	≈ 0.63 L (≈ 1.4 gal)	≈ 0.65 L (≈ 1.4 gal)	≈ 1.6 L (≈ 3.5 gal)
Post blow-down Hold-Up Volume ³ – Single Layer	≈ 0.12 L (≈ 0.26 gal)	≈ 0.16 L (≈ 0.35 gal)	≈ 0.46 L (≈ 1.0 gal)
Post blow-down Hold-Up Volume ³ – Dual Layer	≈ 0.15 L (≈ 0.34 gal)	≈ 0.26 L (≈ 0.58 gal)	≈ 0.80 L (≈ 1.8 gal)

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.

Table 14. Capsule Design Characteristics – 3M™ Zeta Plus™ Encapsulated System Filter Capsules (Production Capsules, Single Cell)

	Single Layer Media	Dual Layer Media
Product Name	Standard Production Capsule E16E01	Standard Production Capsule E16E01
Nominal Surface Area	0.23 m ²	
Nominal Dimensions		
Height by Diameter	2.7 cm x 45.2 cm (2.2 inches x 17.8 inches)	
Weight		
Dry	3.0 kg (6.6 lbs)	3.3 kg (7.3 lbs)
Wet (post Blow-Down) ¹	3.8 kg (8.3 lbs)	4.6 kg (10 lbs)
Volume		
Capsule Fill Volume ²	≈ 3.8 L (≈ 1.0 gal)	≈ 3.4 L (≈ 0.89 gal)
Capsule Post Blow-Down Hold-up Volume ³	≈ 0.7 L (≈ 0.20 gal)	≈ 1.3 L (≈ 0.35 gal)

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.

Table 15. Capsule Design Characteristics – 3M™ Zeta Plus™ Encapsulated System Filter Capsules (Production Capsules, Multi-Cell)

	Single Layer Media	Dual Layer Media
Product Name	Standard Production Capsule E16E11	Standard Production Capsule E16E07
Nominal Surface Area	2.5 m ²	1.6 m ²
Nominal Dimensions		
Height by Diameter	20.3 cm x 45.2 cm (8.0 inches x 17.8 inches)	
Weight		
Dry	10.2 kg (23 lbs)	10.5 kg (23 lbs)
Wet (post Blow-Down) ¹	17.6 kg (39 lbs)	19.3 kg (43 lbs)
Volume		
Capsule Fill Volume ²	≈ 18.1 L (≈ 4.8 gal)	≈ 18.8 L (≈ 5.0 gal)
Capsule Post Blow-Down Hold-up Volume ³	≈ 7.5 L (≈ 2.0 gal)	≈ 9.0 L (≈ 2.4 gal)

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.

Weights and Volumes shown in Table 16 below for standard manifolds were experimentally determined. **Please note that these values are presented for guidance only and are not specifications.**

Table 16. 3M™ Manifold Design Characteristics	
Component	Standard Manifold, Top or Bottom
Nominal Dimensions, Height by Diameter	5.2 cm x 45.2 cm (2.0 inches x 17.8 inches)
Connector	1½" Sanitary Style
Dry Weight	4.4 kg per set (10 lbs per set)
Hold-up Volume ¹	<250 mL per set

1 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.

F. Wetted Surface Areas

The wetted surface areas of components in 3M™ Zeta Plus™ Filter Cartridges, 3M™ Zeta Plus™ BC Series Filter Capsules, 3M™ Zeta Plus™ Encapsulated System Scale-Up Filter Capsules, and 3M™ Zeta Plus™ Encapsulated System Filter Capsules are listed in Tables 17-20, respectively. 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 23.

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 17. 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
8-inch Plug-in Unitizing Post	397	--	--

1 Specific 12-inch and 16-inch cartridges

2 Specific 12-inch cartridges

3 Specific 16-inch cartridges

Table 18. 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
Ring Seal (dual layer media)	36
Edge Seal	Non-wetted Surface

Table 19. Wetted Surface Areas of 3M™ Zeta Plus™ Encapsulated System Scale Up Filter Capsule Components			
Components	Wetted Surface Area [cm²]		
	E0170 Capsule	E0340 Capsule	E1020 Capsule
Separator (per lenticle)	324		
Spacer	-	-	3.7
Flow Inhibitor Disc	439	-	-
Edge Seal (per lenticle)	250	208	
Inner Seal (per lenticle)	47		
End Cap	14.7		
Shell Top	388		679
Shell Bottom	420		
Back-up O-ring	2.5		
O-ring	1.4		

Table 20. Wetted Surface Areas of 3M™ Zeta Plus™ Encapsulated System Filter Capsule (Production Capsule) Components			
Components	Wetted Surface Area [cm²]		
	E16E01 Capsules	E16E07 Capsules	E16E11 Capsules
Number of Cells	1 cell	7 cells	11 cells
Separator Assembly	2,178		
Spacer	825		
Edge Seal (per lenticle)	592	516	592
Inner Seal (per lenticle)	68	79	68
Connectors (Male and Female)	377		
Capsule Shells (2)	3,554	5,477	
O-ring large retainer	28		
O-ring large	14		
O-ring small	4		
Manifold (Total Top and Bottom)	1,047		

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 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) 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.
- 5) 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.
- 6) 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.
- 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 above specification limits for each grade of 3M™ Zeta Plus™ DELI Grade Filter Media are presented in Table 21. The dual layer media specifications represent the specifications of the tighter media layer. The tighter media layer has the smaller nominal pore size of the two layers; the larger the grade number, the tighter or smaller the nominal media pore size. In the Dual Layer Media section of Table 21, the dual layer configuration is shown in parentheses beneath the media grade; the upstream layer is shown first, followed by the downstream layer. Each layer is released according to the single layer media specification, and then assembled into dual layer products.

Table 21. Media Release Properties for 3M™ Zeta Plus™ DELI Series Filter Media					
Product Release Properties	Single Layer Specifications			Dual Layer Specification	Units
	DELI	DEL 1	DEL 1LP	DELI08A (DELI/DELI)	
Pressure Drop at Air Flow	80.0 - 120.0	76.0 - 126.0	76.0 - 126.0	80.0 - 120.0	Inch H ₂ O
Wet Tensile Strength	≥ 1.5	≥ 1.5	≥ 1.5	≥ 1.5	Kg/in
Ca Extraction	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Fe Extraction	≤ 0.040	≤ 0.040	≤ 0.040	≤ 0.040	mg/g
Color Extraction	≤ 8.0	≤ 8.0	≤ 8.0	≤ 8.0	Color Units
Total Nitrogen	≤ 60	≤ 60	≤ 60	≤ 60	ppm
Endotoxin Extraction	< 0.25	≤ 0.25	≤ 0.125	< 0.25	EU/mL

B. Installation and Operation Instructions

The installation and operation of the 3M™ Zeta Plus™ Filters with DELI Grade Media 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-user 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 Required Preconditioning Flush

3M™ Zeta Plus™ Filters with DELI Grade 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, customers must flush the filters before exposure to their product. 3M™ Zeta Plus™ Filters with DELI Grade Media 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.

Detailed preconditioning flush protocols are provided in 3M Installation and Operating Instructions (see Section V.B.). 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 23.

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

Table 22. Minimum Required Preconditioning Flush Volume and Recommended Flux		
Minimum Required Preconditioning Flush Volume	All Products	54 L/m ²
Maximum Recommended Flux of Required Preconditioning Flush	Cartridges	1200 LMH
	Capsules	210 LMH

Table 23. Minimum Required Preconditioning Flush Volume & Nominal Surface Area		
Cartridge Configuration	Nominal Surface Area	Minimum Required Preconditioning Flush Volume [L]
45109 (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
45805 (12-inch diameter cartridge, 9-cell)	0.9 m ²	46
45211 (12-inch diameter cartridge, 15-cell)	1.4 m ²	76
Z16P (16-inch diameter cartridge, 14-cell) ¹	3.2 m ²	173
Capsule Configuration	Nominal Surface Area	Minimum Required Preconditioning Flush Volume [L]
BC0025 Laboratory Capsule	25 cm ²	0.14
E0170 (Scale-Up capsule)	0.017 m ²	0.9
E0340 (Scale-Up capsule)	0.034 m ²	1.8
E1020 (Scale-Up capsule)	0.102 m ²	5.5
E16E01 (Production capsule) ¹	0.23 m ²	12
E16E07 (Production capsule) ¹	1.6 m ²	86
E16E11 (Production capsule) ¹	2.5 m ²	135

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

D. Operating Conditions

Table 24. Operating Conditions		
Maximum Operating Pressure	Laboratory Capsule	2.8 bar (40 psig) maximum inlet pressure
	Scale-Up Capsule	3.1 bar (45 psig)
	Production Capsule	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 Required Preconditioning Flush Volume	All Products	See Section V. C.
Recommended Flux of Required Preconditioning Flush	Cartridges	
	Capsules	
Pre-Use Sterilization	Cartridges	See Section V. E.
	Capsules	

E. Pre-Use Sterilization

3M Zeta Plus™ Filters with DELI Grade Media are not bioburden controlled. They can be autoclaved or *in-situ* steam sterilized per recommended conditions listed in Table 25. The filter cartridges can be steam sterilized per 3M procedure 70-0201-8840-8. Studies were conducted to ensure sterility after autoclave or *in situ* steam sterilization. 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 25. Pre-Use Sterilization Conditions	
Product Class	Autoclave / Steam-in-Place Parameters ¹
Cartridges	<i>in situ</i> 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)
Scale-Up Capsules	Autoclave only, Pre-vac cycle, 30 minutes @ 126 °C (259 °F) maximum (1 cycle)
Production Capsules	Autoclave only, Pre-vac cycle, 30 minutes @ 126 °C (259 °F) maximum (1 cycle)

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

F. Post-Use Sanitization

3M™ Zeta Plus™ Filters with DELI Grade Media may be sanitized by the procedure in Table 26 prior to disposal, if necessary, to comply with local regulations or customer requirements.

Note that the Standard Production Capsules (E16E01, E16E07, E16E11) have a polycarbonate shell and CANNOT be exposed to NaOH or NaClO (Bleach).

Table 26. Post-Use Sanitization Conditions ¹		
Product Class	Caustic Sanitization	Autoclave / Steam-in-Place Parameters
Cartridges	Can be treated with 1M NaOH or 5% NaClO post-use.	Same as Pre-Use Sterilization Conditions (See Table 25)
Laboratory Capsules	Capsule soak for 1 hour with 1M NaOH or 5% NaClO (bleach) ² post-use.	
Scale-Up Capsules		
Production Capsules	Not applicable to polycarbonate Standard Production Capsules.	

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

² Do not use NaClO (bleach) for pre-use sanitization.

VI. Performance Verification

A. Media Pressure Drop vs. Water Flow Rate

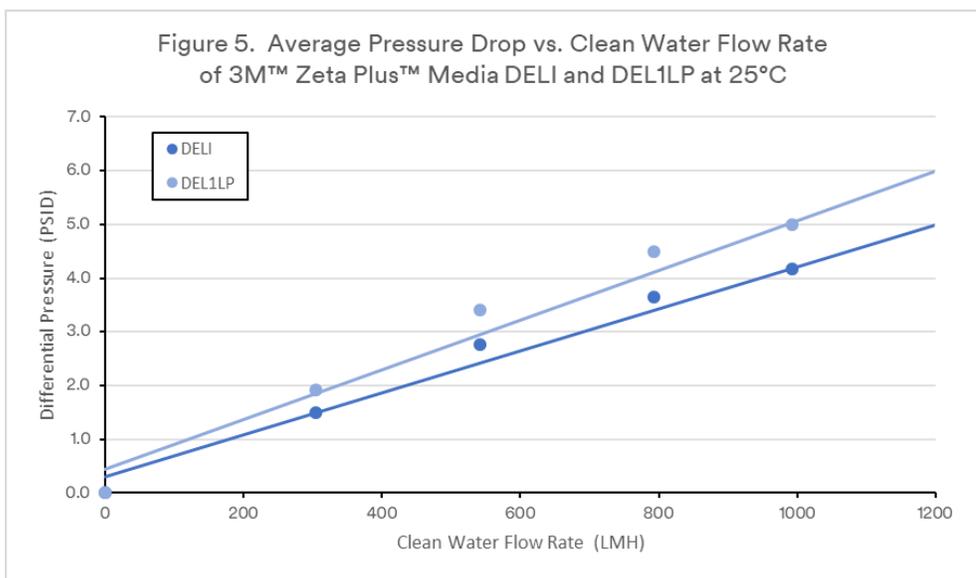
The 90-mm discs of 3M™ Zeta Plus™ DELI and DEL1LP Grade Filter Media were tested for pressure drop as a function of water flow rate in liters/m²/hour (LMH) with 18 Megohm water (25°C), as shown in Table 27 and Figure 5.

3M™ Zeta Plus™ DELI Grade 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 of 3M™ Zeta Plus™ DELI Grade 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 27. Pressure Drop vs. Water Flow Rate of 3M™ Zeta Plus™ DELI and DEL1LP Grade Filter Media at 25°C

Single Layer Media						
Flow Rate	DELI			DEL1LP		
	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2		
LMH	Differential Pressure (PSID)					
	Average	Max	Min	Average	Max	Min
0	0.0	0.0	0.0	0.0	0.0	0.0
304	1.5	1.5	1.5	1.9	1.7	2.2
542	2.8	2.7	2.9	3.4	3.3	3.5
794	3.7	3.6	3.8	4.5	4.2	4.8
992	4.2	3.9	4.4	5.0	4.9	5.2
1204	4.7	4.3	5.1	5.6	5.5	5.6



B. Lipid Reduction – Static Conditions

One 47-mm disc of 3M™ Zeta Plus™ DEL1LP Grade Filter Media per lot from two separate media lots were initially wet out to 239 L/m² with 18 megaohm water (25°C) at a constant flux of 2.0 mL/min/cm². After the flush, excess water was drained from the media. Three model solutions containing 100 ppm, 1000 ppm, and 10000 ppm of Tween® 80 (a non-ionic biological detergent) in water were used to mimic biological hydrophobic contaminants. The discs were static soaked with 10 mL of model solutions per gram of media for 24 hours. Following the static soak, the soak solution was analyzed for Tween 80 by TOC analysis.

An additional 47-mm disc of 3M™ Zeta Plus™ DEL1LP Grade Filter Media per lot from two separate media lots were autoclaved using a pre-vac cycle at 126°C for 60 minutes prior to the flush. The same test procedures which were used for the non-autoclaved samples were followed for the autoclaved samples.

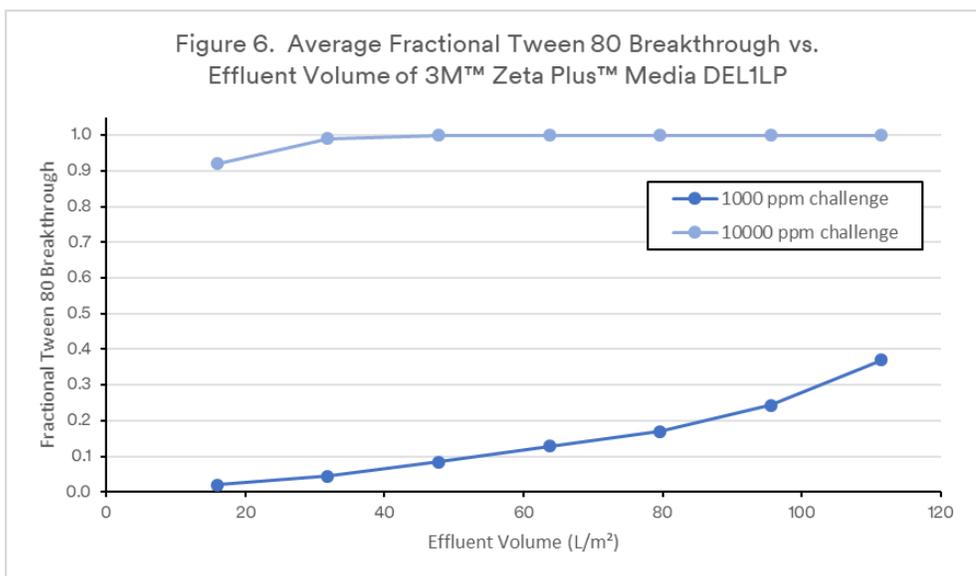
The results for autoclaved and untreated samples are shown in Table 28.

Table 28. Tween 80 Reduction [%] of 3M™ Zeta Plus™ DEL1LP Grade Filter Media – Static Soak				
Nominal Tween 80 Concentration (ppm)	Number of Manufacturing Lots	Total Number of Samples	Tween 80 Reduction (%)	
			No Treatment	Autoclave
			Average	Average
100	2	2	54.0	63.2
1000	2	2	82.0	80.7
10000	2	2	38.5	41.5

C. Lipid Reduction – Dynamic Conditions

47-mm discs of 3M™ Zeta Plus™ Grade Filter Media DEL1LP from two separate media lots were initially wet out to 239 L/m² with 18 megaohm water (25°C) at a constant flux of 2.0 mL/min/cm². Two model solutions containing 1000 ppm and 10000 ppm of Tween® 80 (a non-ionic biological detergent) in water were used to mimic biological hydrophobic contaminants. Following the flush, the 3M™ Zeta Plus™ DELI Grade Filter Media were challenged with the model solution at a constant flux of 0.12 mL/min/cm². Effluent samples were collected sequentially throughout the filtration and were analyzed for Tween 80 by UV-Vis at 234 nm. The results are shown in Table 29 and Figure 6.

Table 29. Fractional Tween 80 Breakthrough of 3M™ Zeta Plus™ DEL1LP Grade Filter Media – Dynamic Flush						
Effluent Volume [L/m ²]	Single Layer Media					
	1000 ppm Challenge			10000 ppm Challenge		
	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 2		
	Average	Max	Min	Average	Max	Min
16	0.02	0.03	0.01	0.92	0.96	0.84
32	0.04	0.09	0.01	0.99	0.99	0.98
48	0.08	0.17	0.02	1.00	1.00	0.99
64	0.13	0.26	0.02	1.00	1.00	0.99
80	0.17	0.32	0.05	1.00	1.00	0.99
96	0.24	0.37	0.17	1.00	1.00	1.00
111	0.37	0.48	0.32	1.00	1.00	0.99



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.

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.

In this Regulatory Support File, 3M provides effluent quality data relating to the required preconditioning flush based on the requirements listed in Table 28. The data provided is on a limited number of lots with product close to its date of manufacture. Except where noted, data should be considered as representative of typical product performance, but not a product specification. 3M has also performed Extractable/Leachable studies consistent with guidance from the USP chapter <665> (draft) and the BioPhorum Operating Group (BPOG) extractable protocol. The extractable/leachable data package is available as an addendum to this RSF upon request.

Table 30. 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

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

The 90-mm discs of 3M™ Zeta Plus™ DELI and DEL1LP 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 of 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 31 and Figure 7. The TN data at selected preconditioning flush volume percentages is shown in Table 32 and Figure 8.

Table 31. Effluent TOC [ppm] vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ DELI and DEL1LP Grade Filter Media						
Flush Volume [%]	Single Layer Media					
	DELI			DEL1LP		
	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 3		
	Average	Max	Min	Average	Max	Min
10%	310	352	268	474	729	314
20%	49.1	62.3	35.9	52.0	75.7	34.8
30%	30.6	43.1	18.1	27.3	33.6	20.9
40%	20.9	28.9	12.9	20.0	22.1	17.4
50%	15.6	19.8	10.9	16.7	17.2	16.0
60%	11.2	13.3	9.1	14.4	15.3	13.7
100%	7.0	7.1	6.9	7.8	8.5	7.1
150%	4.8	5.2	4.5	5.2	5.6	4.8
200%	3.9	4.2	3.7	3.9	4.4	3.7

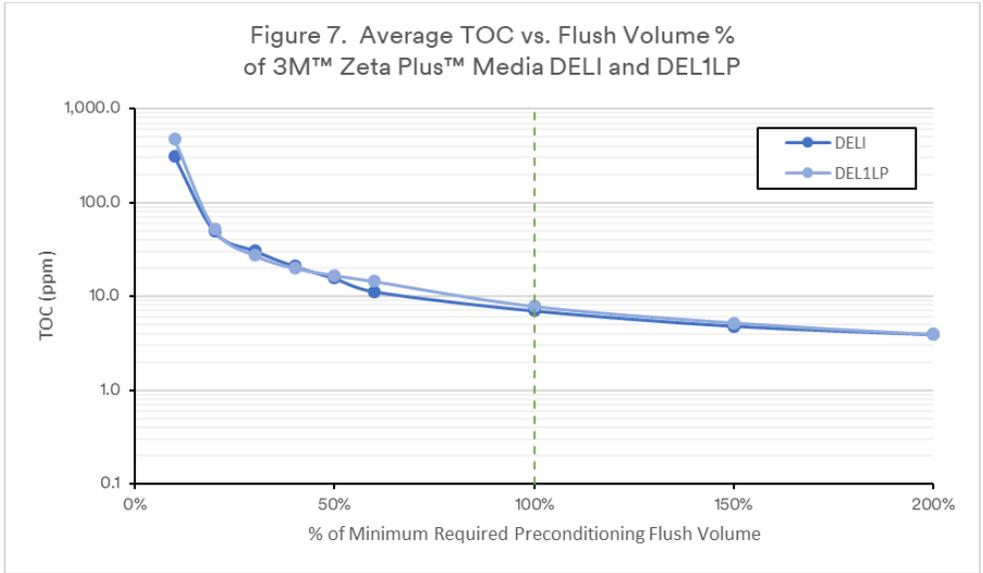
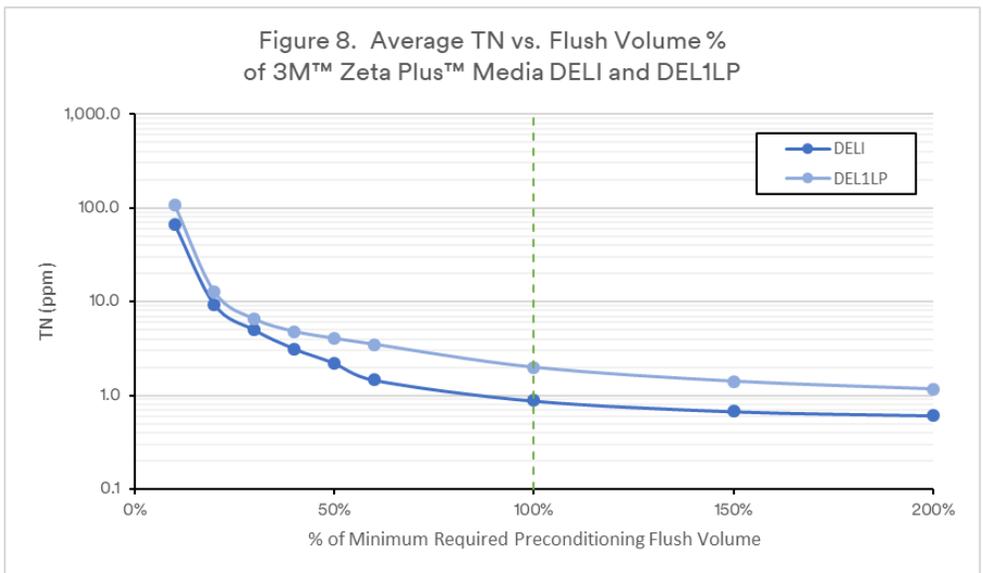


Table 32. Effluent TN [ppm] vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ DELI and DEL1LP Grade Filter Media

Flush Volume [%]	Single Layer Media					
	DELI			DEL1LP		
	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 3		
	Average	Max	Min	Average	Max	Min
10%	66.9	75.3	58.4	109	163	74.0
20%	9.3	12.0	6.6	12.7	18.7	8.4
30%	5.0	7.3	2.7	6.5	7.9	5.1
40%	3.1	4.7	1.6	4.8	5.3	4.3
50%	2.2	3.1	1.3	4.1	4.1	4.0
60%	1.5	1.8	1.1	3.5	3.6	3.4
100%	0.9	1.0	0.8	2.0	2.2	1.9
150%	0.7	0.7	0.7	1.4	1.6	1.3
200%	0.6	0.6	0.6	1.2	1.3	1.1



Additional 90-mm discs of 3M™ Zeta Plus™ DEL1LP Grade Filter Media 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 33 and Figure 9. The TN data for autoclaved samples is shown in Table 34 and Figure 10.

Table 33. Effluent TOC [ppm] vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ DEL1LP Grade Filter Media – Post Autoclave			
Single Layer Media			
DEL1LP			
Flush Volume	Number of Manufacturing Lots: 2		
	Average	Max	Min
10%	616	665	567
20%	95.3	95.9	94.8
30%	44.1	47.7	40.5
40%	27.8	30.2	25.4
50%	19.6	20.7	18.4
60%	15.7	16.4	15.0
100%	7.6	7.8	7.4
150%	4.8	4.9	4.6
200%	3.8	4.1	3.6

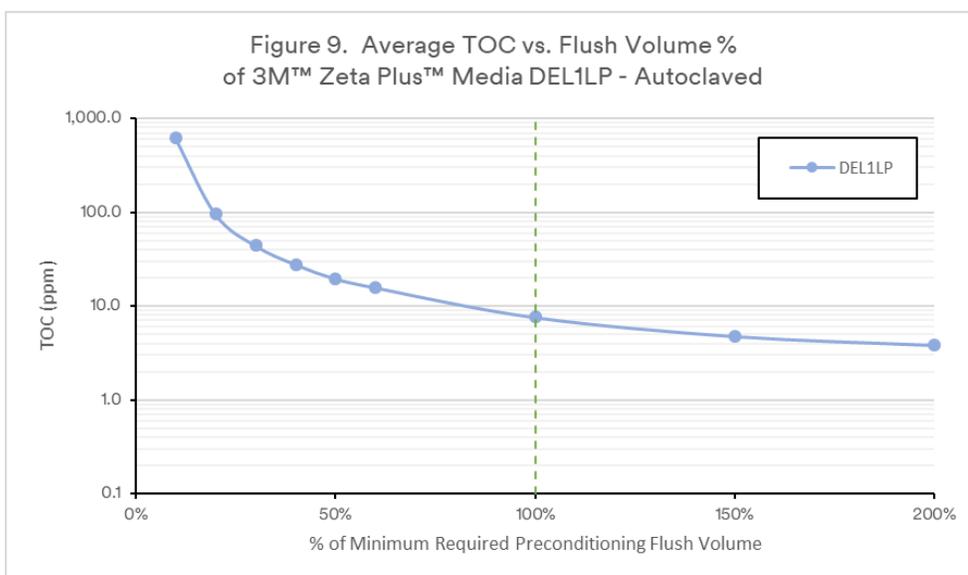
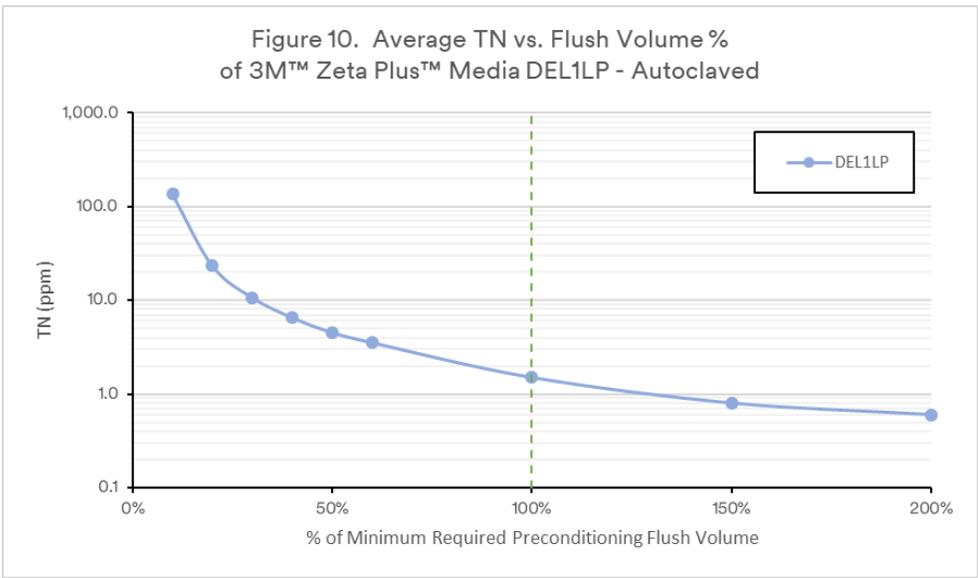


Table 34. Effluent TN [ppm] vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ DEL1LP Grade Filter Media – Post Autoclave			
	Single Layer Media		
	DEL1LP		
Flush Volume	Number of Manufacturing Lots: 2		
[%]	Average	Max	Min
10%	136	146	127
20%	23.4	23.8	23.0
30%	10.7	11.4	10.0
40%	6.5	7.1	6.0
50%	4.5	4.7	4.3
60%	3.5	3.7	3.4
100%	1.5	1.6	1.4
150%	0.8	0.8	0.8
200%	0.6	0.7	0.5

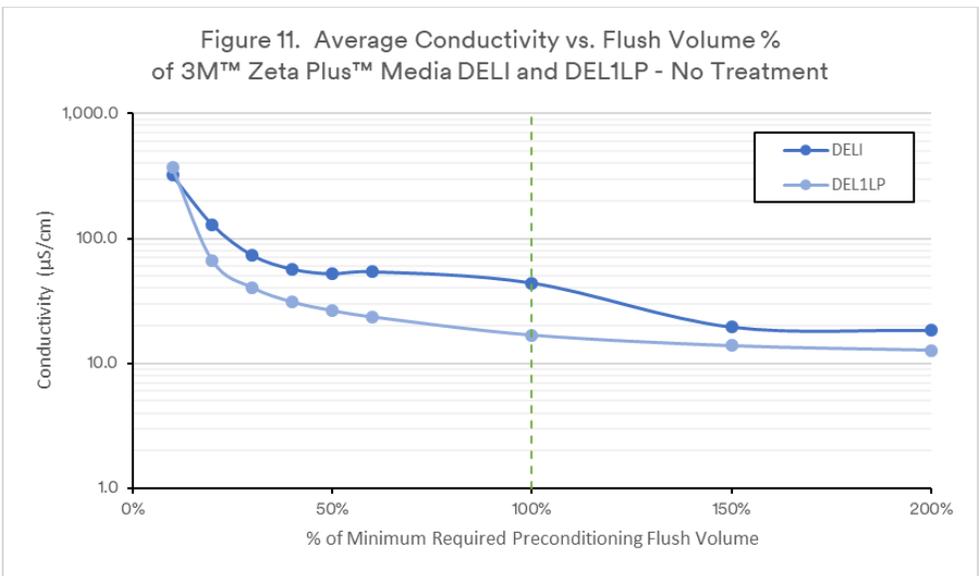


B. USP <645> Conductivity

The 90-mm discs of 3M™ Zeta Plus™ DELI and DEL1LP 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 10%, 20%, 30%, 40%, and so on at 10% increments to 200% of the minimum required preconditioning flush volume. The effluent samples were then measured for conductivity. The conductivity at selected preconditioning flush volume percentages is shown in Table 35 and Figure 11.

Table 35. Effluent Conductivity [$\mu\text{S}/\text{cm}$] vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ DELI and DEL1LP Grade Filter Media – No Treatment

Flush Volume [%]	Single Layer Media					
	DELI			DEL1LP		
	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 3		
	Average	Max	Min	Average	Max	Min
10%	320	404	236	368	451	314
20%	129	199	58.7	66.4	72.7	59.7
30%	73.3	107.5	39.1	40.5	46.3	37.5
40%	56.8	85.2	28.3	31.0	34.8	27.8
50%	52.1	82.0	22.2	26.5	28.4	24.3
60%	54.1	89.0	19.2	23.6	24.6	22.5
100%	44.0	72.7	15.3	16.9	18.1	15.8
150%	19.5	25.5	13.5	13.8	15.1	13.2
200%	18.3	24.0	12.6	12.7	13.2	12.4



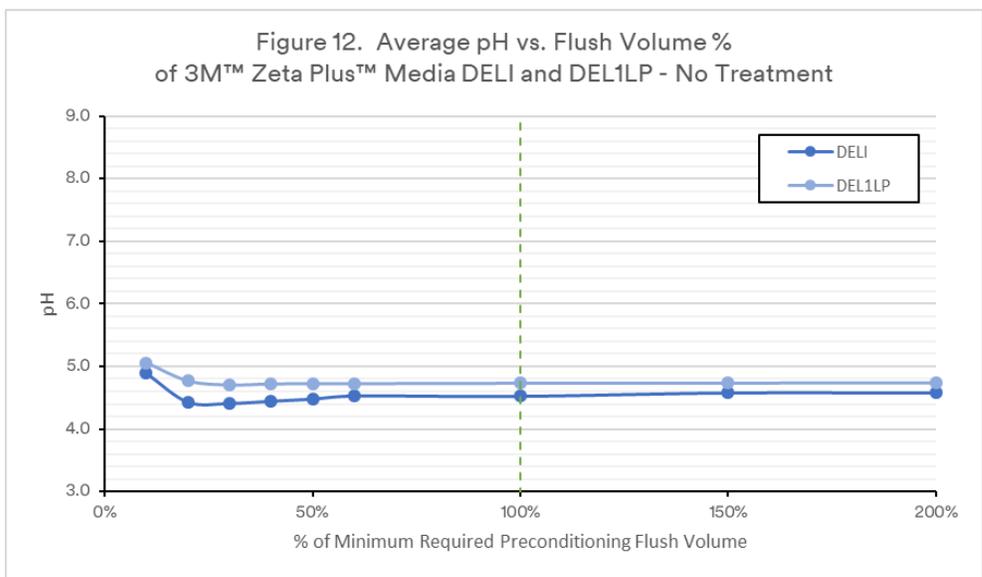
C. USP <791> pH

The 90-mm discs of 3M™ Zeta Plus™ DELI and DEL1LP 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 of 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 minimum required 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 36 and Figure 12. The data showed all tested media effluent had pH in the range of 4.5 to 5.8 after 100% of minimum required preconditioning flush volume. 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 36. Effluent pH vs. Preconditioning Flush Volume % of 3M™ Zeta Plus™ DELI and DEL1LP Grade Filter Media – No Treatment

Flush Volume [%]	Single Layer Media					
	DELI			DEL1LP		
	Number of Manufacturing Lots: 2			Number of Manufacturing Lots: 3		
	Average	Max	Min	Average	Max	Min
DI Water Control	5.9	5.9	5.9	5.1	5.0	5.2
10%	4.9	5.0	5.0	5.1	5.3	4.6
20%	4.4	4.4	4.4	4.8	4.9	4.6
30%	4.4	4.4	4.4	4.7	4.8	4.6
40%	4.5	4.4	4.4	4.7	4.8	4.6
50%	4.5	4.5	4.5	4.7	4.8	4.6
60%	4.5	4.6	4.6	4.7	4.8	4.6
100%	4.5	4.7	4.7	4.7	4.8	4.7
150%	4.6	4.8	4.8	4.7	4.8	4.7
200%	4.6	4.7	4.7	4.7	4.8	4.7



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

The 90-mm discs of 3M™ Zeta Plus™ DELI and DEL1LP Grade Filter Media produced at different global plants were challenged with 18 Megohm DI water (25°C) at a constant flux of 1200 LMH to a total volume of two times of 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 from non-autoclaved samples are shown in Tables 33. The designation “<LOQ” indicates that the measured value is below the Limit of Quantification (LOQ). 3M™ Zeta Plus™ Filter Media contains natural silica; naturally occurring differences are anticipated, and the values below should be taken as representative.

Table 37. Flush Effluent Elemental Impurities for 3M™ Zeta Plus™ DELI and DEL1LP Grade Filter Media (ppb) - No Treatment

ICH Class	Element	LOQ [ppb]	DELI			DEL1LP		
At % of Flush Volume			10%	100%	200%	10%	100%	200%
1	As	0.01	1.55	0.13	0.08	8.49	0.19	0.09
	Cd	0.01	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Hg	0.2	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Pb	0.3	1.09	<LOQ	<LOQ	0.99	<LOQ	<LOQ
2A	Co	0.01	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Ni	1.8	4.8	<LOQ	<LOQ	8.7	<LOQ	<LOQ
	V	0.4	<LOQ	<LOQ	<LOQ	5.8	0.64	0.3
2B	Ag	0.02	<LOQ	<LOQ	<LOQ	0.02	<LOQ	<LOQ
	Au	0.071	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Ir	0.002	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Os	0.275	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Pd	0.017	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Pt	0.002	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Rh	0.001	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Ru	0.002	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Se	0.6	<LOQ	<LOQ	<LOQ	0.06	<LOQ	<LOQ
	Tl	0.01	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
3	Ba	0.3	16.5	1.0	0.8	89.4	17.8	17.8
	Cr	0.6	2.9	<LOQ	<LOQ	3.4	<LOQ	<LOQ
	Cu	4	<LOQ	<LOQ	<LOQ	7	0.6	0.37
	Li	0.2	0.8	<LOQ	<LOQ	4.0	0.2	0.8
	Mo	0.01	0.36	<LOQ	<LOQ	5.35	<LOQ	<LOQ
	Sb	0.02	0.02	<LOQ	<LOQ	0.06	0.01	<LOQ
	Sn	0.2	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Other Elements	Al	0.2	191.9	10.4	3.4	216.9	10.4	3.8
	B	0.6	4.4	<LOQ	<LOQ	8.5	<LOQ	<LOQ
	Ca	17	1045	33	<LOQ	2550	55	33
	Fe	4	<LOQ	<LOQ	<LOQ	136	<LOQ	<LOQ
	K	65	1168	116	65	2715	127	91
	Mg	2	176	4	<LOQ	556	6	3
	Mn	0.3	61.8	2.3	0.9	69.4	1.2	0.6
	Na	3	15586	1403	788	21983	1089	465
	Si	10	2779	746	746	3676	1378	1093
	Sr	0.2	4.9	0.2	<LOQ	33.6	0.9	0.8
	W	0.01	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	Zn	20	<LOQ	<LOQ	<LOQ	23	1.2	7.96
Zr	0.01	0.95	<LOQ	<LOQ	1.07	0.09	<LOQ	

E. USP <788> Particulate Matter in Injections

90-mm discs of 3M™ Zeta Plus™ DELI Grade Filter Media produced at different global plants 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. Filtrate 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™ DELI Grade Filter Media 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 38 and 39.

Table 38. Particulate Matter of 3M™ Zeta Plus™ Media DELI – No Treatment						
Single Layer Media						
DELI						
Number of Manufacturing Lots: 2						
Particulate Size	18 Megohm Water (25°C)	Flush Volume				Static Soak
		33%	66%	100%	200%	
>10 µm	4.1	25.7	14.4	26.7	4.9	46.9
>25 µm	0.1	0.6	0.4	0.4	0.3	1.1

Table 37. Particulate Matter of 3M™ Zeta Plus™ Media 9ELI – Post-Autoclave						
Single Layer Media						
DELI						
Number of Manufacturing Lots: 2						
Particulate Size	18 Megohm Water (25°C)	Flush Volume				Static Soak
		33%	66%	100%	200%	
>10 µm	4.1	86.1	65.4	26.3	2.7	40.8
>25 µm	0.1	1.0	1.0	0.8	0.2	0.7

F. USP <85> Bacterial Endotoxin

As part of the product release tests for every media lot at each global plant, a 45-mm disc of 3M™ Zeta Plus™ DELI Grade Filter 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/m². 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 3M™ Zeta Plus™ DELI Grade Filter Media is < 0.25 EU/mL, 3M™ Zeta Plus™ DEL1 Grade Filter Media is ≤ 0.25 EU/mL, and 3M™ Zeta Plus™ DEL1LP Grade Filter Media is ≤ 0.125 EU/mL. The specification is based on a flush of single layer media, even for dual layer media products. Therefore, the 3M™ Zeta Plus™ DELI Grade Filter 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™ 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, BC Series Filter Capsules, Encapsulated System Filter Capsules, and Encapsulated System Scale-Up Filter Capsules with DELI Grade Media:

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

Shelf Life of 3M™ Manifolds:

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

All 3M™ Zeta Plus™ Filters with DELI Grade Media and 3M™ Manifolds should be stored in a controlled environment with an average temperature between 5 and 30°C with short term excursions to 50°C, and relative humidity less than 90%. All 3M™ Zeta Plus™ Filters with DELI Grade Media and 3M™ Manifolds 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.

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 DELI Grade 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.

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 on request.

Certificates are provided in support of the release of the 3M™ Zeta Plus™ Filters with DELI Grade Media.

The 3M™ Zeta Plus™ Filters with DELI Grade 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 DELI Grade 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 DELI Grade Media are available in the US as courtesy.

Intended Use(s): 3M™ Zeta Plus™ Filters with DELI Grade 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.

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