



February 13, 2023

Subject: Formal Notification of Calcium and Iron Extraction Test Method Change for 3M™ Zeta Plus™ Filter Media

3M Products: 3M™ Zeta Plus™ Depth SP, ZB, LA, LP, VR, M, CP, 01AP, CA, DELI, and DELP Series Filter Media, all finished formats (Capsules, Cartridges, and Sheets)

Filter Media Manufacturing, Media Testing, and Finished Filter Assembly Locations:

3M Stafford Springs, 32 River Road, Stafford Springs, CT, USA 06076

3M Wroclaw, Kowalska 143, 51-424 Wroclaw, Poland

3M Australia, 140 Sunnyholt Road, Blacktown, NSW, Australia 2148

3M Mazerès, 2 rue de Bouque de Lens 31260 Cassagne, France

Finished Filter Assembly-Only Location:

3M Columbia, 5400 Paris Road, Columbia, MO, USA, 65202

3M Ibaraki, 880-21 Fujigaoka, Sekimoto-cho, Kitaibaraki-shi, Ibaraki 319-1725 Japan

3M Guangzhou, 9 Nanxiang Er Road, Science City, Guangzhou, 510663 P.R.China

Dear Valued Customer,

This notification letter is to inform you of a change in test method procedure for our 3M™ Zeta Plus™ SP, ZB, LA, LP, VR, M, CP, 01AP, CA, DELI, and DELP Filter Media manufactured at the “Filter Media Manufacturing...” locations listed above.

NOTE: There is no change to any media release specifications with this test method change.

The change only impacts the Calcium Extraction and Iron Extraction test methods, which currently are tested without any preconditioning flush.

Following implementation of this change, the Zeta Plus filter media will be flushed prior to running Calcium and Iron extraction testing. This updated test method more closely aligns with standard customer use and 3M’s required (SP, ZB, LA, LP, VR, M, DELI, and DELP Series) or recommended (CA, CP, and 01AP Series) pre-conditioning flush.

The Regulatory Support File (RSF) for each Zeta Plus Filter Media Series listed above will be updated to include the pre-conditioning flush in the description of the Calcium and Iron extraction testing. The test property listed on Certificates of Analysis will be updated to reflect the latest RSF revision numbers.

Timing of change

Changes will be implemented on or after May 14, 2023, which provides around 90 days for you to review this change and update your records, in accordance with our standard change notification procedures. Updated RSFs and sample certificates are available upon request from the following email address: spsdagreementsandSurveys.us@mmm.com.

- Table 1 includes a description of the change.
- Table 2 shows a comparison of the current and new test method descriptions that can be found in the RSFs.
- Table 3 shows the updated RSF document revision numbers.

For 3M™ Zeta Plus™ SP Series Filter Media Customers, all media manufacturing locations:

The 3M™ Zeta Plus™ SP Series Filter Media RSF will also include the addition of 3M Australia as a qualified media manufacturing and filter assembly location. The average values for performance verification and effluent quality shown in Sections VI and VII, respectively, of the RSF have been recalculated to include test results from 3M Australia. **There is no impact to media release specifications or any changes to filter media manufactured at 3M Stafford Springs or 3M Wroclaw.**

For 3M™ Zeta Plus™ CP and 01AP Series Filter Media Customers:

The 3M™ Zeta Plus™ CP and 01AP Series Filter Media RSF will also include:

- the addition of 3M Australia as a qualified media manufacturing location for CP Series Media.
- the removal of 3M Wroclaw as a qualified media manufacturing location for CP Series Media.

There is no impact to media release specifications or any changes to filter media manufactured at 3M Stafford Springs or 3M Wroclaw.

We appreciate your continued use of 3M products and look forward to assisting with any questions regarding these changes. We encourage you to contact your 3M account representative if you require further information.

Sincerely,



Brian Ochs
Global Quality Manager
3M Biopharmaceutical Purification Business



Tyler Yoder
Global Portfolio Marketing Manager
3M Biopharmaceutical Purification Business

Table 1: Change Overview

Change Description: <i>(Change Level in parentheses accords with BPSA guidelines)</i> These changes are traced via the lot number of each product.	
1. <i>(Level 2)</i> Change in Test Method	<ul style="list-style-type: none"> Calcium Extraction and Iron Extraction test method procedures will be updated to include a preconditioning flush of media samples. The change only impacts the Calcium Extraction and Iron Extraction test methods, which currently are tested without any preconditioning flush. <ul style="list-style-type: none"> This new test method more closely aligns with standard customer use and 3M's required pre-conditioning flush (3M™ Zeta Plus™ SP, ZB, LA, LP, VR, M, DELI, and DELP Series Filter Media) or recommended pre-conditioning flush (3M™ Zeta Plus™ CP, CA, and O1AP Series Filter Media). Table 2 shows the change in test method descriptions found in the RSFs. There is no impact to any media release specifications due to these test method changes.
2. <i>(Level 2)</i> Changes to Regulatory Support File (RSF) requiring Major Revision but do not change specifications	<ul style="list-style-type: none"> RSFs will reflect the updated test methods. Table 3 includes a list of the updated RSF revision numbers. RSFs have been updated to reflect commercially available product configurations. <i>3M™ Zeta Plus™ SP Series Filter Customers only:</i> As stated above, the Zeta Plus SP Series Media RSF will also reflect the addition of 3M Australia. <ul style="list-style-type: none"> Sections VI and VII in the RSF will be updated to reflect recalculated global average performance verification and effluent quality values by adding 3M Australia. There is no change to media release specifications associated with the addition of 3M Australia. There is no change to any media manufactured at 3M Stafford Springs or 3M Wroclaw. <i>3M™ Zeta Plus™ CP and O1AP Series Filter Customers only:</i> As stated above, the Zeta Plus CP and O1AP Series Media RSF will also reflect the addition of 3M Australia as a qualified media manufacturing location for CP Series Media and the removal of 3M Wroclaw as a qualified media manufacturing location for CP Series Media. <ul style="list-style-type: none"> There is no impact to media release specifications or any changes to filter media manufactured at 3M Stafford Springs or 3M Wroclaw.
3. <i>(Level 2)</i> Changes to Certificate of Analysis or other product certificate	<ul style="list-style-type: none"> For Certificate of Analysis (CoA), the Test Property RSF reference will be updated to the new RSF revision (<i>i.e.</i>, 0123) described above. See Table 3 for a list of updated RSF revision numbers found in the certificate Test Property field.
What is NOT changing:	
<ul style="list-style-type: none"> Product form, fit, or function Product specification Product use or operating instructions 	
Impact Assessment: No change to product form, fit, function, or specifications.	
Qualification Plan: This change harmonizes the media test methods with customer product use requirements regarding the pre-conditioning flush. The updated test method with the pre-conditioning flush has been verified to meet media release specifications. The addition of a preconditioning flush does not affect the analysis of the samples, therefore the analysis using ICP does not need to be revalidated.	

Table 2: Calcium Extraction and Iron Extraction test method description changes in each 3M™ Zeta Plus™ Filter Regulatory Support File

FROM	<p>Calcium Extraction: Determined by soaking media in deionized (DI) water at a ratio of 1 gram of media to 10 mL of water for 24 hours at ambient temperature and analysing the water for soluble calcium. The result is normalised as mg of calcium per gram of media.</p> <p>Iron Extraction: Determined by soaking media in DI water at a ratio of 1 gram of media to 10 mL of water for 24 hours at ambient temperature and analysing the water for soluble iron. The result is normalised as mg of iron per gram of media.</p>
TO	<p>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.</p> <p>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.</p>

Table 3: Updated Regulatory Support File references, only for products with Certificate of Analysis*

Regulatory Support File Document Title	RSF Revision with updated test method
3M™ Zeta Plus™ ZB Series Filters	70020340116 REV 0123
3M™ Zeta Plus™ ZB Series Filters Supplement	Supplement 10-715864 REV 0123
3M™ Zeta Plus™ VR08, VR07, and VR08A Series Filters	70020340116 REV 0123
3M™ Zeta Plus™ SP Series Filters	RSF 70020339548 REV 0123
3M™ Zeta Plus™ SP Series Filters Supplement	RSF Supplement 10-714831 REV 0123
3M™ Zeta Plus™ LA Series Filters	RSF 70020345107 REV 0123
3M™ Zeta Plus™ LA Series Filters Supplement	RSF Supplement 70020425081 REV 0123
3M™ Zeta Plus™ LP Series Filters	RSF 70020188226 REV 0123
3M™ Zeta Plus™ DELI Series Filters	RSF 70020188176 REV 0123
3M™ Zeta Plus™ DELP Series Filters	RSF 70020188192 REV 0123
3M™ Zeta Plus™ 01AP and CP Series Filters	RSF 70020345099 REV 0123
3M™ Zeta Plus™ M Series Filters Supplement	RSF Supplement 10-714825 REV 0123
3M™ Zeta Plus™ CA Series Filters	RSF 70020188168 REV 0123