**Avantor,Inc.**
100 Matsonford Rd., Suite 200
Radnor, PA 19087 USA
www.avantorsciences.com

# Sodium Carbonate

**Product Regulatory Data Sheet**

## *Section 1 – Product Information*

### Products Covered

| Brand | Product Code | Product Description | MOC* code |
|---|---|---|---|
| J.T.Baker® | 3600 | Sodium Carbonate, Monohydrate, Crystal N.F. - F.C.C. | R |
| J.T.Baker® | 3603 | Sodium Carbonate, Monohydrate, Crystal, N.F. Multi-Compendial | R |
| J.T.Baker® | 3605 | Sodium Carbonate, Anhydrous, Granular N.F. - F.C.C. | R |
| J.T.Baker® | 3606 | Sodium Carbonate, Anhydrous, N.F. Multi-Compendial | R |
| J.T.Baker® | 3642 | Sodium Carbonate, Anhydrous N.F., A.C.S. | R |
| J.T.Baker® | BS18 | Sodium Carbonate, Anhydrous, N.F. Multi-Compendial | R |
| J.T.Baker® | LP08 | Sodium Carbonate, Anhydrous N.F. - F.C.C. | R |

*MOC = Management of Change

## *Section 2 – Manufacturing, Packaging and Release Site Information*

The products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

A number of the cGMP produced products that are sold by Avantor may not be originally manufactured at our sites. However, we perform the analytical and stability testing for these products and repackage the products where applicable. With ISO and cGMP procedures, in place at our facilities we can ensure, and take complete responsibility for, the traceability and quality of the finished, packaged product that we offer.

For J.T.Baker® and Macron Fine Chemicals™ brand products, the Original Manufacturer and address will be referenced on the Certificate of Analysis as an alpha or alpha-numeric **manufacturer code** rather than listing the full name and address. This practice is compliant with both ICH Q7 Good Manufacturing Guidance for Active Pharmaceutical Ingredients (APIs) and IPEC guidelines and it meets cGMP requirements. For instructions to decipher the manufacturer reference code please consult the Avantor website. Instructions can be found by visting the Ask Avantor link under the Resources tab or by directly linking to www.askavantor.com Keyword: Manufacturer Code. Additonal information on Avantor suppliers may be available under NDA. Please reach out to the support contact in Section 7 for additional supplier information inquiries.

*Section 3 – Physical/Chemical Information*

**CAS #:** Product codes 3600, 3603: 5968-11-6
Product codes 3605, 3606, 3642, BS18, and LP08: 497-19-8

**Manufacturing Process:** Synthesis. Additional manufacturing process information may be disclosed under NDA upon request from the support contact in Section 7.

**Raw Material Origin:** Chemical

*Section 4 – Regulatory Information*

**DMF:** Avantor may hold Master File(s) for specified product codes, dependant on the country of interest. Inquire with the support contact in Section 7 for additional details.

**BSE/TSE Status:** The subject materials are manufactured from raw materials that contain NO animal parts, products, and/or by-products nor do they come in contact with animal parts, products, and/or by-products.

**Allergen/Hypersensitivities Information:** To the best of our knowledge the allergens listed in the US FDA, EU Directive 2003/89/EC, and TG0-91/92 are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

Avantor does not produce any of the following types of products: Antibiotics, Aflatoxins, Penicillin, Semi-Synthetic Penicillins, Cephalosporins, other Beta-Lactams, Antibiotics, Cytotoxics, Steroids, Medicated Feeds, or Pesticides.

This product is manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other contaminants. However, this product is not tested for the presence of these or any other allergens by Avantor, therefore, we do not have confirmation for the absence of any allergens in the product.

**GMO Information:** The subject materials, including any raw materials and processing aids, are NOT subject to genetic modification.

**Residual Solvents/Organic Volatile Impurities (OVI) Information:** The subject materials (all lots) comply with the requirements of the ICH Q3C Residual Solvents Guideline and USP<467>Residual Solvents. No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

**Elemental Impurities:** Please see attached summary for Elemental Impurity information for listed products.

**Kosher Status:** Certified Kosher – Pareve for year-round use. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on AskAvantor for our most up to date listing of Kosher products. (www.askavantor.com Keyword: Kosher). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

**Halal Status:** The subject materials are not Halal Certified. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on AskAvantor for our most up to date listing of Kosher products. (www.askavantor.com Keyword: Halal). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

**GRAS Status:** The United States Food and Drug Administration (FDA) have acknowledged that some chemicals may be considered Substances Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per specific 21 CFR regnums. For the latest information on whether or not an Avantor product is considered GRAS, please visit the Electronic Code of Federal Regulations.

**Nutritional/Supplement Facts Labeling:** The product codes 3600, 3605, and LP08 listed in Section 1 are bulk food chemicals that are intended for the use in manufacturing of finished food products or for products that are to be processed, labeled, and/or repacked at a site other than where it's originally processed or packed and are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements (21 CFR 101.9(j)(9)).

**Organic Status:** The product codes 3600, 3605, and LP08 listed in Section 1 are not certified as organic. However, to the best of our knowledge, the product is not produced using Ionizing Radiation as described in 21 CFR 179.26 or Sewage Sludge as described in 7 CFR Section 205.2.

---

*Section 5 – Miscellaneous Product Information*

**Certificate of Analysis Date Format:** The Manufactured Date and Expiration/Retest Date on the CofA are reported as YYYY-MM-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2012-10-01.

**Lot Numbering System and Batch Description**: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to AskAvantor for information concerning our lot/batch numbering system. (www.askavantor.com Keyword: Lot Number). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

**Batch Definition**: A "batch" is a homogeneous unit of production; each batch of is from one single batch of the source supplier.

**Shelf Life Information:** If a product has an assigned expiration or retest period, the date will appear on the Certificate of Analysis. For products that do not have assigned dates, please reach out to the support contact in Section 7 for additional stability inquiries.

**Management of Change:** For J.T.Baker® and Macron Fine Chemicals™ brand products please refer to Management of Change link under Working with Avantor tab on the Avantor website. For other branded products, please reach out to the support contact in Section 7 for information on the applicable management of change process.

**Country of Origin Statement:** Country of Origin is indicated on the product Certificate of Analysis. If you require further documentation, please reach out to the Trade Compliance support contact in Section 7.

**Storage Requirements:** Please refer to the product's Certificate of Analysis or Product Specifications. In the absence of specific storage conditions listed on its specification sheet or Certificate of Analysis, products are to be stored in ambient conditions of temperature and humidity. We do not formally tie any specific temperature or humidity range with the 'ambient' storage designation, but an example of a common temperature interpretation is 15-30°C. Our products are also packaged to protect from the normal variation in humidity during storage and shipment. Further handling and storage information may be found in Section 7 of the product's SDS sheet.

**Certificates of Analysis:** For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current list of product specifications using our Certificate/SDS Search tool on our website here. For other branded products, please see the current list of product specifications using the Certificate/SDS Search tool on our website here.

**Safety Data Sheet:** For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current product safety information using our Certificate/SDS Search tool on our website here. For other branded products, please see the current list of product specifications using the Certificate/SDS Search tool on our website here.

**Avantor Site Certifications:** Please see the current Avantor site certifications on our website here.

**Site Quality Overview:** Avantor maintains a self-assesment modeled after IPEC guidelines which describes site and quality system information to support the manufacturing activities of this product. Please reach out to the support contact in Section 7 for a current copy of the Site Quality Overview.

**Packaging Information:** Please reach out to the support contact in Section 7 for current packaging specifications.

---

*Section 6 – Revision History*

Rev. 0; Oct. 1, 2007 – IPEC EIP format
Rev. 1; Jan. 2, 2009 – Section 3: added CAS No for monohydrate form; Section 4: updated residual solvents info to include USP<467>; Section 7: updated phone number for Director of Customer Service

Rev. 2; Jan. 29, 2010 – Entire document: new letterhead and changed all references of "Solv IT Center" to "AskMBI."; Section 7: updated TS manager info. Section 4: added Residual Metallic Catalysts and GRAS statements. (KES)
Rev. 3; April 18, 2011 – Entire document: new letterhead and changed all references of "Solv IT Center" or "AskMBI" to "AskAvantor." Updated website links for new website; Section 7: updated contact information. Removed delisted product J.T. Baker 0360. Added GRAS, Residual Metallic Catalysts, Nutritional and Organic statements. MCH
Rev. 4; August. 25, 2014 – HDQ address change; Section 4: added add'l allergens as listed in EU Directive 2003/89/EC; added Residual Metallic Catalysts statement; separated Kosher/Halal status and added certification statement Section 5: Added COA Date Format statement; added Management of Change information; Section 7: removed contact list table and added CS/TS contact information. (MCH)
Rev. 5; December 8, 2014 – Section 1: Added code 3642. (MCH)
Rev.6; January 7, 2019 – Entire document: new format, letterhead (company name & headquarters address, updated email from @avantormaterials.com to @avantorsciences.com); Section 4: Removed Residual Metallic Catalyst statement, replaced with Elemental Impurities. (MCH) Section 5: added Stroage Requirement, Batch Definition, and Country of Origin Statements
Rev. 7; January 14, 2022 – Entire Document: Minor formatting; Header: Added company name, Avantor, Inc. Section 1: Added product codes BS18 and LP08; Section 2: Minor updating to language; Section 4: Removed Compendial Compliance statement. Updated format of DMF and Allergen/Hypersensitivities statements. Specified certificate availability for different branded products for Kosher and Halal Status statements. Generalized GRAS Status statement; Section 5: Updated Certificate of Analysis Date Format statement. Updated contact information directions for Lot Numbering System and Batch Description, Country of Origin Statement, Shelf Life Information, and Management of Change statements. Moved Nutritional/Supplemental Facts Labeling and Organic status statements and specified product codes. Added Certificates of Analysis, Safety Data Sheet, Avantor Site Certifications, Site Quality Overview, and Packaging Information statements; Section 7: Removed Fax number and Customer Service contact information. Added contacts. Added new product codes to Elemental Impurity assessment. (KH)

---

***This electronic document is valid without a signature.***

---

***Section 7 – Contact Information***


Technical Service

Phone: 1-855-282-6867 and 1-610-573-2600 (outside U.S.), select option 5
Email: Technical.Service@avantorsciences.com

Regulatory Support

Email: regulatory.support@avantorsciences.com

Trade Compliance

Email: Trade.Compliance@avantorsciences.com

---

While the above information is provided in good faith and believed to be accurate as of the date provided, Avantormakes no representations or warranties as to the accuracy or completeness of such information. All Avantor products are subject to Avantor's terms and conditions of sale including the limitations of liability contained therein and any contrary terms and conditions are expressly rejected. As Avantor has no control over purchasers' uses of its products, Avantor expressly disclaims all liability with respect to same.

The most current revision of this document is maintained on our website. Reviews and revisions are performed as warranted due to product changes or as part of the supplier audit cycle and managed under a validated document control system.

**Material Name**: Sodium Carbonate Monohydrate **Product codes**: 3600, 3603 **Date**: July 13, 2018

**Source/Type of Excipient**: ☐ Mineral; ☐ Mineral derived; ☐ Plant; ☐ Plant derived; ☒ Synthetic; ☐ Fermentation derived

Other (explain):

No Class 1, 2A, 2B, or 3 elementals are intentionally added to the production process.

| Elemental Impurity | | Class | Likely to be Present | | | If Known, Please Identify the Expected Concentration /Units (or Range) | Analytical Method Used (and Limit of Detection if Available) | Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.) |
|---|---|---|---|---|---|---|---|---|
| Arsenic (inorganic) | As | 1 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Cadmium | Cd | 1 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Mercury (inorganic) | Hg | 1 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Lead | Pb | 1 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Cobalt | Co | 2A | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Nickel | Ni | 2A | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Vanadium | V | 2A | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |

| Elemental Impurity | | Class | Likely to be Present | | | If Known, Please Identify the Expected Concentration /Units (or Range) | Analytical Method Used (and Limit of Detection if Available) | Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.) |
|---|---|---|---|---|---|---|---|---|
| Silver | Ag | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Gold | Au | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Iridium | Ir | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Osmium | Os | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Palladium | Pd | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Platinum | Pt | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Rhodium | Rh | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Ruthenium | Ru | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Selenium | Se | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Thallium | Tl | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |

| Elemental Impurity | | Class | Likely to be Present | | | If Known, Please Identify the Expected Concentration /Units (or Range) | Analytical Method Used (and Limit of Detection if Available) | Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.) |
|---|---|---|---|---|---|---|---|---|
| Barium | Ba | 3 | Yes ☒ | No ☐ | Unknown ☐ | 0.16 – 0.22 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, range reported |
| Chromium | Cr | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Copper | Cu | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Lithium | Li | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Molybdenum | Mo | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Antimony | Sb | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Tin | Sn | 3 | Yes ☒ | No ☐ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014

David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department

Avantor™ Performance Materials, LLC



**Material Name**: Sodium Carbonate Anhydrous **Product codes**: 3605, 3606, 3642, BS18, LP08 **Date**: July 13, 2018 Rev. 1

**Source/Type of Excipient**: ☐ Mineral; ☐ Mineral derived; ☐ Plant; ☐ Plant derived; ☒ Synthetic; ☐ Fermentation derived

Other (explain):

No Class 1, 2A, 2B, or 3 elementals are intentionally added to the production process.

| Elemental Impurity | | Class | Likely to be Present | | | If Known, Please Identify the Expected Concentration /Units (or Range) | Analytical Method Used (and Limit of Detection if Available) | Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.) |
|---|---|---|---|---|---|---|---|---|
| Arsenic (inorganic) | As | 1 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Cadmium | Cd | 1 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Mercury (inorganic) | Hg | 1 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Lead | Pb | 1 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Cobalt | Co | 2A | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Nickel | Ni | 2A | Yes ☒ | No ☐ | Unknown ☐ | <0.05 – 0.07 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, range reported |
| Vanadium | V | 2A | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Silver | Ag | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Gold | Au | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Iridium | Ir | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |

| Elemental Impurity | | Class | Likely to be Present | | | If Known, Please Identify the Expected Concentration /Units (or Range) | Analytical Method Used (and Limit of Detection if Available) | Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.) |
|---|---|---|---|---|---|---|---|---|
| Osmium | Os | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Palladium | Pd | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Platinum | Pt | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Rhodium | Rh | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Ruthenium | Ru | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Selenium | Se | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Thallium | Tl | 2B | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Barium | Ba | 3 | Yes ☒ | No ☐ | Unknown ☐ | 0.16 – 0.22 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, range reported |
| Chromium | Cr | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Copper | Cu | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |

| Elemental Impurity | | Class | Likely to be Present | | | If Known, Please Identify the Expected Concentration /Units (or Range) | Analytical Method Used (and Limit of Detection if Available) | Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.) |
|---|---|---|---|---|---|---|---|---|
| Lithium | Li | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Molybdenum | Mo | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Antimony | Sb | 3 | Yes ☐ | No ☒ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |
| Tin | Sn | 3 | Yes ☒ | No ☐ | Unknown ☐ | <0.05 ppm | ICP-MS (MRL=0.05 ppm) | 3 commercial batches tested, all below detection limit |

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014

David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department