L-Histidine Monohydrochloride

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered:

<table>
<thead>
<tr>
<th>Brand</th>
<th>Product Code</th>
<th>Product Description</th>
<th>MOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>J.T.Baker®</td>
<td>2081</td>
<td>L-Histidine Monohydrochloride, F.C.C. Multi-Compendial</td>
<td>R</td>
</tr>
</tbody>
</table>

*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 Performance Materials, LLC. may not be originally manufactured at our sites. However, we perform the analytical and stability testing for these products and repackaged 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.

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 our website. Instructions can be found in the Ask Avantor QA Center of the support section of our web site or by directly linking to Ask Avantor Keyword: Manufacturer Code.
Section 3 – Physical/Chemical Information

CAS #: 5934-29-2

Manufacturing Process:
Batch- Fermentation, Purification

Raw Material Origin:
Plant

Section 4 – Regulatory Information

Compendial Compliance: Please see the current product specifications at www.AvantorInc.com.

DMF: Avantor Performance Materials, LLC. does not carry a Drug Master File for these products.

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:
The products listed do not contain cereals containing gluten (i.e. wheat, rye, oats, barley, spelt, kamut or their hybridized strains), malt, triticale, gluten, other grains, corn, soy, soybeans, eggs, yeast, canola, milk, dairy products, fish, crustacean shellfish, seafood products, tree nuts, peanuts, nut products (i.e. Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illiniesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia)), seed products (sesame seeds and products thereof), natural grape products, natural flavors, artificial flavors, artificial colors, celery, mustard, lactose, sulfites, elemental sulfur, preservatives, MSG, disodium guanylate/inosinate, artificial sweeteners, phenylalanine, additives, colorants, dyes, or natural rubber (latex). These products are manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other products.

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 above 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.

Aflatoxins:
Aflatoxins as defined by IPEC (International Pharmaceutical Excipient Council) are a group of structurally related toxic compounds produced by certain strains of the fungi Aspergillus flavus and A. parasiticus. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. Aflatoxicosis is poisoning that results from ingestion of aflatoxins in contaminated food or feed.

Avantor does not analyze the product(s) for the presence of aflatoxin content, does not maintain a specification for aflatoxin and cannot provide any guarantee of complete absence in the product(s) due the nature of aflatoxins.
However, we can confirm the subject materials do not contain, nor are they manufactured with any product commonly affected by aflotoxins. These include cereals (maize, sorghum, pearl millet, rice, wheat), oilseeds (peanut, soybean, sunflower, cotton), spices (chili peppers, black pepper, coriander, turmeric, ginger), and tree nuts (almond, pistachio, walnut, coconut, Brazil nut).

**Kosher Status:**

The subject materials are not Kosher Certified.

Please refer to the customer support section of our website for our most up to date listing of Kosher products. (Ask Avantor Keyword: Kosher)

**Halal Status:**

The subject materials are not Halal Certified.

Please refer to the customer support section of our website for our most up to date listing of Halal products. (Ask Avantor Keyword: Halal)

**GRAS Status:**

These products have not been assessed for GRAS Status.

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L-Histidine Monohydrochloride
Section 5 – Miscellaneous Product Information

Certificate of Analysis Date Format: The Manufactured Date and Expiration/Retest Date on the C of A are reported as YYYY/MM/DD from our ERP system effective April 30, 2012. For example, the Manufactured Date for October 1, 2012 would be reported as 2012/10/01

Lot Numbering System and Batch Description: Please refer to the customer support section of our website for information concerning our lot/batch numbering system. (Ask Avantor Keyword: Lot Number)

Batch Definition: A “batch” is a homogeneous unit of production; each batch of material 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 contact Technical Support through the customer support section of our website for our product stability profiles. (Ask Avantor Keyword: Expiration)

Nutritional/Supplement Facts Labeling: are to be processed, labeled, and/or repacked at a site other than where it’s originally processed or packed, are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements. (21 CFR 101.9(j)(9))

Organic Status: The products 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.

Management of Change: Please refer to the customer support section of our website for information concerning our Management of Change program. (Ask Avantor Keyword: MOC)

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. Please contact our Trade Compliance Department if you require further documentation. (Trade.Compliance@AvantorInc.com)

Storage Requirements: Please refer to the product Certificate of Analysis/Product Specifications. In the absence of specific storage conditions listed on the Avantor specification sheet or certificate of analysis, our 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 SDS sheet.

Section 6 – Revision History

Rev. 0; Oct. 1, 2007 – IPEC EIP format
Rev. 1; Oct. 15, 2008 – Section 4: updated residual solvents information
Rev. 2; August 10, 2011 – Entire document: new letterhead, and changed all references of “Solv IT Center” to “Ask Avantor.” Updated website links for new website; Section 1: added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; added Residual Metallic Catalyst statement; Section 5: Added Nutritional/Supplemental Facts Labeling and Organic Status statements; Section 7: updated contact information; minor formatting. PH/MCH.
Rev. 3; Oct 15, 2012- HDQ address change minor formatting. Section 4: Added add’l allergens as listed in EU Directive 2003/89/EC; updated Residual Metallic Catalysts statement; Section 5: Added Management of Change information; Section 7: Removed contact list table and added CS/TS contact information. (MCH)
Rev. 4; May 15, 2017- Updated template to new Avantor Log/Information. Changed Inc. to LLC. throughout document. Section 4; added information to the allergen statement; removed residual metallic catalysts statement;
added Elemental Impurities statement and summary; added Aflatoxin statement; separated Halal and Kosher statements. Section 5: Added Batch Definition; added Country of Origin Statement; added Storage Requirements. Section 7: Updated contact information. (CMG)

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service
Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650
CS.Specialist@AvantorInc.com

Technical Service
Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650
Technical.Service@AvantorInc.com

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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.

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**Material Name:** L-Histidine Hydrochloride Monohydrate  
**Product codes:** : 2081  
**Date:** June 28, 2016

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

Other (explain):

<table>
<thead>
<tr>
<th>Elemental Impurity</th>
<th>Class</th>
<th>Likely to be Present</th>
<th>If Known, Please Identify the Expected Concentration /Units (or Range)</th>
<th>Analytical Method Used (and Limit of Detection if Available)</th>
<th>Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic (inorganic)</td>
<td>As</td>
<td>Yes ☐ No ☒ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Cd</td>
<td>Yes ☐ No ☒ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Mercury (inorganic)</td>
<td>Hg</td>
<td>Yes ☐ No ☒ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Lead</td>
<td>Pb</td>
<td>Yes ☐ No ☒ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Cobalt</td>
<td>Co</td>
<td>Yes ☐ No ☒ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Nickel</td>
<td>Ni</td>
<td>Yes ☐ No ☒ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Vanadium</td>
<td>V</td>
<td>Yes ☐ No ☒ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Elemental Impurity</td>
<td>Class</td>
<td>Likely to be Present</td>
<td>If Known, Please Identify the Expected Concentration/Units (or Range)</td>
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<tr>
<td>-------------------</td>
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<td>---------------------------------------------------------------------</td>
<td>---------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Silver</td>
<td>Ag</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Gold</td>
<td>Au</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Iridium</td>
<td>Ir</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Osmium</td>
<td>Os</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Palladium</td>
<td>Pd</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Platinum</td>
<td>Pt</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Rhodium</td>
<td>Rh</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Ruthenium</td>
<td>Ru</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Selenium</td>
<td>Se</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Thallium</td>
<td>Tl</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Barium</td>
<td>Ba</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Chromium</td>
<td>Cr</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
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<tr>
<td>Copper</td>
<td>Cu</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;2.0 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Lithium</td>
<td>Li</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Molybdenum</td>
<td>Mo</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Antimony</td>
<td>Sb</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
<tr>
<td>Tin</td>
<td>Sn</td>
<td>Yes ☐ No ☑ Unknown ☐</td>
<td>&lt;0.05 ppm</td>
<td>ICP-MS (MRL=0.05 ppm)</td>
<td>Avg. of 3 batches</td>
</tr>
</tbody>
</table>

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