Puritan Products Inc.
2290 Avenue A
Bethlehem, PA 18017
U.S.: 1-877-778-7482 | Fax: 1-610-866-4270
Outside U.S.: 1-610-573-2600
www.puritanproducts.com
www.avantorsciences.com

Hydrochloric Acid

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC* code
PURITAN PRODUCTS	2632__GMP	HYDROCHLORIC ACID, NF 36.5-38.0% MultiPUR GMP	R
PURITAN PRODUCTS	6365__GMP	HYDROCHLORIC ACID 4% (+/- 0.5%)	R
PURITAN PRODUCTS	6368__GMP	HYDROCHLORIC ACID, NF 36.5-38.0% MultiPUR GMP	R
PURITAN PRODUCTS	6372__GMP	HYDROCHLORIC ACID 6.00N SOLUTION PharmaPUR GMP	R
PURITAN PRODUCTS	6374__GMP	HYDROCHLORIC ACID 3.00 N SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	6377__GMP	HYDROCHLORIC ACID 0.1 N GMP REAGENT	R
PURITAN PRODUCTS	6378__GMP	HYDROCHLORIC ACID 5N PharmaPUR® GMP	R
PURITAN PRODUCTS	6379_GMP	HYDROCHLORIC ACID 0.24N SOLUTION PharmPUR GMP	R
PURITAN PRODUCTS	6380__GMP	HYDROCHLORIC ACID .5N(+/-.015N)	R
PURITAN PRODUCTS	6384__GMP	HYDROCHLORIC ACID 1.0N(+/-.02N)	R
PURITAN PRODUCTS	6396__GMP	HYDROCHLORIC ACID 2N PharmaPUR®	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. The subject materials prepared by Puritan Products, 2290 Avenue A, Bethlehem, PA 18017 are manufactured from hydrochloric acid, NF from an approved supplier and water purified according to USP requirements for manufacturing. The products do not originate from any component of animal or plant.

A number of the cGMP produced products that are sold by Puritan Products Inc. may not be originally manufactured at our sites. However, we perform the analytical 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 responsibility for, the traceability and quality of the finished, packaged product that we offer. For information regarding supply chain, please contact technical service at the address provided in section 7 of this document.

Section 3 – Physical/Chemical Information

CAS #: 7647-01-0

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

Section 4 – Regulatory Information

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

Animal origin (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.

Neither Avantor nor the Original Manufacturer 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.

The subject materials are not manufactured from, or processed with any potential allergenic products or ingredients such as peanuts or byproducts, tree nuts or byproducts, fish, milk, eggs, shellfish, soya or soybean products, wheat or gluten, synthetic or natural colors, chemical additives. The raw material is manufactured from synthesized or manufactured compounds on dedicated equipment and processed in a closed system not handled by employees.

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: No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

Melamine
The subject materials supplied by Puritan products are not produced or processed with melamine or materials considered to be at risk for melamine contamination. The raw materials used for the subject materials are not considered to be at risk of melamine contamination and the products are not tested for melamine contamination

Phthalates: Phthalates are not intentionally added during the manufacture of the hydrochloric acid products, nor are they used during the storage, analysis, or packaging of our products. To the best of our knowledge Phthalates, including di(2-ethylhexyl) phthalate (DEHP), are not present in the packaging materials used for the product.

Elemental Impurities: The subject products have not been assessed for Elementental Impurities.

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 MM/DD/YYYY

Lot Numbering System:
All Puritan Products brand chemicals have lot numbers containing 11 digits.
The first four digits of the lot number are the product code
The next three digits of the lot number represent the Julian date
The next two digits represent the last two digits of the year
The last two digits represent the sequence of lot numbers assigned that day
Please refer to the customer support section of our website for more information concerning our lot/batch numbering system. https://www.puritanproducts.com/resources-support/technical-resources/how-to-interpret-lot-number/

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. Dates are assigned in conformance with Puritan's Product Shelf Life/Expiration Date Policy (https://www.puritanproducts.com/wp-content/uploads/2018/04/7P10F1-Shelf-Life-Policy-19-FEB-2018-1.pdf) except where otherwise noted on the product CoA. The expiration date of a product is the shelf life period added to the manufacture date of the product and extended until the end of the month. Shelf life periods are valid for unopened containers only. For products that do not have assigned dates please contact Technical Support through the customer support section of our website

Management of Change: Puritan actively identifies changes both internally (our processes), and externally (our suppliers' processes) and requires our suppliers to have an MOC program, to which we subscribe and are notified when there are changes that impact our supply chain of certain products. We notify the appropriate personnel in your organization who have registered for our MOC program If your company purchased a Puritan Products brand material directly from us within the past three years, then the notice will be sent directly to the contacts within your organization. If your company purchased an affected Puritan Products brand product through one of our distribution channels, then the key personnel in the distribution channel will be notified Please refer to our website for additional information https://www.puritanproducts.com/quality/management-of-change/

Country of Origin Statement: The subject materials are manufactured in the United States of America.

Storage Requirements: Please refer to the product Certificate of Analysis. In the absence of specific storage conditions listed on the Product Certificate of Analysis, Purtian 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; April 19, 2021– Entire Document new format to align with IPEC EIP and Avantor global quality
Rev. 1; May 13, 2021 –Added product 6379_GMP HYDROCHLORIC ACID 0.24N SOLUTION PharmPUR GMP

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service
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