

### **GMP BIOTECH PRODUCT**

## L-ARGININE HYDROCHLORIDE

USP, EP, JP, GMP

CAS #: 1119-34-2

Formula: C<sub>6</sub>H<sub>14</sub>N<sub>4</sub>O<sub>2</sub> • HCl

F.W.: 210.66 g/mol

#### LARH-6350

## **BIO QUALIFIED GRADE**

LAINII-0550	
Analysis	SPECIFICATIONS
Appearance and Color	White or Almost White Crystalline Powder or Colorless Crystals
Ammonium (EP/JP)	< = 200 ppm
Appearance of Solution (EP)	Clear, Colorless Solution
Assay, Dried Basis (USP/EP/JP)	98.5 - 101.0%
Chloride Content (USP)	16.5 - 17.1%
Clarity and Color of Solution (JP)	Passes Test
Endotoxin	< = 5 EU/g
Identification, IR (USP-A/EP-B/JP-1)	Conforms to Reference Standard
Identification, Specific Optical Rotation (EP-A/USP/JP)	+21.5° to +23.5°
Identification C (EP)	Passes Test
Identification D (EP)	Passes Test
Identification, Chlorides (EP-E/JP-2)	Passes Test
Loss on Drying (USP/EP/JP)	<= 0.20%
Microbial Content TAMC TYMC	< = 100 CFU/g < = 10 CFU/g
Ninhydrin-Positive Each Individual Substances Impurity	< = 0.2%
(USP/EP) Total Impurities	< = 0.5%
pH (1 in 10) (JP)	4.7 - 6.2
Related Substances (USP/JP)	Passes Test
Residue on Ignition / Sulfated Ash (USP/EP/JP)	< = 0.1%
Sulfate (USP/EP/JP)	< = 280 ppm
Trace Metals  Arsenic (As) Iron (Fe) (EP) Lead (Pb)	< = 2 ppm < = 10 ppm < = 20 ppm

# Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

L-Arginine Hydrochloride is the monohydrochloride version of the base amino acid, L-Arginine. This product is synthesized under cGMP conditions.

#### **General Product Description**

- Appears as a white to almost white crystalline powder or colorless crystals
- GMP manufactured in accordance with the certified management system
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: L-Arginine monohydrochloride, L Arg. HCl, (25)-2-amino-5-(diaminomethylideneamino) pentanoic acid; hydrochloride
- Visit the product page on our website (<u>www.biospectra.us</u>) for additional information, supporting regulatory documents, and CoAs.

## **Storage and Shipping Conditions**

Refer to SDS.

#### **Standard Shelf Life Policy**

Each Certificate of Analysis (CoA) will contain a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

#### **Package Sizes**

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg

#### **Standard Lead Time**

2-4 weeks

### **Country of Origin: India**

Blended, tested and packaged in Bangor, PA, USA under cGMP conditions

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