

## **GMP BIOTECH PRODUCT**

# L-ARGININE HYDROCHLORIDE

BIOTECH, 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**

Analysis	SPECIFICATIONS
Appearance	White or almost white crystalline powder or colorless crystals
Ammonium (EP/JP)	≤ 200 ppm
Appearance of Solution (EP)	Clear, Colorless Solution
Arsenic (JP)	<u>&lt;</u> 2 ppm
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 IU/g
Heavy Metals (JP)	≤ 20 ppm
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, TLC (EP)	Passes Test
Identification D, Color (EP)	Passes Test
Identification, Chlorides (EP-E/JP-2)	Passes Test
Iron (EP)	≤ 10 ppm
Loss on Drying (USP/EP/JP)	<u>&lt;</u> 0.20%
Microbial Content TAMC TYMC	≤ 100 CFU/g ≤ 10 CFU/g
Ninhydrin-Positive Each Individual Substances Impurity (USP/EP) Total Impurities	≤ 0.2% ≤ 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)	<u>&lt;</u> 0.028%

## **Country of Origin: India**

Blended, Tested, Packaged in Bangor, PA, USA under full GMP conditions.

# Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

L-Arginine Hydrochloride is the mono hydrochlorinated version of the base amino acid, L-Arginine. This product is synthesized under full GMP conditions.

### **General Product Description**

- Appears as a white or near white crystalline powder
- Manufactured under a Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- 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/derivatives.
- Is not subject to genetic modification
- Synonyms: L-Arginine monohydrochloride,
  (S)-(+)-Arginine hydrochloride, L Arg. HCl
- Visit the product page on our website (<u>www.biospectra.us</u>) for additional information, supporting regulatory documents, and CofAs.

# **Storage and Shipping Conditions** Refer to SDS.

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

Each Certificate of Analysis (CofA) will contain a 2-year retest/recertification 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**

1-2 weeks