

GMP BIOTECH PRODUCT

L-ARGININE HYDROCHLORIDE

BIOTECH, USP, EP, JP, GMP

CAS #: 1119-34-2

Formula: C₆H₁₄N₄O₂ HCl

F.W.: 210.66 g/mol

LARH-6350

BIO QUALIFIED GRADE

| Analysis | SPECIFICATIONS |
|--|---|
| ANALYSIS | |
| Appearance | White or almost white crystalline powder or |
| | colorless crystals |
| Ammonium (EP/JP) | <u><</u> 200 ppm |
| Appearance of Solution (EP) | Clear, Colorless Solution |
| Arsenic (JP) | <u><</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 | <u><</u> 5 EU/g |
| Heavy Metals (JP) | <u><</u> 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) | <u>≤</u> 10 ppm |
| Loss on Drying (USP/EP/JP) | <u>≤</u> 0.20% |
| Microbial Content TAMC TYMC | ≤ 100 CFU/g ≤ 10 CFU/g |
| Ninhydrin-Positive Each Individual | <u>≤</u> 0.2% |
| Substances Impurity (USP/EP) Total Impurities | <u><</u> 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><</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