

GMP BIOTECH PRODUCT

L-ARGININE HCl BIOTECH, MEETS USP, EP, JP, GMP BIO QUALIFIED GRADE / LARH-6201

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

L-Arginine HCl is the mono hydro-chlorinated version of the base amino acid, L-Arginine. This product is synthesized and purified under full GMP conditions and meets multicompendial applications.

SPECIFICATIONS

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)		≤ 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
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)		<u><</u> 10 ppm
Loss on Drying (USP/EP/JP)		\leq 0.20%
Ninhydrin-Positive	Each Individual Impurity	≤ 0.2%
Substances (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)		<u>≤</u> 0.1%
Sulfate (USP/EP/JP)		≤ 0.028%



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General Product Description:

 $\begin{aligned} & Molecular \ Formula: \ C_6H_{14}N_4O_2 \cdot HCl \\ & Molecular \ Weight: \ 210.66 \ g/mol \end{aligned}$

CAS Number: 1119-34-2

L-Arginine HCl Biotech:

- Appears as a white or near white crystalline powder
- Is manufactured under an ISO Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- Has no known major food allergens (as defined by FDA and WHO)
- The final product nor its raw materials are not derived from nor come into contact with animals, animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: L-Arginine monohydrochloride, (S)-(+)-Arginine hydrochloride, L Arg. HCl

Shelf Life Policy:

Three-year expiry from the date of manufacture.

Storage and Shipping Conditions:

Please refer to the SDS for storage and shipping conditions.

Package Size:

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