

GMP BIOTECH PRODUCT

L-ARGININE HYDROCHLORIDE

BIOTECH, MEETS USP, EP, JP, GMP BIO QUALIFIED GRADE / LARH-6350

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

L-Arginine Hydrochloride 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

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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
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)	<u>≤</u> 10 ppm
Loss on Drying (USP/EP/JP)	≤ 0.20%
Microbial Content TAMO	_ &
Ninhydrin-Positive Substances Each Individual Impurity (USP/EP) Total Impurities	_ ``-
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)	<u>≤</u> 0.028%



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General Product Description:

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

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
- Is 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