BIOBUFFER SOLUTIONS

GMP Amino Acid

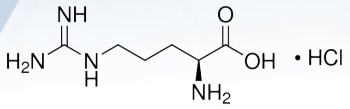
GMP Manufactured Product

ARGININE(L) HCl, USP, EP, JP, GMP Grade

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES 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 for use in GMP Pharmaceutical Production. Primary application is as a nutrient to cell culture media along with other GMP Pharma applications.

Lead Time (If No Stock): 3-months
Minimum Order Quantity: 500kg



CAS #: 1119-34-2
Molecular Formula:
$C_6H_{14}N_4O_2 \cdot HCl$
Solubility in Water (g/L): 40
F.W.: 210.66 g/mol

BIO PHARMA GRADE | Product Code: LARH-4220

$C_6H_{14}N_4O_2 \cdot HCl$ · F.W. 210.66 g/mol · CAS# 1119-34-2

These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

USP Compendia

ANALYSIS	SPECIFICATIONS
Assay (dried basis)	98.5% - 101.0%
Chloride Content	16.5% - 17.1%
Impurities — Individual Impurities Total Impurities	≤ 2.0% ≤ 0.5%
Identification, IR	Conforms with Reference
Identification, Optical Rotation, Specific Rotation	+21.5° to +23.5°
Loss on Drying	≤ 0.20%
Residue on Ignition, Sulfated Ash	≤ 0.1%
Sulfate	≤ 0.028%
Related Substances	Passes Test

EP Compendia

ANALYSIS	SPECIFICATIONS
Appearance	White or almost white crystalline powder or colorless crystals
Ammonium	≤ 0.02%
Appearance of Solution	Clear, Colorless Solution
Assay (dried basis)	98.5% - 101.0%
Identification, Specific Optical Rotation	+21.5° to +23.5°
Identification, IR	Conforms to Reference Standard
Identification C, TLC	Passes Test
Identification D, Color	Passes Test
Identification, Chlorides	Passes Test

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EP Compendia

ANALYSIS		SPECIFICATIONS
Iron		≤ 10 ppm
Loss on Drying		≤ 0.20%
Ninhydrin-positive substances	Each Individual Impurity Total Impurities	≤ 0.2% ≤ 0.5%
Residue on Ignition, Sulfated Ash		≤ 0.1%
Sulfates		≤ 0.028%

JP Compendia

ANALYSIS	SPECIFICATIONS
Ammonium	≤ 0.02%
Arsenic	≤ 2ppm
Assay (dried basis)	98.5 – 101.0%
Clarity and Color of Solution	Passes Test
Identification, IR	Conforms to Reference Standard
Identification, Specific Optical Rotation	+21.5 to +23.5°
Identification, Chlorides	Passes Test
Heavy Metals	≤ 20ppm
Loss on Drying	≤ 0.20%
pH (1 in 10)	4.7 – 6.2
Related Substances	Passes Test
Residue on Ignition, Sulfated Ash	≤ 0.1%
Sulfate	≤ 0.028%

General Product Description:

- L-Arginine HCl is produced at our cGMP platform in India and then shipped to our Bangor, PA facility where it is tested and repackaged under cGMP conditions.
- L-Arginine HCl is a white or almost white crystalline powder.
- Molecular Formula: $C_6H_{14}N_4O_2 \cdot HCl$
- Molecular Weight: 210.66 g/mol.
- CAS Number: 1119-34-2
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all L-Arginine HCl, LARH-4220 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- L-Arginine HCl manufactured at our cGMP Platform in India and any raw materials used in the manufacture of L-Arginine HCl at BioSpectra are not subject to genetic modification.
- Synonyms: L-Arginine monohydrochloride, (S)-(+)-Arginine hydrochloride, Arg, HCl, (S)-(+)-2-Amino-5-[(aminoiminomethyl)amino] pentanoic acid monohydrochloride

GMP Compliance:

Bio Pharma Grade L-Arginine HCl, LARH-4220 is suitable for use as a process chemical. It is manufactured in accordance with International Organization for Standardization (ISO) registered Quality Managed Systems. This grade of L-Arginine HCl is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Retest Date:

The recommended expiration period for L-Arginine HCl is two years from the date of manufacture.

Storage and Shipping Conditions:

Ship and Store in ambient temperature.

Package Sizes:

10kg, 25kg and 50kg pails.

Country of Origin:

India