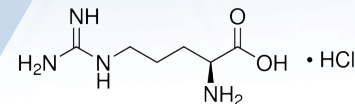


L-ARGININE HCl, USP, EP, JP, GMP Grade

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

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.



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
Appearance		White or almost white crystalline powder
Assay (dried basis)		98.5% - 101.5%
Chloride Content		16.5%- 17.1%
Chromatographic Purity		Conforms
Impurities	Individual Impurities Total Impurities	NMT 0.5% NMT 2.0%
Identification A (IR)		Passes Test
Loss on Drying @ 105°C		≤ 0.2%
Optical Rotation, Specific Rotation		+21.4° to +23.6°
Residue on Ignition		≤ 0.1%
Sulfate		≤ 0.03%

EP Compendia

ANALYSIS		SPECIFICATIONS
Ammonium		≤ 0.02%
Appearance of Solution		Passes Test
Assay (dried substance)		98.5% - 101.0%
Identification (A) Specific Optical Rotation		+21.0° to +23.5°
Identification B (IR)		Passes Test
Identification C		Passes Test
Identification D		Passes Test

EP Compendia

ANALYSIS		SPECIFICATIONS
Identification E- Chlorides		Passes Test
Iron		≤ 10 ppm
Loss on Drying@105°C		≤ 0.2%
Ninhydrin-positive substances	For each Impurity Total Impurities Reporting Threshold	NMT 0.2% NMT 0.5% 0.05%
Sulfated Ash		≤ 0.1%
Sulfate		≤ 300 ppm

JP Compendia

ANALYSIS		SPECIFICATIONS
Ammonium		NMT 0.02%
Arsenic		NMT 2ppm
Assay (dried basis)		98.5 - 101.5%
Clarity and Color of Solution		Passes Test
Identification 1 (IR)		Passes Test
Identification 2		Passes Test
Heavy Metals		≤ 20ppm
Loss on Drying		NMT 0.20%
Optical Rotation		+21.5 to +23.5°
pH (1 in 10)		4.7 -6.2
Related Substances		Passes Test
Residue on Ignition		NMT 0.1%
Sulfate		NMT 0.028%

Additional Analyses

ANALYSIS		SPECIFICATIONS
UV Absorbance	At 280nm	≤ 0.137
	At 400nm	≤ 0.023

General Product Description:

- The manufacturing of L-Arginine HCl LARH-4220 is performed at BioSpectra's Bangor, PA facility utilizing multi-use equipment. Equipment used in the manufacturing of LARH-4220 is cleaned in accordance with BioSpectra's Process Cleaning Validation Master Plan.
- 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 BioSpectra 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 the IPEC-PQG Joint Good Manufacturing Practice Guide. 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.