BIOSPECTRA
Premium Pharmaceutical Ingredients

GMP Process Chemical

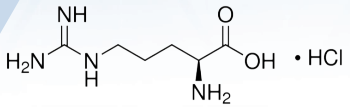
GMP Manufactured Product

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.

Lead Time: 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

Made in the USA

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 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

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

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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	NMT0.20%
Optical Rotation	+21.5 to +23.5°
pH (1 in l0)	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 At 400nm	≤ 0.137 ≤ 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.

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