

# **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 (If No Stock): 3-months Minimum Order Quantity: 500kg H<sub>2</sub>N H O OH • HCI

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<sub>6</sub>H<sub>14</sub>N<sub>4</sub>O<sub>2</sub>·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		Concordant 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		≤ 0.03%	

# **EP** Compendia

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

#### **EP Compendia**

А	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		≤ 0.0300%

#### JP Compendia

ANALYSIS	SPECIFICATIONS
Ammonium	≤ 0.02%
Arsenic	≤2ppm
Assay (dried basis)	98.5 – 101.0%
Clarity and Color of Solution	Clear and Colorless
Identification, IR	Passes Test
Identification, Specific Optical Rotation	+21.5 to +23.5°
Identification, Chlorides	Passes Test
Heavy Metals	≤ 20ppm
Loss on Drying	≤ 0.20%
рН	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<sub>6</sub>H<sub>14</sub>N<sub>4</sub>O<sub>2</sub> 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 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.

# **Country of Origin:**

India