

L-GLUTAMINE, USP, LBLE, GMP Excipient Grade

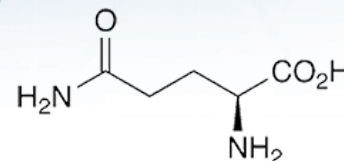
Low Bioburden, Low Endotoxin, GMP Manufactured

INTENDED FOR USE AS AN EXCIPIENT

Glutamine is an α -amino acid that is used in the biosynthesis of proteins. This product is synthesized and purified under full GMP conditions for use in GMP Pharmaceutical Production. L-Glutamine is used as a supplement energy source for certain types of mammalian cells and is used in other biopharmaceutical manufacturing applications.

Lead Time: 3-6 months

Minimum Order Quantity: If stock- 25kg/ No Stock- 150kg



CAS #: 56-85-9

Molecular Formula: $C_5H_{10}N_2O_3 \cdot 2H_2O$

Solubility in Water (g/L): 36

F.W.: 146.14 g/mol

pH (6M) @ 20°C: 4.5 - 6.0

BIO PHARMA GRADE | Product Code: LGLM-4250

$C_5H_{10}N_2O_3 \cdot 2H_2O$ F.W. 146.14 g/mol. CAS# 56-85-9

ANALYSIS	SPECIFICATIONS
Assay (dried basis)	98.5% - 101.5%
Appearance and Color	White crystals or crystalline powder
Chloride and Sulfate, <i>Chloride</i>	$\leq 0.05\%$
Chloride and Sulfate, <i>Sulfate</i>	$\leq 0.03\%$
Endotoxin	≤ 33.33 EU/g
Identification A (IR)	Passes Test
Iron	≤ 10 ppm
Loss on Drying	$\leq 0.3\%$
Optical Rotation, Specific Rotation @ 20°C	+6.3° to +7.3°
Residue on Ignition	$\leq 0.10\%$
Related Compounds	$\leq 0.5\%$



General Product Description:

- L-Glutamine 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-Glutamine is a White Crystalline product.
- Molecular Formula: $C_5H_{10}N_2O_3 \cdot 2H_2O$
- Molecular Weight: 146.14 g/mol.
- CAS Number: 56-85-9
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all L-Glutamine, LGLM-4250 at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- L-Glutamine manufactured at our cGMP platform in India and any raw materials used in the manufacture of L-Glutamine at BioSpectra are not subject to genetic modification.
- Synonyms: (S)-2,5-Diamino-5-oxopentanoic acid, L- Glutamic acid 5-amide.

GMP Compliance:

Bio Pharma Grade L-Glutamine, LGLM-4250 is suitable for use as an excipient. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide For Excipients. This grade of L-Glutamine is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Retest Date:

The recommended retest period for L-Glutamine is two years from the date of manufacture.

Storage and Shipping Conditions:

Ship and Store in ambient temperature.

Package Sizes:

10kg, 25 kg and 50 kg pails.

Country of Origin:

India

This product is then repacked and retested under cGMP at our Bangor USA cGMP FDA Regulated Facility.