

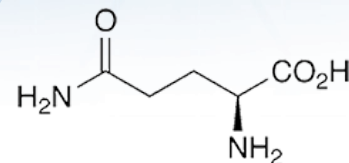
L-GLUTAMINE, USP, GMP Excipient Grade

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: C₅H₁₀N₂O₃ · 2H₂O

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

C₅H₁₀N₂O₃ · 2H₂O 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> | ≤ 0.05% |
| Chloride and Sulfate, <i>Sulfate</i> | ≤ 0.03% |
| Identification A (IR) | Passes Test |
| Iron | ≤ 10 ppm |
| Loss on Drying | ≤ 0.3% |
| Optical Rotation, Specific Rotation @ 20°C | +6.3° to +7.3° |
| Residue on Ignition | ≤ 0.10% |
| Related Compounds | ≤ 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.