



BioKyowa Inc.

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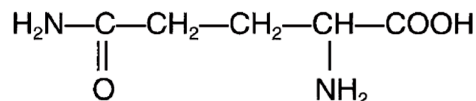
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Specification of L-GLUTAMINE CAS No.: 56-85-9

Edition date: 11.3.2019

Revision index: 6

MOLECULAR STRUCTURE AND FORMULA



C₅H₁₀N₂O₃ : 146.14
N : 19.17%

DESCRIPTION

White crystalline powder
Odorless
Slightly characteristic taste

SPECIFICATION AND PROCEDURE

Test Item	Acceptance Criteria	Methods
APPEARANCE	WHITE CRYSTALLINE POWDER	Visual
IDENTIFICATION	PASS TEST	USP
STATE OF SOLUTION (T%)	NOT LESS THAN 98.0%	In-house
pH	4.0 ~ 6.0	USP
SPECIFIC ROTATION (AT 20°C)	+6.3 ~ +7.3°	USP
CHLORIDE (Cl)	NOT MORE THAN 0.020%	USP
SULFATE (SO ₄)	NOT MORE THAN 0.020%	USP
IRON (Fe)	NOT MORE THAN 10ppm	USP
ARSENIC	NOT MORE THAN 1.4ppm	USP
CADMIUM	NOT MORE THAN 0.5ppm	USP
LEAD	NOT MORE THAN 0.5ppm	USP
MERCURY	NOT MORE THAN 0.2ppm	USP
FOREIGN AMINO ACIDS	NOT MORE THAN 0.5%	USP
LOSS ON DRYING	NOT MORE THAN 0.20%	USP
RESIDUE ON IGNITION	NOT MORE THAN 0.10%	USP
INSOLUBLE FOREIGN MATTER	PASS TEST	FCC
ASSAY(DRY BASIS)	99.0 ~ 101.0%	USP
TOTAL COUNT (CFU)	NOT MORE THAN 1,000 /g	USP
YEAST AND MOLDS (CFU)	NOT MORE THAN 100 /g	USP
COLIFORM	NEGATIVE/g	USP

STATEMENT

We hereby certify that the commodity described above meets the monograph requirements of the current USP and FCC; and meets the requirements of residual solvents in those pharmacopoeias. Foreign Amino Acids Testing - Meets requirements for Related Compounds as required by USP, and Ninhydrin-positive substances as required by EP. Made in USA by fermentation using a non-pathogenic microbe, and without animal origin raw materials. Intended use for our product is as raw material or ingredient for further processing. Our product is not intended for API usage.

STORAGE

Keep containers tightly closed in a dry, well-ventilated place at room temperature

RETEST DATE

3 years from manufacturing date