



GONMISOL
FINE INGREDIENTS

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Certificate of analysis

Certificado de analisis

**L-Threonine
EP5 USP29 AJI97**

Batch	Manufactured	Expiration	Quantity
CP3521071501	15/07/21	14/07/24	3000 Kg

AJI97

Identification	Infrared Absorption	Qualified
Specific rotation [α] _{D20}	-27.6° to -29.0°	-28.2
State of Solution (Transmittance)	Clear and Colorless not less than 98.0%	98.7%
Chloride (Cl)	Not more than 0.020%	< 0.02%
Ammonium (NH ₄)	Not more than 0.02%	< 0.02%
Sulfate (SO ₄)	Not more than 0.020%	< 0.02%
Iron (Fe)	Not more than 10 ppm	< 10 ppm
Heavy metals (Pb)	Not more than 10 ppm	< 10 ppm
Arsenic (As ₂ O ₃)	Not more than 1 ppm	< 1 ppm
Other amino acids	Conforms	Qualified
Loss on drying	Not more than 0.20%	0.11%
Residue on ignition	Not more than 0.10%	0.07%
Assay	99.0 to 101.0%	99.3%
PH	5.2 to 6.2	5.71

SPECIAL SPECIFICATION (EU)

Arsenic	Less than 2 ppm	< 1 ppm
Lead	Less than 3 ppm	< 2 ppm
Mercury	Less than 0.1 ppm	< 0.1 ppm
Cadmium	Less than 1 ppm	< 1 ppm

EP5

Characters	White or almost white crystalline powder or shiny flakes	Qualified
Identification	As per EP5 (Chemical examine & Infrared Absorption)	Qualified
Appearance of solution	Clear and not more intensely coloured than reference solution	Qualified
pH	5.0 to 6.5	5.71
Specific rotation	-27.6° to -29.0°	-28.2°
Ninhydrin-positive substances	Examine by thin-layer chromatography	Qualified
Chlorides	Not more than 200 ppm	< 200 ppm
Sulphates	Not more than 300 ppm	< 300 ppm
Ammonium	Not more than 200 ppm	< 200 ppm
Iron (Fe)	Not more than 10 ppm	< 10 ppm
Heavy Metals (Pb)	Not more than 10 ppm	< 10 ppm
Loss on drying	Not more than 0.5%	0.11%



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**L-Threonine
EP5 USP29 AJI97**

Batch	Manufactured	Expiration	Quantity
CP3521071501	15/07/21	14/07/24	3000 Kg
Sulphated ash		Not more than 0.1%	0.07%
Assay		99.0 to 101.0%	99.3%
SPECIAL SPECIFICATION (EU)			
Arsenic		Less than 2 ppm	< 1 ppm
Lead		Less than 3 ppm	< 2 ppm
Mercury		Less than 0.1 ppm	< 0.1 ppm
Cadmium		Less than 1 ppm	< 1 ppm
USP29			
Identification		Infrared Absorption	Qualified
Specific rotation		-26.7° to -29.1°	-28.2°
pH		5.0 to 6.5	5.71
Loss on drying		Not more than 0.2%	0.11%
Residue on ignition		Not more than 0.4%	0.07%
Chloride		Not more than 0.05%	< 0.02%
Sulphate		Not more than 0.03%	< 0.03%
Iron		Not more than 0.003%	< 0.001%
Heavy Metals		Not more than 0.0015%	< 0.001%
Chromatographic purity		As per USP29 (By TLC)	Qualified
Individual Impurity		< 0.5%	< 0.5%
Total Impurity		< 2.0%	< 2.0%
Organic volatile impurities		Meets the requirements	Qualified
Residual Solvents		Meets the requirements	Qualified
Assay		98.5 to 101.5%	99.3%
SPECIAL SPECIFICATION (EU)			
Arsenic		Less than 2 ppm	< 1 ppm
Lead		Less than 3 ppm	< 2 ppm
Mercury		Less than 0.1 ppm	< 0.1 ppm
Cadmium		Less than 1 ppm	< 1 ppm

Conclusion: Material conforms to the AJI97 EP5 USP29 Standard.