

Total plate count

Productos Químicos Gonmisol S.A. T: (+34) 93 313 61 18 F: (+34) 93 314 74 27 Camí de la Verneda 47-49 Sant Adrià de Besòs 08930 Barcelona - Spain (EU)

Certificate of analysis

Certificado de análisis

Qualified

L-LYSINE HCL EP USP AJI

EP USP AJI					
Batch	Manufactured	Expiration	Quantity		
CP0121121301	13/12/2021	12/12/2024	5.000 Kg		
EP5					
Characters	A white, crystal	line powder or colorless	s crystals.	Qualified	
Identification	As per EP5 (C	hemical examine & Infra	ared Absorption)	Qualified	
Appearance of solution	Clear and not r	nore intensely coloured	than reference solution.	Qualified	
Specific rotation	+21.0° to +22.5	20		+21.0°	
Ninhydrin-positive substance	es Examine by thi	n-layer chromatography	,	Qualified	
Sulphates	Not more than	300 ppm		< 200 ppm	
Ammonium	Not more than 2	200 ppm		< 200 ppm	
Iron (Fe)	Not more than	30 ppm		< 10 ppm	
Heavy metals (Pb)	Not more than	10 ppm		< 10 ppm	
Loss on drying	Not more than	Not more than 0.5%		0.19%	
Sulphated ash	not more than (not more than 0.1%		0.06%	
Assay	98.5% ~ 101.0	98.5% ~ 101.0%		99.5%	
Special Specification (EU)					
Arsenic	Less than 2 pp	m		< 1 ppm	
Lead	Less than 3 pp	m		< 1 ppm	
Mercury	Less than 0.1 p	ppm		< 0.1 ppm	
Cadmium	Less than 1 pp	m		< 1 ppm	
Microbiology					

≤10.000 cfu/g



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Batch	Manufactured	Expiration	Quantity	
CP0121121301	13/12/2021	12/12/2024	5.000 Kg	
Yeast/moulds count	≤1.000 cfu/g			Qualified
Escherichia coli	1g/Absent			Qualified
Salmonella	25g/Absent			Qualified
Staphylococcus aureus	Absent			Qualified
USP29				
Identification	Infrared Absorption			Qualified
Appearance	Fresh materials, fre	e flowing, odourless, whit	e color and no black spe	c Qualified
Specific rotation	+20.4° to +21.4°			+21.0°
Loss on drying	Not more than 0.4%	, D		0.19%
Residue on ignition	Not more than 0.1%	, D		0.06%
Sulfate	Nor more than 0.03	%		< 0.02%
Iron	Not more than 0.00	3%		< 0.001%
Heavy metals	Not more than 0.00	15%		< 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 requirem	ents		Qualified
Content of chloride	19.0% ~ 19.6%			19.28%
Residual solvents	Meets the requirem	ents		Qualified
Assay	98.5 to 101.5%			99.5%



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CP0121121301	13/12/2021	12/12/2024	5.000 Kg	
Special Specification (EU)				
Arsenic		Less than 2 ppm		< 1 ppm
Lead		Less than 3 ppm		< 1 ppm
Mercury		Less than 0.1 ppm		< 0.1 ppm
Cadmium		Less than 1 ppm		< 1 ppm
Microbiology				
Total plate count		≤10.000 cfu/g		Qualified
Yeast/moulds count		≤1.000 cfu/g		Qualified
Escherichia coli		1g/Absent		Qualified
Salmonella		25g/Absent		Qualified
Staphylococcus aureus		Absent		Qualified
AJI97				
Identification		Infrared Absorption		Qualified
Specific rotation [a] 20 D		+20.8° to +21.5°		+21.0°
State of solution (Transmitta	nce)	Clear and colorless not les	ss than 98.0%	99.2%
Chloride (CI)		19.12 to 19.51%		19.28%
Ammonium (NH4)		Not more than 0.02%		< 0.02%
Sulfate (SO4)		Not more than 0.02%		< 0.02%
Iron (Fe)		Not more than 10 ppm		< 10 ppm
Heavy metals (Pb)		Not more than 10 ppm		< 10 ppm



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CP0121121301	13/12/2021	12/12/2024	5.000 Kg	
Other amino acids		Conforms		Qualified
Loss on drying		Not more than 0.4	0%	0.19%
Residue on ignition		Not more than 0.1	0%	0.06%
Assay		98.5 to 101.0%		99.5%
рН		5.0 to 6.0		5.6
Special Specification (EU	J)			
Arsenic		Less than 2 ppm		< 1 ppm
Lead		Less than 3 ppm		< 1 ppm
Mercury		Less than 0.1 ppm	1	< 0.1 ppm
Cadmium		Less than 1 ppm		< 1 ppm
Microbiology				
Total plate count		≤10.000 cfu/g		Qualified
Yeast/moulds count		≤1.000 cfu/g		Qualified
Escherichia coli		1g/Absent		Qualified
Salmonella		25g/Absent		Qualified
Staphylococcus aureus		Absent		Qualified

Conclusion: Material conforms to the EP5 USP29 AJI97 Standard.