TECHNICAL DATA SHEET

152896-TDS-ENG-2026

N-ACETIL-L-LEUCINA Farma		
DESCRIPTION DCI: ACETYLLEUCINE	DESCRIPTION DOE: ACETILLEUCINA	
CAS Nº: 1188-21-2	EC Nº: 214-706-3	AEMPS CODE: 8141A
MOL. WEIGHT: 173,21	MOL. FORMULA: C8H15NO3	ARTICLE CODE: 152896

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Specific rotation	-22º / -26º
Estado de la solución	=> 95.0 %
Heavy metals	=< 20 ppm
Arsenic	=< 2 ppm
Loss on drying	=< 0.5 %
Residue on ignition	=< 0.3 %
Assay	97.5 - 102.5 %
Microbiological control	
TAMC	=< 100 CFU/g
TYMC	=< 100 CFU/g
E. Coli	Absence/1g
S. Aureus	Absence/1g
C. Albicans	Absence/1g
P. Aeruginosa	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

N-Acetyl-L-Leucine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

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