

TECHNICAL DATA SHEET

012829-TDS-ENG-2025

LISOZIMA HCL PHARMA		
DESCRIPTION DCI: LYSOZYME HYDROCHLORIDE		DESCRIPTION DOE: LISOZIMA HIDROCLORURO
CAS Nº: 9066-59-5	EC Nº: 232-954-0	AEMPS CODE: 938CH
MOL. WEIGHT: 14400	MOL. FORMULA: C616H963N193O182S1C	ARTICLE CODE: 012829

ATTRIBUTES	SHOULD BE
Appearance	White to off-white granular solid
Solubility	Freely soluble in water and practically insoluble in ethanol
Identification (1)	Complies
Identification (2)	Complies
Clarity of solution	Clear
pH	3.0 - 5.0
Chlorides	=< 3.5 %
Residue on ignition	=< 2.0 %
Loss on drying	=< 8.0 %
Nitrogen	16.8 - 18.6 %
Assay	
Potency	=> 0.9 mg/mg
Purity (protein content)	=> 95.0 %
Microbiological control	
TAMC	< 100 CFU/g
TYMC	< 100 CFU/g
Salmonella	Absence/10g
Escherichia coli	Absence/1g
Bile Tolerant Gram (-) Bacteria	Absence/1g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a cool and dry place.

REMARKS

Lysozyme Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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

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product before use.