METAPHARMACEUTICAL IND SL
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LISOZIMA HCL PHARMA

PRODUCT CODE: 012829	CAS Nº: 9066-59-5	ANALYSIS Nº: 127/24	
MANUFACTURER BATCH:	003/22	CERTIFICATE ID:	42.175
SUPPLIER BATCH:	0091222	MANUFACTURING DATE:	24/08/2022
METAPH BATCH:	0110524	RETEST DATE:	23/08/2025

ATTRIBUTES	SHOULD BE	IS
Appearance	White to off-white granular solid	White granular solid
Solubility	Freely soluble in water and practically insoluble in ethanol	Complies (*)
Identification (1)	Complies	Complies
Identification (2)	Complies	Complies
Clarity of solution	Clear	Complies
pH	3.0 - 5.0	3.0
Chlorides	=< 3.5 %	3.5 %
Residue on ignition	=< 2.0 %	0.4 %
Loss on drying	=< 8.0 %	2.1 %
Nitrogen	16.8 - 18.6 %	17.1 %
Assay		
Potency	=> 0.9 mg/mg	1.4 mg/mg
Purity (protein content)	=> 95.0 %	99.5 %
Microbiological control		
TAMC	< 100 CFU/g	< 10 UFC/g
TYMC	< 100 CFU/g	< 10 UFC/g
Salmonella	Absence/10g	Absence/10g
Escherichia coli	Absence/1g	Absence/1g
Bile Tolerant Gram (-) Bacteria	Absence/1g	Absence/1g

COMPLIES WITH

Manufacturer Specifications

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.

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

Store in a cool and dry place.

Analysis date: 04/07/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001220