



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230388

Product:	LACTOSE
Lot:	230388
Expiry date:	04/12/2025
Reference:	Cumple PhEur11.0
Synonyms:	Lactosa monohidrato. Azúcar de leche.
Formula:	C ₁₂ H ₂₂ O ₁₁ ·H ₂ O
Molecular weight:	360,3 g/mol

Assay	Result	Specification
Identification	Conform (A,D)	Test RFE/Ph. Eur.
Organoleptic properties	Conform	RFE/Ph. Eur.
Appearance of solution	Conform	<=0,4 ml NaOH 0,1 M
Acidity or alkalinity	0,3 ml NaOH 0,1 M	<= 0,4 ml NaOH 0,1M
Heavy metals	< 5 ppm	(+54,4°)-(+55,9°)
Specific rotation	+55,0	<= 0,25
A(210-220nm, 1%, 1cm)	0,018	<= 0,07
A(270-300nm, 1%, 1cm)	0,006	<= 0,04
A(400nm, 10%, 1cm)	0,000	4,5-5,5%
Water content - K.F.	4,9 %	4,5-5,5 %
Sulphated ashes	0,1 %	Test RFE/Ph. Eur.
Microbiological control	Conform	
Total aerobic count	< 10 ² UFC/g	<= 10 ² UFC/g
Absence of E. coli	Conform	

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 07/02/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Product	Name	Capacity	Batch
1156042	LACTOSA	250 g	230388-N-1
1156044	LACTOSA	1 kg	230388-P-1
1156044	LACTOSA	1 kg	230388-P-2
1156048	LACTOSA	5 kg	230388-Q-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at

Acofarma.
Original manufacturer's certificate available on request.

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