



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224413

Product:	LIDOCAINE HYDROCHLORIDE
Lot:	224413
Expiry date:	30/05/2026
Reference:	Cumple PhEur10.8
Synonyms:	Lignocaina clorhidrato monohidrato.
Formula:	C ₁₄ H ₂₃ ClN ₂ O·H ₂ O
Molecular weight:	288,8 g/mol

Assay	Result	Specification	
Identification	Conform (B,D)	Test PhEur (B,D)	
Organoleptic properties	Conform	PhEur	
Appearance of the S solution (5% acq.)	Conform	Clear and colorless	
pH of aqueous solution 0,5%	5,4	4,0-5,5	
Related substances (HPLC)	Conform	Test PhEur	
Moisture - K.F.	6,3 %	5,5 - 7,0 %	
Sulphated ashes	0,01 %	<= 0,1%	
Assay	99.4 %	99,0-101,0%	
Impurity A	< 0,01 %	<= 0,01 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,5 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Elemental impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder. Very soluble in water, freely soluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 08/09/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00340 SWATI SPENTOSE PRIVATE LIMITED (UNIT-I)

Manufacturer batch: LDH-721011

Product	Name	Capacity	Batch
1157042	LIDOCAINA CLORHIDRATO	25 g	224413-G-1
1157042	LIDOCAINA CLORHIDRATO	25 g	224413-G-2
1157042	LIDOCAINA CLORHIDRATO	25 g	224413-G-3

1157044	LIDOCAINA CLORHIDRATO	100 g	224413-J-1
1157044	LIDOCAINA CLORHIDRATO	100 g	224413-J-2
1157047	LIDOCAINA CLORHIDRATO	1 kg	224413-P-1
1157047	LIDOCAINA CLORHIDRATO	1 kg	224413-P-2
1157050	LIDOCAINA CLORHIDRATO	25 kg	224413-T-1
1200191	LIDOCAINA CLORHIDRATO	250 g	224413-N-1
1200191	LIDOCAINA CLORHIDRATO	250 g	224413-N-2

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.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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Date of edition: 05/04/2026

