



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 214797

Product:	LIDOCAINE HYDROCHLORIDE
Lot:	214797
Expiry date:	01/10/2025
Reference:	Cumple PhEur10.5
Synonyms:	Lignocaina clorhidrato monohidrato.
Formula:	C ₁₄ H ₂₃ ClN ₂ O·H ₂ O
Molecular weight:	288,8 g/mol

Assay	Result	Specification	
Assay	100,8 %	99,0-101,0%	
Sulphated ashes	0,02 %	<= 0,1%	
Moisture - K.F.	6,5 %	5,5 - 7,0 %	
Related substances (HPLC)	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Identification	Conform (B,D)	Test PhEur (B,D)	
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Total impurities	<= 0,05 %	<= 0,5 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
pH of aqueous solution 0,5%	5,4	4,0-5,5	
Appearance of the S solution (5% acq.)	Conform	Clear and colorless	
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,001 %	<= 0,01 %	

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: 08/09/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

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

Manufacturer batch: LDH-120084

Product	Name	Capacity	Batch
1157042	LIDOCAINA CLORHIDRATO	25 g	214797-G-1
1157042	LIDOCAINA CLORHIDRATO	25 g	214797-G-2
1157042	LIDOCAINA CLORHIDRATO	25 g	214797-G-3

1157042	LIDOCAINA CLORHIDRATO	25 g	214797-G-4
1157044	LIDOCAINA CLORHIDRATO	100 g	214797-J-1
1157044	LIDOCAINA CLORHIDRATO	100 g	214797-J-2
1157044	LIDOCAINA CLORHIDRATO	100 g	214797-J-3
1157044	LIDOCAINA CLORHIDRATO	100 g	214797-J-4
1157047	LIDOCAINA CLORHIDRATO	1 kg	214797-P-1
1157047	LIDOCAINA CLORHIDRATO	1 kg	214797-P-2
1157047	LIDOCAINA CLORHIDRATO	1 kg	214797-P-3
1157047	LIDOCAINA CLORHIDRATO	1 kg	214797-P-4
1200191	LIDOCAINA CLORHIDRATO	250 g	214797-N-1
1200191	LIDOCAINA CLORHIDRATO	250 g	214797-N-2
1200191	LIDOCAINA CLORHIDRATO	250 g	214797-N-3

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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