



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 252173**

Product:	LIDOCAINE HYDROCHLORIDE
Lot:	252173
Expiry date:	30/03/2030
Reference:	Cumple PhEur11.8
Synonyms:	Lignocaina clorhidrato monohidrato.
Formula:	C <sub>14</sub> H <sub>23</sub> CIN <sub>2</sub> O·H <sub>2</sub> O
Molecular weight:	288,8 g/mol

Assay	Result	Specification	
Identification	Conform (B,D)	Test PhEur (B,D)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		
pH	5,2	4,0 - 5,5	
Related substances (HPLC)	Conform	Test PhEur	
Water	6,6 %	5,5 - 7,0 %	
Sulphated ashes	0,07 %	<= 0,1%	
Assay	100,3 %	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	#
Nitrosamine impurities	Conform		#

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: 09/12/2025

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

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

Manufacturer batch: LDH-125015

Product	Name	Capacity	Batch
1157042	LIDOCAINA CLORHIDRATO	25 g	252173-G-1
1157044	LIDOCAINA CLORHIDRATO	100 g	252173-J-1

1157044	LIDOCAINA CLORHIDRATO	100 g	252173-J-2
1157047	LIDOCAINA CLORHIDRATO	1 kg	252173-P-1
1157047	LIDOCAINA CLORHIDRATO	1 kg	252173-P-2
1157050	LIDOCAINA CLORHIDRATO	25 kg	252173-T-1
1200191	LIDOCAINA CLORHIDRATO	250 g	252173-N-1
1200191	LIDOCAINA CLORHIDRATO	250 g	252173-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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