



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 222825

Product:	LIDOCAINE BASE
Lot:	222825
Expiry date:	31/12/2026
Reference:	Cumple PhEur10.7
Synonyms:	Lignocaína.
Formula:	C ₁₄ H ₂₂ N ₂ O
Molecular weight:	234,3 g/mol

Assay	Result	Specification	
Identification	Conform (A)	Test PhEur (A)	
Organoleptic properties	Conform	PhEur	
Chlorides	< 35 ppm	<= 35 ppm	
Sulphates	< 0,1 %	<= 0,1%	
Related substances (HPLC)	Conform	Test PhEur	
Moisture - K.F.	0,10 %	<= 1,0 %	
Sulphated ashes	0,05 %	<= 0,1%	
Assay	100,5 %	99,0-101,0%	
Impurity A	0,002 %	<= 0,01 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	<= 0,05 %	<= 0,5 %	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Elemental impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, very soluble in ethanol (96 per cent) and in methylene chloride.

Conservation: In tightly closed containers. PROTECT FROM LIGHT.

Date of analysis: 30/05/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

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

Manufacturer batch: LDB-722005

Product	Name	Capacity	Batch
1157001	LIDOCAINA BASE	25 g	222825-G-2
1157003	LIDOCAINA BASE	100 g	222825-J-4
1157004	LIDOCAINA BASE	250 g	222825-N-2
1157005	LIDOCAINA BASE	1 kg	222825-P-2

1157006	LIDOCAINA BASE	5 kg	222825-Q-3
1370213	LIDOCAINA BASE (FLB)	100 g	222825-J-3
1370218	LIDOCAINA BASE (FLB)	5 kg	222825-Q-4

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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