



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 211553

Product:	LIDOCAINE BASE
Lot:	211553
Expiry date:	01/08/2025
Reference:	Cumple PhEur10.4
Synonyms:	Lignocaína.
Formula:	C ₁₄ H ₂₂ N ₂ O
Molecular weight:	234,3 g/mol

Assay	Result	Specification	
Total impurities	0,05 %	<= 0,5 %	
Identification	Conform (A)	Test PhEur (A)	
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Organoleptic properties	Conform	PhEur	
Elemental impurities	Conform	Test PhEur	#
Chlorides	<= 35 ppm	<= 35 ppm	
Sulphates	<= 0,1 %	<= 0,1%	
Related substances (HPLC)	Conform	Test PhEur	
Moisture - K.F.	0,09 %	<= 1,0 %	
Sulphated ashes	0,04 %	<= 0,1%	
Assay	100,9 %	99,0-101,0%	
Impurity A	0,001 %	<= 0,01 %	
Unspecified Impurities	0,05 %	<= 0,10 %	

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 moisture.

Date of analysis: 08/04/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

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

Manufacturer batch: LDB-120020

Product	Name	Capacity	Batch
1157003	LIDOCAINA BASE	100 g	211553-J-2
1157003	LIDOCAINA BASE	100 g	211553-J-3
1157004	LIDOCAINA BASE	250 g	211553-N-1
1157005	LIDOCAINA BASE	1 kg	211553-P-1

1157005	LIDOCAINA BASE	1 kg	211553-P-2
1157006	LIDOCAINA BASE	5 kg	211553-Q-1
1157006	LIDOCAINA BASE	5 kg	211553-Q-2
1370197	LIDOCAINA BASE (FLB) (INACTIVO)	100 g	211553-J-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.

(#) Parameter controlled by the manufacturer

(=) UE certificate

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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