



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250690

Product:	BUPIVACAINE HYDROCHLORIDE
Lot:	250690
Expiry date:	30/10/2029
Reference:	Cumple PhEur11.7
Synonyms:	
Formula:	C ₁₈ H ₂₉ ClN ₂ O·H ₂ O
Molecular weight:	342,9 g/mol

Assay	Result	Specification	
Optical rotation	(0,00 °)	(-0,10°)-(+0,10°)	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Appearance of solution	Conform	Test PhEur	
Elemental impurities	Conform	Test PhEur	#
Acidity or alkalinity	Conform	Test PhEur	
Nitrosamine impurities	Conform	Test PhEur	#
Identification	Conform (A,C,D)	Test PhEur (A,C,D)	
Organoleptic properties	Conform	PhEur	
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	99,7 %	98,5-101,0%	
Impurity F	0,47 ppm	<= 50 ppm	
Loss on drying	5,4 %	4,5 - 6,0 %	

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 28/04/2025

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00057 SIMS SOCIETA ITALIANA MEDICINALE SCANDICCI S.R.L.

Manufacturer batch: 207146

Product	Name	Capacity	Batch
1114010	BUPIVACAINE CLORHIDRATO	100 g	250690-J-1
1114012	BUPIVACAINE CLORHIDRATO	1 kg	250690-P-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

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