



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 216155

Product:	BUPIVACAINE HYDROCHLORIDE
Lot:	216155
Expiry date:	15/10/2026
Reference:	Cumple PhEur10.6
Synonyms:	
Formula:	C ₁₈ H ₂₉ ClN ₂ O·H ₂ O
Molecular weight:	324,9 g/mol

Assay	Result	Specification	
Impurity B	< 0,5 %	<= 0,5 %	
Total impurities	< 1,0 %	<=1,0 %	
Unspecified Impurities	< 0,10 %	<= 0,10 %	
Related substances (GC)	Conform	Test PhEur	
Optical rotation	-0,00°	(-0,10°)-(+0,10°)	
Loss on drying (1 g, 105°C)	5,0 %	4,5-6,0%	
Impurity F	0,22 ppm	<= 50 ppm	
Organoleptic properties	Conform	PhEur	
Residual solvent: Isopropanol	<= 5000 ppm	<= 5000 ppm	#
Identification	Conform (A,D,E)	Test PhEur (A,C,D)	
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Acidity or alkalinity	Conform	Test PhEur	
Appearance of solution	Conform	Test PhEur	
Elemental impurities	Conform	Test PhEur	#
Assay	99,0 %	98,5-101,0%	
Sulphated ashes	0,00 %	<= 0,1 %	

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/03/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01005 MOEHS IBÉRICA, S.L.

Manufacturer batch: 68

Product	Name	Capacity	Batch
1114010	BUPIVACAINE CLORHIDRATO	100 g	216155-J-1
1114012	BUPIVACAINE CLORHIDRATO	1 kg	216155-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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