



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233091

Product:	BUPIVACAINE HYDROCHLORIDE
Lot:	233091
Expiry date:	30/05/2028
Reference:	Cumple PhEur11.2
Synonyms:	
Formula:	C ₁₈ H ₂₉ ClN ₂ O·H ₂ O
Molecular weight:	342,9 g/mol

Assay	Result	Specification	
Identification	Conform (A,C,D)	Test PhEur (A,C,D)	
Organoleptic properties	Conform	PhEur	
Residual solvent: Isopropanol	<= 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	#
Impurity B	<= 0,5 %	<= 0,5 %	
Unspecified Impurities	<= 0,10 %	<= 0,10 %	
Total impurities	<= 1,0 %	<= 1,0 %	
Sulphated ashes	0,01 %	<= 0,1 %	
Assay	98,7 %	98,5-101,0%	
Optical rotation	- 0,001°	(-0,10°)-(+0,10°)	
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Related substances (GC)	Conform	Test PhEur	
Impurity F	0,44 ppm	<= 50 ppm	
Loss on drying	5,3 %	4,5 - 6,0 %	

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 08/08/2023

Judgement:
APPROVED

Responsible: M.Mesa

Technical director: Montserrat Enrique

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

Manufacturer batch: 203225

Product	Name	Capacity	Batch
1114010	BUPIVACAINA CLORHIDRATO	100 g	233091-J-1

1114010	BUPIVACAINA CLORHIDRATO	100 g	233091-J-2
1114012	BUPIVACAINA CLORHIDRATO	1 kg	233091-P-1
1114012	BUPIVACAINA CLORHIDRATO	1 kg	233091-P-2
1114012	BUPIVACAINA CLORHIDRATO	1 kg	233091-P-3

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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