



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 222587

Product:	SCOPOLAMINE BUTYLBROMIDE
Lot:	222587
Expiry date:	11/10/2026
Reference:	Cumple PhEur 10.7
Synonyms:	Hioscina Butilbromuro, Butilescopolamina
Formula:	C ₂₁ H ₃₀ BrNO ₄
Molecular weight:	440,4 g/mol

Assay	Result	Specification	
Identification	Conform (A,C,F)	Test PhEur (A,C,F)	
Organoleptic properties	Conform		
Appearance of solution	Conform	Test PhEur	
Acidity or alkalinity	Conform	Test PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	-18	(-18) - (-20)	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,08 %	<= 2,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	99,1 %	98,0 - 101,0 %	
Impurity A	<= 0,05 %	<= 0,15 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	<= 0,05 %	<= 0,4 %	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. Freely soluble in water and in methylene chloride, sparingly soluble in anhydrous ethanol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 01/06/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00295 BOEHRINGER INGELHEIM PHARMA GmbH & Co. Kg.

Manufacturer batch: 1105266

Product	Name	Capacity	Batch
1000520	ESCOPOLAMINA BUTILBROMURO	5 g	222587-E-1

1000521	ESCOPOLAMINA BUTILBROMURO	25 g	222587-G-1
1000522	ESCOPOLAMINA BUTILBROMURO	100 g	222587-J-1
1000523	ESCOPOLAMINA BUTILBROMURO (INACTIVO)	250 g	222587-N-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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