



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 214946

Product:	GLYCOPYRROLATE
Lot:	214946
Expiry date:	27/12/2025
Reference:	Cumple PhEur10.5
Synonyms:	Glicopirronio bromuro.
Formula:	C ₁₉ H ₂₈ BrNO ₃
Molecular weight:	398.34 g/mol

Assay	Result	Specification	
Assay	99,7 %	99,0-101,0%	
Loss on drying (3h, 105°C)	0,03 %	<= 0,5 %	
Sulphated ashes	<= 0,1 %	<= 0,1%	=
Related substances (HPLC)	Conform	Test PhEur	=
Impurity N	<= 0,2 %	<= 0,2%	#
Identification	Conform (A,B)	Test PhEur (A,B)	
Total impurities	<= 0,5 %	<= 0,5 %	=
Organoleptic properties	Conform	PhEur	
Residual solvent: Isopropanol	<= 3000 ppm	<= 3000 ppm	#
Appearance of solution	Conform	Clear and colorless	=
Residual solvent: Heptane	<= 1000 ppm	<= 1000 ppm	#
Acidity or alkalinity	Conform	Test PhEur	=
Residual solvent: Methanol	<= 1000 ppm	<= 1000 ppm	#
Impurity E	<= 0,2 %	<= 0,2 %	=
Impurity I	<= 0,3 %	<= 0,3 %	=
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=

Organoleptic characteristics: White or almost white crystalline powder. Freely soluble in water, soluble in ethanol 96%, very slightly soluble in methylene chloride

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/09/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01007 PCAS FINLAND OY

Manufacturer batch: 20017159

Product	Name	Capacity	Batch
1112000	GLICOPIRROLATO	1 g	214946-D-1

1112000	GLICOPIRROLATO	1 g	214946-D-4
1370201	GLICOPIRROLATO (FLB) (INACTIVO)	1 g	214946-D-2
1370201	GLICOPIRROLATO (FLB) (INACTIVO)	1 g	214946-D-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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Date of edition: 24/06/2025