



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233770

Product:	GLYCOPYRROLATE
Lot:	233770
Expiry date:	30/08/2028
Reference:	Cumple PhEur11.2
Synonyms:	Glicopirronio bromuro.
Formula:	C ₁₉ H ₂₈ BrNO ₃
Molecular weight:	398.34 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		=
Acidity or alkalinity	Conform	Test PhEur	=
Loss on drying (3h, 105°C)	0,00 %	<= 0,5 %	
Sulphated ashes	<= 0,1 %	<= 0,1%	=
Related substances (HPLC)	Conform	Test PhEur	=
Impurity N	< 0,2 %	<= 0,2%	=
Assay	99,2 %	99,0-101,0%	
Impurity E	< 0,05 %	<= 0,2 %	=
Impurity I	< 0,05 %	<= 0,3 %	=
Unspecified Impurities	< 0,05 %	<= 0,10 %	=
Total impurities	< 0,05 %	<= 0,5 %	=
Residual solvent: Isopropanol	<= 3000 ppm	<= 3000 ppm	#
Residual solvent: Heptane	<= 1000 ppm	<= 1000 ppm	#
Residual solvent: Methanol	<= 1000 ppm	<= 1000 ppm	#

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: 21/11/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01007 PCAS FINLAND OY

Manufacturer batch: 23010973

Product	Name	Capacity	Batch
1112000	GLICOPIRROLATO	1 g	233770-D-1

1112000	GLICOPIRROLATO	1 g	233770-D-3
1112000	GLICOPIRROLATO	1 g	233770-D-5
1112000	GLICOPIRROLATO	1 g	233770-D-6
1370201	GLICOPIRROLATO (FLB) (INACTIVO)	1 g	233770-D-2
1370201	GLICOPIRROLATO (FLB) (INACTIVO)	1 g	233770-D-4

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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